

Cover Page for Statistical Analysis Plan

Sponsor name:	Novo Nordisk A/S
NCT number	NCT02500706
Sponsor trial ID:	NN1218-4131
Official title of study:	Efficacy and Safety of Faster-acting Insulin Aspart compared to NovoRapid® both in combination with Insulin Degludec in Adults with Type 1 Diabetes
Document date:	13-March-2018

16.1.9 Documentation of statistical methods

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Statistical Analysis Plan

Trial ID: NN1218-4131

Efficacy and Safety of Faster-acting Insulin Aspart compared to NovoRapid[®] both in combination with Insulin Degludec in Adults with Type 1 Diabetes

onset[®] 8

*Redacted statistical analysis plan
Includes redaction of personal identifiable information only.*

Author:



Clinical Statistics

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List of abbreviations

ADA	American Diabetes Association
AE	adverse event
ANOVA	analysis of variance
BG	blood glucose
BMI	body mass index
CI	confidence interval
ECG	electrocardiogram
FAS	full analysis set
FPG	fasting plasma glucose
HbA1c	glycosylated haemoglobin
HDL	high density lipoprotein
ICH	International Council for Harmonisation
IMP	investigational medical product
LDL	low density lipoprotein
LSMean	estimated mean treatment effect
MAR	missing at random
MCMC	Markov Chain Monte Carlo
MedDRA	Medical Dictionary for Regulatory Activities
PG	plasma glucose
PP	per protocol
PPG	postprandial glucose
SAP	statistical analysis plan
SAS	safety analysis set
SD	standard deviation
SMPG	self-measured plasma glucose
TEAE	treatment-emergent adverse event

1 Introduction

1.1 Trial information

This is a phase 3b, 26-week, multicentre, multinational, partly double-blind, randomised, active controlled, treat-to-target, three-armed parallel trial with an 8-week run-in period comparing the efficacy and safety of fast-acting insulin aspart with NovoRapid[®], both in combination with insulin degludec in a basal-bolus regimen. The trial includes two blinded dosing arms - mealtime fast-acting insulin aspart and mealtime NovoRapid[®] and an open-label postmeal fast-acting insulin aspart dosing arm (Figure 1-1).

The total duration of the trial is approximately 40 weeks divided into the following periods:

An approximate 2-week screening period

An 8-week run-in period primarily for optimisation of the basal insulin and subject training

An 26-week treatment period

An 30-day follow-up period

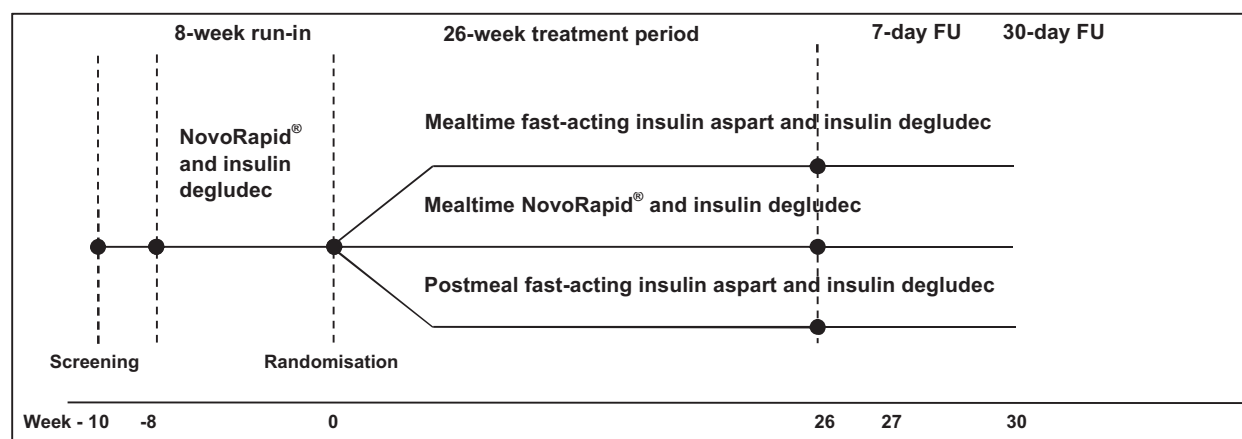


Figure 1-1 Trial design

The trial includes a screening period followed by weekly visits/phone contacts during the trial. At Visit 2 all eligible subjects will be enrolled in an 8-week run-in period and start treatment with NovoRapid[®] and insulin degludec. After the run-in period, subjects with an $HbA_{1c} \leq 9.5\%$ (80 mmol/mol) will be randomised (1:1:1) to mealtime NovoRapid[®] or to receive either mealtime fast-acting insulin aspart or postmeal fast-acting insulin aspart in addition to insulin degludec.

For further details see the trial protocol.

1.2 Scope of the statistical analysis plan

This SAP is based on the protocol Efficacy and Safety of Faster-acting Insulin Aspart compared to NovoRapid® both in combination with Insulin Degludec in Adults with Type 1 Diabetes, final version 1.0, Local Amendment no.1 version 1.0, Global Amendment no.2 version 1.0, and Local Amendment no.3 version 1.0. It contains a more detailed description for deriving and calculation of endpoints. Furthermore, it details changes to the statistical considerations presented in the protocol.

The changes to the statistical considerations proposed in this SAP and the reasons for the changes will be reported in the clinical trial report.

2 Statistical considerations

General considerations

In general, for endpoints evaluated as a change from baseline and/or where a baseline adjustment is made, baseline is defined as information collected at the randomisation visit (Visit 10). In case a measurement is not available at the randomisation visit, the most recent measurement prior to the randomisation visit will be used as baseline.

Two observation periods are defined, “in-trial” and “on-treatment”, and it will be specified which period each analysis will use.

- In-trial: the observation period from date of randomisation and until last trial-related subject-site contact. The in-trial observation period includes data collected after treatment discontinuation.
- On-treatment: the observation period from date of first dose of randomised NovoRapid®/fast-acting insulin aspart and no later than 7 days after the day of last dose of randomised NovoRapid®/fast-acting insulin aspart. The on-treatment observation period includes data collected up to and including 7 days after treatment discontinuation.

All efficacy endpoints will be summarised and analysed using the full analysis set (FAS), unless otherwise stated. Safety endpoints will be summarised using the safety analysis set (SAS) and analysed using the FAS.

Presentation of results from a statistical analysis will include the estimated mean treatment effects (LSMeans) for change from baseline, if applicable. Estimated mean treatment differences (or ratios) will be presented together with two-sided 95% confidence intervals for all endpoints analysed statistically.

For endpoints measured over time mean values will be plotted to explore the trajectory over time. For survival endpoints, e.g. drop-out pattern, Kaplan-Meier plots are presented for each treatment.

Data collected before randomisation will only be summarised descriptively.

Subjects that prematurely discontinue from treatment or withdraw from trial will attend end of treatment visit called Visit 36A. Data collected at these visits will be reallocated to the next scheduled visit where the given assessment is planned. As a general rule, all observed values from randomised subjects will be used in all statistical analyses, but in case two different values are associated to the same visit in time, the use of a given value will depend on the estimand of interest. For the primary estimand the reallocated on-treatment value will not be used and for the secondary estimand the reallocated on-treatment value will be used. The estimands will be defined in the next section.

Testing strategy and estimands

The primary objective, confirming the effect of treatment with mealtime fast-acting insulin aspart compared to NovoRapid[®] both in combination with insulin degludec in adults with type 1 diabetes, will be assessed by the change from baseline HbA_{1c} using a non-inferiority approach.

More specifically the upper limit of the 95% confidence interval (CI) should be compared to a non-inferiority margin of 0.4%. If it is below or equal to 0.4%, non-inferiority will be considered confirmed and effect demonstrated.

The trial also aims to compare treatment arms for a number of confirmatory secondary endpoints. The family-wise type I error rate will be controlled in the strong sense using a hierarchical (fixed sequence) testing procedure for the primary estimand. This is based on a priority ordering of the null-hypotheses, and testing them in this order using the two-sided 95% CI approach until a non-significant result appears. The effect is that rejection of the null hypothesis only will be confirmed for analyses where all previous null-hypotheses have been rejected in favour of fast-acting insulin aspart.

The steps in the hierarchical testing procedure are:

Step 1 (Primary analysis): HbA_{1c} non-inferiority of mealtime fast-acting insulin aspart versus mealtime NovoRapid[®]

Step 2: HbA_{1c} non-inferiority of postmeal fast-acting insulin aspart versus mealtime NovoRapid[®]

Step 3: 1-hour postprandial glucose (PPG) increments superiority of mealtime fast-acting insulin aspart versus mealtime NovoRapid[®]

Step 4: HbA_{1c} superiority of mealtime fast-acting insulin aspart versus mealtime NovoRapid[®]

Step 5: 1,5-anhydroglucitol superiority of mealtime fast -acting insulin aspart versus mealtime NovoRapid®

Primary Estimand (de facto)

The primary estimand is defined as the treatment difference between subjects randomised to fast-acting insulin aspart and NovoRapid® both in combination with insulin degludec, in adults with type 1 diabetes assessed by change from baseline in HbA_{1c} 26 weeks after randomisation for all randomised subjects regardless of treatment discontinuation or use of ancillary therapies. This estimand is a de facto estimand addressing effectiveness.

The primary estimand assesses the expected glycaemic benefit a future population with type 1 diabetes can achieve if prescribed to fast-acting insulin aspart as compared to NovoRapid®. By not putting any restrictions on the treatment adherence, this estimand aims at a difference as close as possible to the one that can be expected in real-world clinical practice, provided that the treatment adherence and use of ancillary therapies reflect clinical practice. Thereby the primary estimand provides a treatment difference for clinicians concerning the glycaemic effect of fast-acting insulin aspart compared to NovoRapid® in the day to day life in individual subjects with type 1 diabetes in an adult population.

Secondary Estimand (de jure)

Unlike the primary estimand, a second estimand is defined as the treatment difference in change from baseline in HbA_{1c} 26 weeks after randomisation between fast-acting insulin aspart and NovoRapid® both in combination with insulin degludec in adult subjects with type 1 diabetes if subjects continue on-treatment until 26 weeks. This estimand is a de jure estimand, addressing efficacy.

As an alternative to the primary estimand, this estimand provides a more hypothetical treatment difference, but may also be the most sensitive for a non-inferiority comparison, since the intake of ancillary medication may equalize the treatment effect resulting in a difficult assessment if a difference is seen with respect to ancillary medication.

The two estimands described above define what needs to be estimated to evaluate treatment differences in change from baseline in HbA_{1c}. By replacing in these descriptions HbA_{1c} with a different endpoint, one obtains analogous primary and secondary estimands specific for this endpoint (similarly for any sensitivity analyses associated with the estimands). This will be done for the following endpoints:

- Change from baseline in 1-hour PPG increment 26 weeks after randomisation (meal test)
- Change from baseline in 1,5-anhydroglucitol 26 weeks after randomisation

2.1 Sample size calculation

The primary objective of this trial is to confirm the effect of treatment with mealtime fast-acting insulin aspart in combination with insulin degludec. This is done by showing that mealtime fast-acting insulin aspart is non-inferior to mealtime NovoRapid® both in combination with insulin degludec in terms of glucose lowering effect as assessed by mean change from baseline in HbA_{1c} 26 weeks after randomisation using a non-inferiority margin of 0.4% (absolute). The non-inferiority margin of 0.4% (absolute) was chosen as described in section protocol section 5.2.1. The statistical evaluation will be done as described in section 2.3.

The trial also aims to confirm the effect of treatment with mealtime fast-acting insulin aspart and postmeal fast-acting insulin aspart, for a number of secondary confirmatory endpoints using the hierarchical testing procedure as described in section 2. The sample size is determined to ensure a sufficient power for the first step (the primary objective: HbA_{1c} non-inferiority of mealtime fast-acting insulin aspart) and the second step (HbA_{1c} non-inferiority of postmeal fast-acting insulin aspart) in the hierarchical testing procedure.

In, previous trials where faster aspart has been investigated in similar designs, the completion rates have been high. Therefore it is expected that treatment discontinuation might be as low as 8% where trial discontinuation constitutes half of these.

Power for the non-inferiority steps are based on a t-statistic under the assumption of a one-sided test of size 2.5%. A zero mean treatment difference for the comparison between mealtime fast-acting insulin aspart and mealtime NovoRapid® is expected, and for the comparison of postmeal fast-acting insulin aspart and mealtime NovoRapid® a mean difference of 0.1% in favor of mealtime NovoRapid® is expected. As trials in this population where subjects discontinuing treatment are followed up are limited, a conservative estimate of the standard deviation (SD) in change from baseline in HbA_{1c} of 1.2% was chosen. The power calculation is done using 'proc power' in SAS 9.4. Please refer to Table 2-1 for assumption of the sample size calculation.

Table 2-1 Specifications assumed for sample size calculation

	Statistical test	Significance level	Analysis population	Non-inferiority margin	SD	Mean difference	Randomisation scheme
Step 1	2-group t-test	One-sided 2.5%	FAS	0.4% (absolute)	1.2	0.0	1:1
Step 2	2-group t-test	One-sided 2.5%	FAS	0.4% (absolute)	1.2	0.1	1:1

Table 2-2 Sensitivity of sample size to power in each step

		Primary (Step 1)			Step 2		
N total	N per arm	Mean	SD	Power (step	Mean	SD	Power (step 2)
FAS	FAS	Diff		1) (%)	Diff		(%)
813	271	0	1.2	97.2	0.1	1.2	82.8
999	333	0	1.2	99.0	0.1	1.2	89.6
1176	392	0	1.2	99.7	0.1	1.2	93.8

From the [Table 2-2](#) it can be seen that, based on the previously defined assumptions, a total of 333 subjects per arm give 99.0% power to conclude HbA_{1c} non-inferiority in the first step. This sample size gives 89.6% marginal power to conclude HbA_{1c} non-inferiority in the second step which is considered sufficient.

2.2 Definition of analysis sets

The following analysis sets are defined in accordance with the ICH-E9 guideline¹.

- FAS includes all randomised subjects. In exceptional cases, randomised subjects may be excluded from the FAS. In such cases, the reason for exclusion will be justified and documented. Subjects in the FAS will contribute to the evaluation “as randomised”.
- Per Protocol (PP) Analysis Set includes all subjects in the full analysis set, excluding subjects who:
 - have violated any inclusion criteria
 - have fulfilled any exclusion criteria

Subjects in the PP analysis set will contribute to the evaluation “as treated”.

- SAS includes all subjects receiving at least one dose of the investigational product or its comparator. Subjects in the SAS will contribute to the evaluation “as treated”.

Randomised subjects who are lost to follow up, and where no information on exposure to the investigational product or its comparator is available after randomisation, will be handled as unexposed.

Before data are released for statistical analysis, a blinded review of all data will take place to identify protocol deviations that may potentially affect the results. Furthermore, extreme values and outliers will be identified by the statistician during programming and data review, according to ICH-E9¹. This will be performed using a fake randomisation.

The subjects or observations to be excluded, and the reasons for their exclusion must be documented and signed by those responsible before database lock. The subjects and observations excluded from analysis sets, and the reason for this, will be described in the clinical trial report.

2.3 Primary endpoint

The primary endpoint is change from baseline in HbA_{1c} 26 weeks after randomisation.

Primary analysis:

- 1) The primary estimand will be addressed by the below primary analysis based on all subjects included in FAS and using the in-trial observation period. Note that if subjects withdraw consent to contribute additional information or are completely lost to follow-up, missing data will still occur. The primary analysis will be implemented as a statistical model using multiple imputation where the subjects without HbA_{1c} measurements at scheduled visits will have their change from baseline HbA_{1c} value(s) imputed from the available information from the treatment the subject has been randomised to. Note that this resembles in essence a mixed model of repeated measurements analysis, but subjects without post-randomisation measurements contribute to the analysis, as the missing values will be imputed. The analysis will be implemented as follows:
 - In the first step, intermittent missing values are imputed using a Markov Chain Monte Carlo (MCMC) method, in order to obtain a monotone missing data pattern. This imputation is done for each group separately and 100 copies of the dataset will be generated.
 - In the second step, for each of the 100 copies of the dataset, an analysis of variance model with region and bolus adjusting method at randomisation (principles of flexible dosing based on the carbohydrate content of the meal or using bolus dosing algorithms) as a factors, and baseline HbA_{1c} as a covariate is fitted to the change in HbA_{1c} from baseline to week 4 for each treatment group separately. The estimated parameters, and their variances, from these models are used to impute missing values at week 4 for subjects in each treatment group, based on region, bolus adjusting method and baseline HbA_{1c}.
 - In the third step, for each of the 100 copies of the dataset, missing values at week 8 are imputed in the same way as for week 4. The imputations are based on an analysis of variance model with region and bolus adjusting method as a factors and baseline HbA_{1c} and change from baseline in HbA_{1c} at week 4 as covariates.
 - This stepwise procedure is then repeated sequentially for week 12, 16, 20, 24 and 26

- For each of the complete data sets, the change from baseline to week 26 is analysed using an analysis of variance model with treatment, region, and bolus adjusting method as factors, and baseline HbA_{1c} as a covariate.
- The estimates and standard deviations for the 100 data sets are pooled using Rubin's formula:

$$m_{MI} = \frac{1}{100} \sum_{i=1}^{100} m_i, \quad SD_{MI} = \sqrt{\frac{1}{100} \sum_{i=1}^{100} SD_i^2 + \left(1 + \frac{1}{100}\right) \left(\frac{1}{100 - 1}\right) \sum_{i=1}^{100} (m_i - m_{MI})^2},$$

where m_i and SD_i are the estimated means and standard deviations for the 100 copies of the dataset, and m_{MI} and SD_{MI} are the pooled estimates.

- From m_{MI} and SD_{MI} , the 95% CI for the treatment differences is calculated (see also the second step in the hierarchy).

Non-inferiority of mealtime fast-acting insulin aspart will be considered confirmed if the upper boundary of the two-sided 95% CI is below or equal to 0.4% or equivalent if the p-value for the one-sided test of

$$H_0: D > 0.4\% \text{ against } H_A: D \leq 0.4\%$$

is less than or equal to 2.5%, where D is the mean treatment difference (mealtime fast-acting insulin aspart minus mealtime NovoRapid®).

Note that as the anticipated number of subjects discontinuing treatment, but not trial is low, imputations based on such subjects will not be feasible.

Provided that the hierarchical testing allows, the evaluation of HbA_{1c} non-inferiority of postmeal fast-acting insulin aspart and HbA_{1c} superiority of mealtime fast-acting insulin aspart (steps 2 and 4 in the hierarchical testing procedure) will be based on the same statistical model as the primary analysis in 1), and supplemented with the associated sensitivity analyses (analysis 3b and 3c below).

Furthermore similar sensitivity analyses can be made to further investigate the remaining confirmatory hypothesis.

Sensitivity analyses for the primary analysis addressing the primary estimand

- 2) First, the primary analysis in 1) will be repeated, but excluding all factors except treatment from the multiple imputation and analysis of variance models while still including baseline

HbA1c as a covariate. This analysis will explore the influence of the different factors. The analysis will use the in-trial observation period.

- 3) The primary analysis approach chosen for this trial relies on the assumption that missing data is missing at random (MAR). This assumption implies that the HbA1c for subjects leaving the trial, after their withdrawal, develops in a similar way as the HbA1c for similar subjects that remain in the trial (not necessarily on treatment) and had similar development of HbA1c before withdrawal. The MAR assumption may be questionable for subjects withdrawing at own will. Therefore the statistical model using multiple imputation will be repeated with the following alterations:
- Imputation will be done from the treatment arm that the subject was randomised to and a value of 0.4% (the non-inferiority margin) is added to the change in HbA_{1c} at 26 weeks for subjects, on either of the fast-acting insulin aspart arms, with an imputed value at week 26². The analysis will use the in-trial observation period.
 - Missing values at week 26 will be imputed from the comparator arm (NovoRapid[®]). This will serve as a sensitivity analysis for the superiority analysis. It does not rely on the MAR assumption, but assumes that subjects on fast-acting insulin aspart without a measurement at week 26 switch to NovoRapid[®]. The imputation will be done such that the treatment effect diminishes gradually (conditional imputation). The analysis will use the in-trial observation period.
 - Missing values at week 26 will be imputed from the comparator arm (NovoRapid[®]). This will serve as a supplementary sensitivity analysis for the superiority analysis. It does not rely on the MAR assumption, but assuming that subjects on fast-acting insulin aspart without a measurement at week 26 switch to NovoRapid[®]. The imputation will be done such that the treatment effect diminishes immediately (unconditional imputation). The analysis will use the in-trial observation period.

Analyses addressing the secondary estimand

- The secondary estimand will be addressed using the same statistical model using multiple imputations as the primary analysis in 1) except using the on-treatment observation period.
- A tipping point analysis based on a statistical model using multiple imputations similar to 1), using the on-treatment observation period, will be made. In this analysis, observations for subjects without a measurement are imputed based on the treatment arm they were randomised to and subjects without a measurement in the fast-acting insulin aspart group under investigation are given a penalty. Specifically, for treatment differences involving the mealtime fast-acting insulin aspart group, only subjects in this group are given a penalty, and vice versa for treatment differences involving the postmeal fast-acting insulin aspart group. This is done to investigate the robustness of the conclusion in the primary analysis with respect to the MAR

assumption and mimics a scenario where the HbA_{1c} of the subjects without a measurement in the fast-acting insulin aspart group under investigation evolve less favourably than predicted. As a first step imputations will be done without penalty assuming MAR in the treatment group. Second, a penalty will be added to the imputed values for week 26 in the fast-acting insulin aspart group under investigation. This is done repeatedly, gradually increasing the penalty until the conclusions of the primary analysis no longer hold. The specific value of the penalty that changes the conclusion will be used to evaluate the robustness of the conclusion of the primary analysis.

- 6) A tipping point analysis based on a statistical model using multiple imputation, similar to 5) but with the modification that subjects without a measurement that discontinued treatment due to non-eligibility (subjects discontinuing fast-acting insulin aspart/NovoRapid® prematurely due to criteria 1, 2, 3, and 4) in the fast-acting insulin aspart group under investigation will not have a penalty added to the imputed values. These analyses are motivated by the fact that data from subjects prematurely discontinuing fast-acting insulin aspart/NovoRapid® due to non-eligibility can reasonably be assumed to be missing completely at random. The analysis will use the on-treatment observation period.
- 7) The same statistical model using multiple imputation as the analysis in 4), but using the PP analysis set and analysed using the on-treatment observation period. This analysis will investigate the situation that subjects deviate from the ideal treatment during the on-treatment observation period and will serve as a sensitivity analysis for the non-inferiority analysis.

2.4 Secondary endpoints

2.4.1 Confirmatory secondary endpoints

If the effect of mealtime fast-acting insulin aspart can be confirmed in the primary analysis, the trial also aims to compare treatment arms for a number of confirmatory secondary endpoints.

The steps as stated earlier in Section 2 in the hierarchical testing procedure are:

Step 1 (Primary analysis): HbA_{1c} non-inferiority of mealtime fast-acting insulin aspart versus mealtime NovoRapid®

Step 2: HbA_{1c} non-inferiority of postmeal fast-acting insulin aspart versus mealtime NovoRapid®

Step 3: 1-hour PPG increments superiority of mealtime fast-acting insulin aspart versus mealtime NovoRapid®

Step 4: HbA_{1c} superiority of mealtime fast-acting insulin aspart versus mealtime NovoRapid®

Step 5: 1,5-anhydroglucitol superiority of mealtime fast-acting insulin aspart versus mealtime NovoRapid®

The secondary analysis 4) will also be repeated for the confirmatory secondary endpoints. The analysis will be based on the FAS and using the on-treatment observation period.

Change from baseline in HbA_{1c} 26 weeks after randomisation (step 2)

If the primary objective is confirmed, the effect of treatment with postmeal fast-acting insulin aspart in terms of glycaemic control is to be investigated by showing that post meal fast-acting insulin aspart is non-inferior to NovoRapid[®] both in combination with insulin degludec in terms of glucose lowering effect as assessed by change from baseline in HbA_{1c} 26 weeks after randomisation.

Non-inferiority will be evaluated based on the two-sided 95% CI of mean treatment difference (postmeal fast-acting insulin aspart minus mealtime NovoRapid[®]) obtained from the primary statistical analysis in 1).

Change from baseline in 1-hour PPG increments 26 weeks after randomisation (meal test) (step 3)

As the third step of the hierarchical testing procedure, change from baseline in 1-hour PPG increments (meal test) 26 weeks after randomisation will be tested for superiority of mealtime fast-acting insulin aspart compared to mealtime NovoRapid[®]. The 1-hour PPG increment will be analysed based on the laboratory-measured values in the meal test, and is derived using the 1-hour PPG measurement minus the pre-prandial PG.

The 1-hour PPG increment primary estimand will be addressed using an analysis of variance model (ANOVA) including treatment, region, and bolus adjusting method as factors and 1-hour PPG increment at baseline as covariate. Superiority will be confirmed if the upper boundary of the two-sided 95% CI of the mean treatment difference (mealtime fast-acting insulin aspart minus mealtime NovoRapid[®]) is below 0.

Change from baseline in HbA_{1c} 26 weeks after randomisation (step 4)

As the fourth step of the hierarchical testing procedure, superiority of HbA_{1c} 26 weeks after randomisation with mealtime faster-acting insulin aspart compared to NovoRapid[®] is to be confirmed. The confidence interval from the same statistical model as used for the primary analysis in 1) will be used to determine superiority. Superiority will be confirmed if the upper boundary of the two-sided 95% CI of the mean treatment difference (mealtime fast-acting insulin aspart minus mealtime NovoRapid[®]) is below 0%-points.

Change from baseline in 1,5-anhydroglucitol 26 weeks after randomisation (step 5)

Step 5 in the hierarchical testing procedure is to confirm superiority of changes from baseline in 1,5-anhydroglucitol 26 weeks after randomisation with mealtime fast-acting insulin aspart compared to mealtime NovoRapid[®].

The analysis for the primary 1,5-anhydroglucitol estimand will be done using all subjects included in FAS and using the in-trial observation period. The change from baseline in 1,5-anhydroglucitol will be analysed using a model similar to 1) except with the baseline 1,5-anhydroglucitol as a covariate. Superiority will be confirmed if the upper boundary of the two-sided 95% CI of the mean treatment difference (mealtime fast-acting insulin aspart minus mealtime NovoRapid®) is below 0.

2.4.2 Supportive secondary endpoints

For all supportive secondary endpoints, mealtime fast-acting insulin aspart will be compared to mealtime NovoRapid®, and postmeal fast-acting insulin aspart will be compared to mealtime NovoRapid®, unless otherwise stated.

2.4.2.1 Efficacy endpoints

All endpoints except insulin dose in this section will be assessed using the FAS and the in-trial observation period and repeated using the on-treatment observation period. Insulin dose will be presented using SAS and will therefore only use the on-treatment observation period.

Change from baseline in FPG after 26 weeks of treatment

Change from baseline in FPG 26 weeks after randomisation will be analysed based on all planned post-baseline measurements until or at 26 weeks using a model similar to 1), except with baseline FPG as covariate.

Percentage of Subjects reaching HbA_{1c} target 26 weeks after randomisation:

HbA_{1c} < 7.0%

A dichotomous (responder/non-responder) endpoint will be defined based on whether a subject has met the ADA HbA_{1c} target (HbA_{1c} <7.0%) 26 weeks after randomisation.

This responder endpoint will be analysed based on a logistic regression model using treatment, region, and bolus adjusting method as factors, and baseline HbA_{1c} as covariate. In analysis of the in-trial data, subjects without an HbA_{1c} measurement at week 26 will be treated as non-responders. In the on-treatment observation period analysis, subjects who discontinue fast-acting insulin aspart/NovoRapid® or withdraw from trial or have no HbA_{1c} measurement at week 26 will be included as non-responders.

HbA_{1c} < 7.0% without severe hypoglycaemia

A dichotomous (responder/non-responder) endpoint will be defined based on whether a subject has met the ADA HbA_{1c} target (HbA_{1c} <7.0%) 26 weeks after randomisation without treatment-emergent severe hypoglycaemic episodes.

This responder endpoint will be analysed based on a logistic regression model using treatment, region, and bolus adjusting method as factors and baseline HbA_{1c} as covariate. In analysis of the in-trial data, subjects without an HbA_{1c} measurement at week 26 will be treated as non-responders. In the on-treatment observation period analysis, subjects who discontinue fast-acting insulin aspart/NovoRapid® or withdraw from trial or have no HbA_{1c} measurement at week 26 will be included as non-responders.

HbA_{1c} < 7.0% without severe hypoglycaemia and minimal weight gain (<3.0%)

A dichotomous (responder/non-responder) endpoints will be defined based on whether a subject has met the ADA HbA_{1c} target (HbA_{1c} <7.0%) 26 weeks after randomisation without treatment-emergent severe hypoglycaemic episodes, and with minimal weight gain from baseline to 26 weeks after randomisation (defined as less than a 3% increase).

This responder endpoint will be analysed based on a logistic regression model using treatment, region, and bolus adjusting method as factors and baseline HbA_{1c} and baseline body weight as covariates. In analysis of the in-trial data, subjects without an HbA_{1c} measurement at week 26 or without body weight measurement at week 26 will be treated as non-responders. In the on-treatment observation period analysis, subjects who discontinue fast-acting insulin aspart/NovoRapid® or withdraw from trial or have no HbA_{1c} measurement at week 26 or have no body weight measurement at week 26 will be included as non-responders.

Change from baseline in 30- min, 1- hour, 2- hour, 3- hour and 4- hour PPG and 30- min, 2- hour, 3- hour and 4- hour PPG increment 26 weeks after randomisation (meal test)

Laboratory measured PG from the meal test will be analysed for 30, 60, 120, 180, and 240 minutes PPG separately. The corresponding PPG increments will be derived separately using each PPG measurement minus the pre-prandial PG.

Change from baseline in PPG and PPG increment endpoints 26 weeks after randomisation will be analysed separately using an ANOVA model including treatment, region, and bolus adjusting method as factors, and the corresponding baseline value as covariate.

Note as the meal test is only preformed once post baseline, subjects with no post baseline meal test will not contribute to the analysis.

Change from baseline in 7-9-7-point self-measured plasma glucose (SMPG) profile 26 weeks after randomisation:

In general, analyses will be based on the entire 7-9-7-point profile except for the analyses of nocturnal endpoints where information in the 9-point profile will be utilised. Duration of main meals and time of injection of bolus insulin, which will be collected in connection with 7-9-7 point profiles, will be summarised descriptively.

PPG and PPG increments based on the 7-9-7-point profiles will be derived separately for PG measurements made 1 hour after a meal. In the following section this distinction will be considered implicit and without further explanation.

Pre-prandial PG and PPG will be recorded by the subjects as part of two 7-point and one 9-point SMPG profile prior to the visits. Individual mean mealtime PPG (post-breakfast, post-lunch, post-main evening meal) will be derived from the three profiles. Overall mean PPG will be derived from the individual derived mealtime PPG values.

PPG increment for each meal (breakfast, lunch, main evening meal) will be derived from the 7-point and 9-point profile as the difference between PPG values and the PG value before meal in each separate profile. The mean of the derived increments will then be calculated separately for each meal. Mean 1-hour PPG increments over all meals will be derived as the mean of all corresponding mean meal increments.

Change from baseline in mean of the 7-9-7-point profile

The mean of the 7-9-7-point profile is defined as the area under the curve profile divided by the measurement time, and is calculated using the linear trapezoidal technique.

Change from baseline in the mean of the 7-9-7-point profile 26 weeks after randomisation will be analysed using a model similar to 1) except with the corresponding baseline value as covariate.

Change from baseline in mean PPG and PPG increment over all three meals

Change from baseline in mean PPG and PPG increment 26 weeks randomisation will be analysed separately using a model similar to 1), except with the corresponding baseline value as covariate.

Change from baseline in individual meal (breakfast, lunch and main evening meal) PPG and PPG increment

Change from baseline in PPG and PPG increment endpoints 26 weeks after randomisation for the individual meals (breakfast, lunch, main evening meal) will be analysed separately using a model similar to 1) except with the corresponding baseline value as covariate.

Fluctuation in 7-9-7-point profile

The fluctuation in the 7-9-7-point profile is defined as:

$$\frac{1}{T} \int_0^T |PG(t) - \overline{PG}| dt,$$

where T , $PG(t)$ and \overline{PG} denotes the length of the profile, the PG value at time t and the mean of the profile, respectively.

Fluctuation in the 7-9-7-point profile will be logarithmically transformed and analysed in the same way as the mean of the profile is analysed except with the corresponding log-transformed baseline values as covariate.

Estimated treatment means and the estimated treatment difference with corresponding 95% CI will be back-transformed to the original scale, resulting in estimated geometric means, a treatment ratio and a 95% CI for the treatment ratio.

Change in the nocturnal SMPG measurements

Change from baseline in nocturnal PG values 26 weeks after randomisation will be assessed by considering the differences between PG values available at bedtime, at 4 AM and the before breakfast value the following day: (4 AM PG value minus at bedtime PG value), (before breakfast PG value minus at bedtime PG value) and (before breakfast PG value minus 4 AM PG value).

Change in the nocturnal SMPG measurements will be analysed in the same way as mean of the profile is analysed, except with the corresponding baseline values as covariate.

Percentage of subjects reaching PPG target (based on mean of PPG measurements in SMPG) 26 weeks after randomisation:

Overall PPG (1 hour) ≤ 7.8 mmol/L [140 mg/dL]

A dichotomous endpoint will be defined based on whether a subject has reached an overall mean 1-hour PPG ≤ 7.8 mmol/L [140 mg/dL] 26 weeks after randomisation, where PPG is derived from the 7- and 9-point profile.

This responder endpoint will be analysed based on a logistic regression model using treatment, region, and bolus adjusting method as factors, and baseline overall mean 1-hour PPG as covariate. In analysis of the in-trial data, subjects without an overall mean 1-hour PPG at week 26 will be treated as non-responders. In the on-treatment observation period analysis, subjects who discontinue fast-acting insulin aspart/NovoRapid® or withdraw from trial or have no overall mean 1-hour PPG measurement at week 26 will be included as non-responders.

Overall PPG (1 hour) ≤ 7.8 mmol/L [140 mg/dL] without severe hypoglycaemia

A dichotomous endpoint will be defined based on whether a subject has reached an overall mean 1-hour PPG ≤ 7.8 mmol/L [140 mg/dL] 26 weeks after randomisation without any treatment-emergent severe hypoglycaemic episodes. This responder endpoint will be analysed based on a logistic regression model using treatment, region, and bolus adjusting method as factors, and

baseline overall mean 1-hour PPG as covariate. In analysis of the in-trial data, subjects without an overall mean 1-hour PPG at week 26 will be treated as non-responders. In the on-treatment observation period analysis, subjects who discontinue fast-acting insulin aspart/NovoRapid® or withdraw from trial or have no overall mean 1-hour PPG measurement at week 26 will be included as non-responders.

Overall PPG (1 hour) ≤ 7.8 mmol/L [140 mg/dL] and HbA_{1c} < 7.0% and minimal weight gain (<3.0%) without severe hypoglycaemia

A dichotomous endpoint will be defined based on whether a subject has reached an overall mean 1-hour PPG ≤ 7.8 mmol/L [140 mg/dL], have HbA_{1c} < 7.0% and has had minimal weight gain (increase in body weight from baseline <3.0%) 26 weeks after randomisation, and without any treatment-emergent severe hypoglycaemic episodes.

This responder endpoint will be analysed based on a logistic regression model using treatment, region, and bolus adjusting method as factors, and baseline overall mean 1-hour PPG, baseline HbA_{1c} and baseline body weight as covariates. In analysis of the in-trial observation period, subjects without an overall mean 1-hour PPG or an HbA_{1c} value or a body weight at week 26 will be treated as non-responders. In the on-treatment observation period analysis, subjects who discontinue fast-acting insulin aspart/NovoRapid® or withdraw from trial or have no overall mean 1-hour PPG measurement at week 26 or have no HbA_{1c} measurement at week 26 or have no body weight measurement at week 26 will be included as non-responders.

Insulin dose (basal insulin dose, total and individual meal insulin dose)

The insulin doses will be summarised descriptively by treatment week according to regimen, both by meal type and as total daily dose in units and units/kg (total daily and separately for each mealtime dose). Insulin doses will be summarised using the on-treatment observation period and using the SAS.

Change from baseline in lipids-lipoproteins profile 26 weeks after randomisation (total cholesterol, high density lipoproteins, low density lipoproteins)

Change from baseline in lipid endpoints (low density lipoprotein (LDL), high density lipoprotein (HDL), and total cholesterol) will be analysed separately using a model-similar to 1). The lipid endpoints will be log-transformed before they are analysed including the corresponding baseline measurement which is included in the analysis as a covariate. The treatment difference and associated 95% CIs will be back-transformed providing results in terms of ratios of geometric means on the original scale.

2.4.2.2 Safety endpoints

All safety endpoints will be compared using the on-treatment observation period. In terms of adverse events, as a minimum, serious adverse events will be tabulated separately also using the in-trial observation period.

All events in the in-trial observation period will be listed with information about whether it appeared in the on-treatment observation period or not.

Number of treatment-emergent Adverse Events

AEs will be coded using the Medical Dictionary for Regulatory Activities (MedDRA). AEs will be presented based on system organ class and preferred terms.

A Treatment-Emergent Adverse Event (TEAE) is defined as an event that has an onset date on or after the first day of exposure to randomised treatment, and no later than seven days after the last day of randomised treatment.

TEAEs are summarised descriptively, whereas AE's not defined as treatment-emergent are presented in listings, including AEs reported in the 30-day follow-up period. The summaries of TEAEs are made displaying the number of subjects with at least one event, the percentage of subjects with at least one event, the number of events and the event rate per 100 patient years of exposure. These summaries are done by seriousness, severity, relation to insulin treatment, relation to technical complaint, premature treatment discontinuation due to AEs, withdrawal from trial due to AEs and outcome.

Furthermore, summary tables based on system organ class and preferred terms are made for:

- all TEAEs
- serious TEAEs
- possibly or probably related TEAEs
- severe TEAEs
- TEAEs with preferred term that are experienced by at least 5% of the subjects in any treatment arm or by at least 5% of all subjects

For AEs where additional information is recorded, this will be listed.

AEs occurring during the run-in period are considered non treatment-emergent and will be summarised separately.

Number of treatment-emergent injection site reactions

Treatment-emergent injection site reactions occurring during the trial will be summarised and listed. No formal statistical analysis will be made.

Classification of Hypoglycaemia:

Treatment-emergent: hypoglycaemic episodes will be defined as treatment-emergent if the onset of the episode occurs on or after the first day of IMP administration after randomisation and no later than one day after the last day on IMP.

Nocturnal hypoglycaemic episodes: are episodes occurring between 00:01 and 05.59 both inclusive.

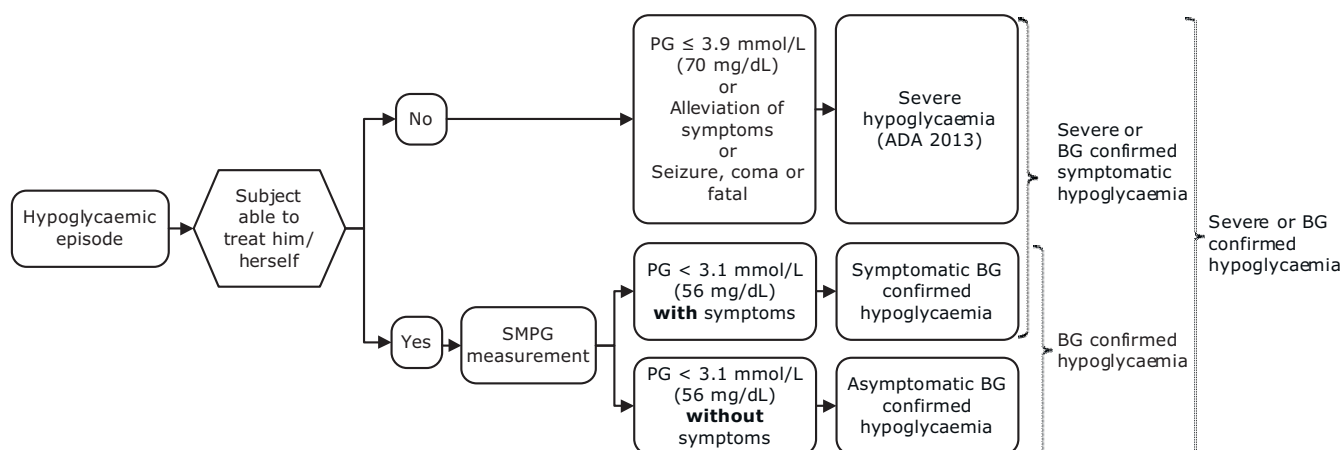
Hypoglycaemic episodes are classified according to the Novo Nordisk classification of hypoglycaemia (see [Figure 2-1](#) and the ADA classification of hypoglycaemia [Figure 2-2](#)).

Novo Nordisk classification of hypoglycaemia

In normal physiology, symptoms of hypoglycaemia occur below a PG level of 3.1 mmol/L (56 mg/dL)³. Therefore, Novo Nordisk has included hypoglycaemia with PG levels below this cut-off point in the definition of blood glucose (BG) confirmed hypoglycaemia.

Novo Nordisk uses the following classification ([Figure 2-1](#)) in addition to the ADA classification:

- Severe hypoglycaemia according to the ADA classification⁴.
- Symptomatic BG confirmed hypoglycaemia: An episode that is BG confirmed by plasma glucose value <3.1 mmol/L (56 mg/dL) **with** symptoms consistent with hypoglycaemia.
- Asymptomatic BG confirmed hypoglycaemia: An episode that is BG confirmed by plasma glucose value <3.1 mmol/L (56 mg/dL) **without** symptoms consistent with hypoglycaemia.
- Severe or BG confirmed symptomatic hypoglycaemia: An episode that is severe according to the ADA classification⁴ or BG confirmed by a plasma glucose value <3.1 mmol/L (56 mg/dL) **with** symptoms consistent with hypoglycaemia.
- BG confirmed hypoglycaemia: An episode that is BG confirmed by a plasma glucose value <3.1 mmol/L (56 mg/dL) **with** or **without** symptoms consistent with hypoglycaemia.
- Severe or BG confirmed hypoglycaemia: An episode that is severe according to the ADA classification⁴ or BG confirmed by a plasma glucose value <3.1 mmol/L (56 mg/dL) **with** or **without** symptoms consistent with hypoglycaemia.

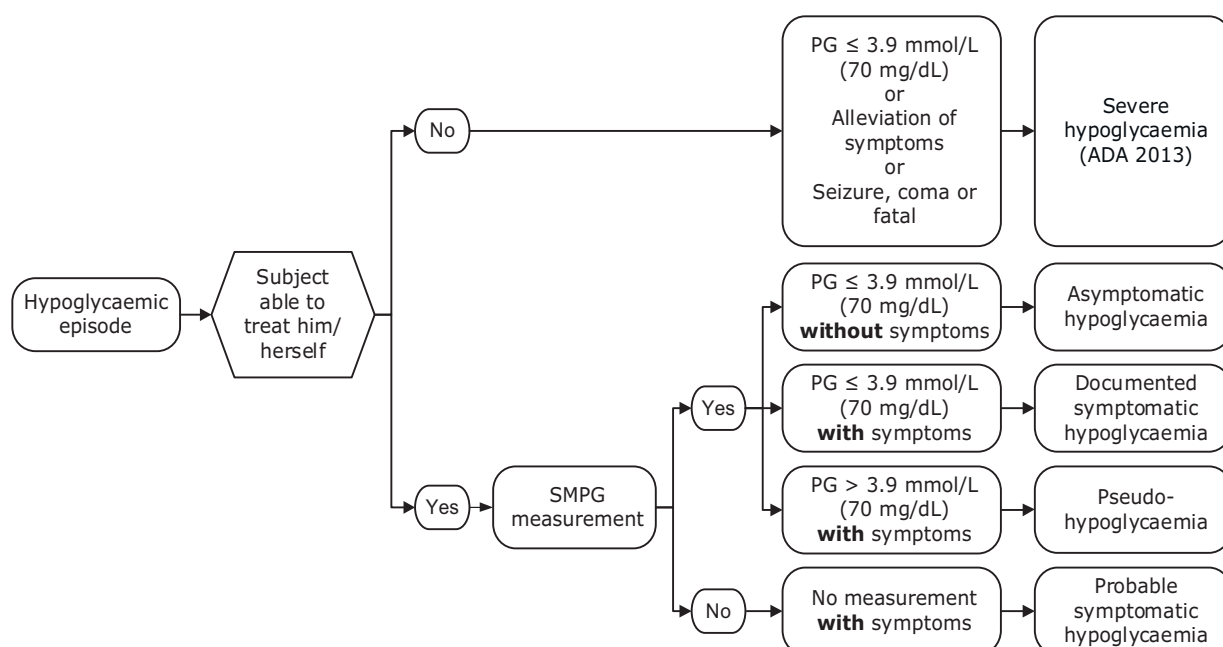


Note: Glucose measurements are performed with capillary blood calibrated to plasma equivalent glucose values

Figure 2-1 Novo Nordisk classification of hypoglycaemia

ADA classification of hypoglycaemia⁴

- Severe hypoglycaemia: An episode requiring assistance of another person to actively administer carbohydrate, glucagon, or take other corrective actions. Plasma glucose concentrations may not be available during an event, but neurological recovery following the return of plasma glucose to normal is considered sufficient evidence that the event was induced by a low plasma glucose concentration.
- Asymptomatic hypoglycaemia: An episode not accompanied by typical symptoms of hypoglycaemia, but with a measured plasma glucose concentration ≤ 3.9 mmol/L (70 mg/dL).
- Documented symptomatic hypoglycaemia: An episode during which typical symptoms of hypoglycaemia are accompanied by a measured plasma glucose concentration ≤ 3.9 mmol/L (70 mg/dL).
- Pseudo-hypoglycaemia: An episode during which the person with diabetes reports any of the typical symptoms of hypoglycaemia with a measured plasma glucose concentration > 3.9 mmol/L (70 mg/dL) but approaching that level.
- Probable symptomatic hypoglycaemia: An episode during which symptoms of hypoglycaemia are not accompanied by a plasma glucose determination but that was presumably caused by a plasma glucose concentration ≤ 3.9 mmol/L (70 mg/dL).



Note: Glucose measurements are performed with capillary blood calibrated to plasma equivalent glucose values

Figure 2-2 ADA classification of hypoglycaemia

Data on treatment-emergent hypoglycaemic episodes are presented in terms of the number of subjects with at least one event (N), the percentage of subjects with at least one event (%), the number of events (E) and the event rate per 100 years of exposure (R). Separate summaries are made by severity considering all episodes, nocturnal and daytime episodes using Novo Nordisk and ADA classified episodes. Episodes will also be summarised overall and by category in relation to time since start of meal, as occurring within the following time intervals:

- During first 1, 2, and 4 hours after start of meal
- Between 1 (exclusive) to 2 hours (inclusive) after start of meal
- Between 2 (exclusive) to 3 hours (inclusive) after start of meal
- Between 3 (exclusive) to 4 hours (inclusive) after start of meal
- Between 2 hours (exclusive) to 4 hours (inclusive) after start of meal

Non-treatment-emergent hypoglycaemic episodes will be listed.

The number of treatment-emergent severe or BG confirmed hypoglycaemic episodes (all, daytime, nocturnal, 1 hour, 2 hour, 4 hour, 1 [exclusive] to 2 hours [inclusive], 2 [exclusive] to 3 hours [inclusive], 3 [exclusive] to 4 hours [inclusive], and from 2 hours [exclusive] to 4 hours [inclusive] after start of meal) will be analysed using a negative binomial regression model with a log -link function and the logarithm of the time period for which a hypoglycaemic episode is considered treatment-emergent as offset. The model will include treatment, region, and bolus adjusting method as factors. To the extent where data allow, separate analyses will be performed for all severe episodes.

Physical examination

The physical examination parameters (head, ears, eyes, nose, throat, neck, respiratory system, cardiovascular system, gastrointestinal system incl. mouth, musculoskeletal system, central and peripheral nervous system, skin), and their change from baseline, will be summarised descriptively in shift tables. All findings will be listed.

Vital signs

Vital signs include diastolic blood pressure, systolic blood pressure and pulse. The measurements will be summarised descriptively using both the actual values as mean change.

ECG

Electrocardiogram (ECG) findings will be summarised descriptively including summaries of the change from baseline. Change from baseline will be summarised as normal/abnormal not clinically significant/abnormal clinically significant categorisation in shift tables.

Fundoscopy/fundus photography

Fundus photography/fundoscopy findings will be summarised descriptively including summaries of the change from baseline. Change from baseline will be summarised as normal/abnormal not clinically significant/abnormal clinically significant categorisation in shift tables.

Clinical laboratory assessments

Change from baseline 26 weeks after randomisation in central laboratory assessments:

Haematology
Biochemistry
Urinalysis

Individual laboratory values will be compared to their relevant reference range (when existing) and flagged as being below or above the range. The measurements will be summarised descriptively using both the actual values as mean change and the low/normal/high categorisation in shift tables.

Change from baseline in anti-insulin aspart (specific and cross-reacting with human insulin) antibody development

The measurements and their change from baseline will be summarised descriptively. The correlation to other relevant variables such as bolus insulin dose and HbA 1c are illustrated using graphs.

Change from baseline in body weight and body mass index (BMI) 26 weeks after randomisation

The measurements will be summarised descriptively using both the actual values and change from baseline.

Change from baseline in body weight will be analysed using a model similar to 1), except with the corresponding baseline measurement as covariate. The analysis will be based on the safety analysis set and the on-treatment observation period.

3 Changes to the statistical analyses planned in the protocol

General considerations

It has been clarified how data collected at visit 36A is handled.

Sample size calculation

Erroneous descriptions in [Table 2-1](#) have been corrected.

Statistical analysis

In the sensitivity analysis 2) for change from baseline in HbA1c, baseline HbA1c has been added to the model as a covariate.

In the statistical analysis in the protocol, it is not clear if missing values or values for subjects discontinuing treatment/withdraw from trial should be imputed. Some of the following changes have been implemented to account for this issue.

In the sensitivity analysis for change from baseline in HbA1c, it has been changed from subjects withdrawing from trial to subjects without a measurement at week 26 to be aligned with the primary analysis.

In the statistical sensitivity analysis 3b) for change from baseline in HbA1c, copy reference has been changed to conditional imputation. Also in the statistical sensitivity analysis for 3c), jump to reference has been changed to unconditional imputation to clarify the method used.

In the statistical analysis addressing the secondary estimand 5) and 6) for change from baseline in HbA1c, tipping point analyses for treatment difference for the comparison between postmeal faster-acting insulin aspart and mealtime NovoRapid® have been added.

It has been clarified that the statistical analysis 4) will be repeated as for the confirmatory secondary endpoints.

In the statistical analysis for percentage of subjects reaching HbA1c or PPG (SMPG) target, it has been clarified that subjects without an HbA1c measurement or 1-hour mean PPG measurement at week 26 will be handled as non-responders in the on-treatment observation period analysis.

In the statistical analysis for percentage of subjects reaching HbA_{1c} target without severe hypoglycaemia and minimal weight gain, it has been clarified that subjects without an HbA1c measurement or a weight measurement at week 26 will be handled as non-responders in the on-treatment observation period analysis.

In the statistical analysis for percentage of subjects reaching HbA_{1c} and PPG (SMPG) targets without severe hypoglycaemia and minimal weight gain, it has been clarified that subjects without an HbA1c measurement or an 1-hour mean PPG measurement or a weight measurement at week 26 will be handled as non-responders in the on-treatment observation period analysis.

In the statistical analysis for treatment-emergent severe or BG confirmed hypoglycaemic episodes, the bolus adjusting method has been added to the model as a covariate.

In the statistical analysis for change from baseline in body weight and BMI, it has been clarified that the analysis will be based on the safety analysis set and the on-treatment observation period.

Fluctuation in 7-9-7-point

Change from baseline has been removed for fluctuation in the 7-7-9-point SMPG profile as it is analysed logarithmically transformed and change from baseline values could be negative.

AEs where additional information is recorded

For AEs where additional information is recorded, this will be only listed.

Hypoglycaemic episodes

The endpoints treatment-emergent hypoglycaemic episodes occurring within 1 (exclusive) to 2 hours (inclusive), 2 (exclusive) to 3 hours (inclusive), 3 (exclusive) to 4 hours (inclusive) after start of the meal have been added to further investigate the safety of fast-acting insulin aspart.

It has been clarified that separate statistical analysis will only be for all severe hypoglycaemic episodes as the number is expected to be very low.

4 References

¹ International Conference on Harmonisation. ICH Harmonised Tripartite Guideline. Statistical principles for clinical trials E9. International Conference on Harmonisation E9 Expert Working Group. September 1998.

² Koch G. Comments on 'Current issues in non-inferiority trials'. Statistics in Medicine 2008;27(3):333-342.

³ Schwartz NS, Clutter WE, Shah SD, Cryer PE. Glycemic thresholds for activation of glucose counterregulatory systems are higher than the threshold for symptoms. J Clin Invest 1987; 79(3):777-781.

⁴ Seaquist ER, Anderson J, Childs B, Cryer P, Dagogo-Jack S, Fish L et al. Hypoglycemia and Diabetes: A Report of a Workgroup of the American Diabetes Association and The Endocrine Society. Diabetes Care 2013; 36(5):1384-1395.

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Statistical documentation

1: HbA1c 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=C64849B Planned Treatment for Period 30 (N)=2

Obs	PARAM	Description	Value
1	HbA1c (%)	Data Set	WORK.ENDPOINT_PARAM
2	HbA1c (%)	Method	Monotone-data_MCMC
3	HbA1c (%)	Multiple Imputation Chain	Multiple Chains
4	HbA1c (%)	Initial Estimates for MCMC	EM Posterior Mode
5	HbA1c (%)	Start	Starting Value
6	HbA1c (%)	Prior	Jeffreys
7	HbA1c (%)	Number of Imputations	100
8	HbA1c (%)	Number of Burn-in Iterations	200
9	HbA1c (%)	Seed for random number generator	73804

Parameter Code=C64849B Planned Treatment for Period 30 (N)=3

Obs	PARAM	Description	Value
10	HbA1c (%)	Data Set	WORK.ENDPOINT_PARAM
11	HbA1c (%)	Method	Monotone-data_MCMC
12	HbA1c (%)	Multiple Imputation Chain	Multiple Chains
13	HbA1c (%)	Initial Estimates for MCMC	EM Posterior Mode
14	HbA1c (%)	Start	Starting Value
15	HbA1c (%)	Prior	Jeffreys
16	HbA1c (%)	Number of Imputations	100
17	HbA1c (%)	Number of Burn-in Iterations	200
18	HbA1c (%)	Seed for random number generator	1221371123

HbA1c 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=C64849B Planned Treatment for Period 30 (N)=4

Obs	PARAM	Description	Value
19	HbA1c (%)	Data Set	WORK.ENDPOINT_PARAM
20	HbA1c (%)	Method	Monotone-data_MCMC
21	HbA1c (%)	Multiple Imputation Chain	Multiple Chains
22	HbA1c (%)	Initial Estimates for MCMC	EM Posterior Mode
23	HbA1c (%)	Start	Starting Value
24	HbA1c (%)	Prior	Jeffreys
25	HbA1c (%)	Number of Imputations	100
26	HbA1c (%)	Number of Burn-in Iterations	200
27	HbA1c (%)	Seed for random number generator	662262896

Fast-acting insulin aspart
NN1218-4131

Clinical Trial Report
Statistical document

Date: 14 February 2018
Version: 1.0
Status: Page:

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Novo Nordisk

HbA1c 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with MCMC
Missing data pattern

Parameter Code=C64849B Planned Treatment for Period 30 (N)=2

Obs	PARAM	Group	BASE_ Miss	visit1400_ Miss	visit1800_ Miss	visit2200_ Miss	visit2600_ Miss	visit3000_ Miss	visit3400_ Miss	visit3600_ Miss	Freq	Percent
1	HbA1c (%)	1	X	X	X	X	X	X	X	X	330	96.49
2	HbA1c (%)	2	X	X	X	X	X	X	X	O	1	0.29
3	HbA1c (%)	3	X	X	X	X	X	X	.	X	3	0.88
4	HbA1c (%)	4	X	X	X	X	X	.	X	X	1	0.29
5	HbA1c (%)	5	X	X	X	O	O	O	O	O	1	0.29
6	HbA1c (%)	6	X	X	.	X	X	X	X	X	2	0.58
7	HbA1c (%)	7	X	X	.	.	X	X	X	X	1	0.29
8	HbA1c (%)	8	X	X	O	O	O	O	O	O	2	0.58
9	HbA1c (%)	9	X	.	X	X	X	.	.	X	1	0.29

Obs	BASE	visit1400	visit1800	visit2200	visit2600	visit3000	visit3400	visit3600
1	7.454242	-0.106970	-0.133636	-0.172424	-0.114848	-0.129091	-0.097576	-0.124242
2	6.700000	0.100000	-0.300000	-0.400000	0	0	0.200000	.
3	7.666667	-0.133333	-0.133333	-0.300000	-0.333333	-0.500000	.	0.266667
4	7.300000	-1.000000	-1.700000	-1.800000	-2.500000	.	-1.500000	-1.200000
5	7.300000	0	-0.200000
6	8.000000	-0.250000	.	0.100000	0.050000	-0.350000	0	0.150000
7	7.800000	0	.	.	0	-0.200000	-0.700000	-0.700000
8	7.750000	0.200000
9	6.300000	.	0.100000	0	-0.100000	.	.	-0.100000

nn1218/nn1218-4131/ctr_20180214_er
13FEB2018:21:55:26 - a_hba_stat_diff.sas/a_hba_stat_in_fas_app.txt

Fast-acting insulin aspart
NN1218-4131

Clinical Trial Report
Statistical document

Date: 14 February 2018
Version: 1.0
Status: Page:

Final
6 of 4425
Novo Nordisk

HbA1c 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with MCMC
Missing data pattern

Parameter Code=C64849B Planned Treatment for Period 30 (N)=3

Obs	PARAM	Group	BASE_ Miss	visit1400_ Miss	visit1800_ Miss	visit2200_ Miss	visit2600_ Miss	visit3000_ Miss	visit3400_ Miss	visit3600_ Miss	Freq	Percent
10	HbA1c (%)	1	X	X	X	X	X	X	X	X	325	95.31
11	HbA1c (%)	2	X	X	X	X	X	X	.	X	3	0.88
12	HbA1c (%)	3	X	X	X	X	X	X	O	O	1	0.29
13	HbA1c (%)	4	X	X	X	X	X	.	X	X	2	0.59
14	HbA1c (%)	5	X	X	X	X	X	O	O	O	1	0.29
15	HbA1c (%)	6	X	X	X	X	.	X	X	X	1	0.29
16	HbA1c (%)	7	X	X	X	X	.	.	.	X	1	0.29
17	HbA1c (%)	8	X	X	X	X	O	O	O	O	3	0.88
18	HbA1c (%)	9	X	X	X	O	O	O	O	O	1	0.29
19	HbA1c (%)	10	X	X	.	X	X	X	X	X	1	0.29
20	HbA1c (%)	11	X	X	O	O	O	O	O	O	1	0.29

Obs	BASE	visit1400	visit1800	visit2200	visit2600	visit3000	visit3400	visit3600
10	7.410154	-0.048923	-0.017538	-0.039692	0.026462	0.024615	0.032308	-0.010462
11	6.700000	-0.100000	-0.166667	-0.300000	0.033333	0.366667	.	0.100000
12	7.000000	-0.300000	-0.100000	-0.200000	-0.400000	-0.300000	.	.
13	7.350000	0.100000	-0.250000	-0.200000	0	.	0.800000	0.650000
14	8.000000	-0.600000	-0.600000	-0.800000	-0.700000	.	.	.
15	7.100000	0.100000	0.600000	1.000000	.	1.500000	1.600000	1.200000
16	8.100000	-0.400000	0.500000	0.700000	.	.	.	1.300000
17	7.500000	-0.100000	0.066667	0.233333
18	7.400000	0.600000	0.900000
19	7.400000	0.100000	.	0.100000	0.300000	0	0.100000	0.300000
20	6.600000	0.200000

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The MI Procedure with MCMC
Missing data pattern

Parameter Code=C64849B Planned Treatment for Period 30 (N)=3

(continued)

Obs	PARAM	Group	BASE_ Miss	visit1400_ Miss	visit1800_ Miss	visit2200_ Miss	visit2600_ Miss	visit3000_ Miss	visit3400_ Miss	visit3600_ Miss	Freq	Percent
21	HbA1c (%)	12	X	.	X	X	X	X	X	X	1	0.29

Obs	BASE	visit1400	visit1800	visit2200	visit2600	visit3000	visit3400	visit3600
21	7.800000	.	-0.200000	-0.600000	-0.700000	-0.300000	-0.300000	-0.200000

Parameter Code=C64849B Planned Treatment for Period 30 (N)=4

Obs	PARAM	Group	BASE_ Miss	visit1400_ Miss	visit1800_ Miss	visit2200_ Miss	visit2600_ Miss	visit3000_ Miss	visit3400_ Miss	visit3600_ Miss	Freq	Percent
22	HbA1c (%)	1	X	X	X	X	X	X	X	X	328	95.91
23	HbA1c (%)	2	X	X	X	X	X	X	X	O	1	0.29
24	HbA1c (%)	3	X	X	X	X	X	X	.	X	2	0.58
25	HbA1c (%)	4	X	X	X	X	X	.	.	X	1	0.29

Obs	BASE	visit1400	visit1800	visit2200	visit2600	visit3000	visit3400	visit3600
22	7.405488	-0.064939	-0.049390	-0.067683	-0.034451	-0.078354	-0.068598	-0.107012
23	6.900000	0.100000	-0.100000	-0.400000	-0.200000	-0.100000	-0.100000	.
24	8.000000	-0.100000	0.350000	0.300000	0.350000	0.450000	.	0
25	8.700000	0.500000	0.300000	-0.100000	-0.700000	.	.	0

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The MI Procedure with MCMC
Missing data pattern

Parameter Code=C64849B Planned Treatment for Period 30 (N)=4

(continued)

Obs	PARAM	Group	BASE_ Miss	visit1400_ Miss	visit1800_ Miss	visit2200_ Miss	visit2600_ Miss	visit3000_ Miss	visit3400_ Miss	visit3600_ Miss	Freq	Percent
26	HbA1c (%)	5	X	X	X	X	X	O	O	O	1	0.29
27	HbA1c (%)	6	X	X	X	X	.	X	X	X	1	0.29
28	HbA1c (%)	7	X	X	X	X	.	.	X	X	1	0.29
29	HbA1c (%)	8	X	X	X	X	O	O	O	O	2	0.58
30	HbA1c (%)	9	X	X	X	.	X	X	X	X	1	0.29
31	HbA1c (%)	10	X	X	.	X	X	X	X	X	1	0.29
32	HbA1c (%)	11	X	X	O	O	O	O	O	O	1	0.29
33	HbA1c (%)	12	X	.	X	X	X	X	X	O	1	0.29
34	HbA1c (%)	13	X	O	O	O	O	O	O	O	1	0.29

Obs	BASE	visit1400	visit1800	visit2200	visit2600	visit3000	visit3400	visit3600
26	7.800000	0.300000	0.400000	0.300000	0.200000	.	.	.
27	7.900000	0	-0.600000	0	.	-0.100000	0	0
28	7.300000	-1.000000	0.400000	0.200000	.	.	1.400000	1.400000
29	7.400000	0.300000	0.600000	0.550000
30	7.100000	-0.300000	-0.200000	.	0.700000	0.500000	0.100000	-0.200000
31	7.200000	-0.700000	.	-0.700000	-0.700000	-0.800000	-0.800000	-0.800000
32	7.900000	0.200000
33	6.900000	.	1.100000	1.400000	1.500000	1.300000	1.100000	.
34	7.800000

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The MI Procedure with Monotone Regression
Model Information

Parameter Code=C64849B Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM	Description	Value
1	1	HbA1c (%)	Data Set	WORK.MONOTONE
2	1	HbA1c (%)	Method	Monotone
3	1	HbA1c (%)	Number of Imputations	1
4	1	HbA1c (%)	Seed for random number generator	73904

Parameter Code=C64849B Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM	Description	Value
5	1	HbA1c (%)	Data Set	WORK.MONOTONE
6	1	HbA1c (%)	Method	Monotone
7	1	HbA1c (%)	Number of Imputations	1
8	1	HbA1c (%)	Seed for random number generator	627673144

Parameter Code=C64849B Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM	Description	Value
9	1	HbA1c (%)	Data Set	WORK.MONOTONE
10	1	HbA1c (%)	Method	Monotone
11	1	HbA1c (%)	Number of Imputations	1
12	1	HbA1c (%)	Seed for random number generator	947009354

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The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=C64849B Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM	Group	REGION1_ Miss	BOLAD1_ Miss	BASE_ Miss	visit1400_ Miss	visit1800_ Miss	visit2200_ Miss
1	1	HbA1c (%)	1	X	X	X	X	X	X
2	1	HbA1c (%)	2	X	X	X	X	X	X
3	1	HbA1c (%)	3	X	X	X	X	X	.
4	1	HbA1c (%)	4	X	X	X	X	.	.

Obs	visit2600_ Miss	visit3000_ Miss	visit3400_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit1400
1	X	X	X	X	338	98.83	7.456509	-0.110167
2	X	X	X	.	1	0.29	6.700000	0.100000
3	1	0.29	7.300000	0
4	2	0.58	7.750000	0.200000

Obs	visit1800	visit2200	visit2600	visit3000	visit3400	visit3600
1	-0.135817	-0.175411	-0.122485	-0.137318	-0.101920	-0.123964
2	-0.300000	-0.400000	0	0	0.200000	.
3	-0.200000
4

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The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=C64849B Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM	Group	REGION1_ Miss	BOLAD1_ Miss	BASE_ Miss	visit1400_ Miss	visit1800_ Miss	visit2200_ Miss
5	1	HbA1c (%)	1	X	X	X	X	X	X
6	1	HbA1c (%)	2	X	X	X	X	X	X
7	1	HbA1c (%)	3	X	X	X	X	X	X
8	1	HbA1c (%)	4	X	X	X	X	X	X
9	1	HbA1c (%)	5	X	X	X	X	X	.
10	1	HbA1c (%)	6	X	X	X	X	.	.

Obs	visit2600_ Miss	visit3000_ Miss	visit3400_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit1400
5	X	X	X	X	334	97.95	7.405689	-0.047668
6	X	X	.	.	1	0.29	7.000000	-0.300000
7	X	.	.	.	1	0.29	8.000000	-0.600000
8	3	0.88	7.500000	-0.100000
9	1	0.29	7.400000	0.600000
10	1	0.29	6.600000	0.200000

Obs	visit1800	visit2200	visit2600	visit3000	visit3400	visit3600
5	-0.016874	-0.038922	0.030414	0.035022	0.046757	0.002395
6	-0.100000	-0.200000	-0.400000	-0.300000	.	.
7	-0.600000	-0.800000	-0.700000	.	.	.
8	0.066667	0.233333
9	0.900000
10

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The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=C64849B Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM	Group	REGION1_ Miss	BOLAD1_ Miss	BASE_ Miss	visit1400_ Miss	visit1800_ Miss	visit2200_ Miss
11	1	HbA1c (%)	1	X	X	X	X	X	X
12	1	HbA1c (%)	2	X	X	X	X	X	X
13	1	HbA1c (%)	3	X	X	X	X	X	X
14	1	HbA1c (%)	4	X	X	X	X	X	X
15	1	HbA1c (%)	5	X	X	X	X	.	.
16	1	HbA1c (%)	6	X	X	X	.	.	.

Obs	visit2600_ Miss	visit3000_ Miss	visit3400_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit1400
11	X	X	X	X	335	97.95	7.412537	-0.068657
12	X	X	X	.	2	0.58	6.900000	0.253558
13	X	.	.	.	1	0.29	7.800000	0.300000
14	2	0.58	7.400000	0.300000
15	1	0.29	7.900000	0.200000
16	1	0.29	7.800000	.

Obs	visit1800	visit2200	visit2600	visit3000	visit3400	visit3600
11	-0.048101	-0.066159	-0.030567	-0.074046	-0.064202	-0.103582
12	0.500000	0.500000	0.650000	0.600000	0.500000	.
13	0.400000	0.300000	0.200000	.	.	.
14	0.600000	0.550000
15
16

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=C64849B Planned Treatment for Period 30 (N)=2 Imputed Variable=visit1800

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
1	1	HbA1c (%)	Intercept			0.00528	-0.024152
2	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)		-0.00414	-0.174527
3	1	HbA1c (%)	REGION1	EUROPE		-0.01094	0.082624
4	1	HbA1c (%)	REGION1	JAPAN		-0.02761	-0.003080
5	1	HbA1c (%)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.03216	0.000774
6	1	HbA1c (%)	BASE			-0.09533	-0.081146
7	1	HbA1c (%)	visit1400			0.79489	0.801511

Parameter Code=C64849B Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
8	1	HbA1c (%)	Intercept			0.00686	0.040311
9	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)		0.02897	0.103162
10	1	HbA1c (%)	REGION1	EUROPE		0.02996	-0.004806
11	1	HbA1c (%)	REGION1	JAPAN		-0.03287	-0.021275
12	1	HbA1c (%)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.03100	-0.031332
13	1	HbA1c (%)	BASE			-0.08697	-0.099733
14	1	HbA1c (%)	visit1400			0.07031	0.149503
15	1	HbA1c (%)	visit1800			0.76995	0.681092

Parameter Code=C64849B Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
16	1	HbA1c (%)	Intercept			-0.03730	-0.067983
17	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)		-0.16215	-0.264385

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=C64849B Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2600

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Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
18	1	HbA1c (%)	REGION1	EUROPE		0.10932	0.149667
19	1	HbA1c (%)	REGION1	JAPAN		-0.01231	-0.004004
20	1	HbA1c (%)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.0001918	0.024271
21	1	HbA1c (%)	BASE			-0.08361	-0.074793
22	1	HbA1c (%)	visit1400			-0.01487	-0.038410
23	1	HbA1c (%)	visit1800			0.01507	0.122848
24	1	HbA1c (%)	visit2200			0.83504	0.758671

Parameter Code=C64849B Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3000

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
25	1	HbA1c (%)	Intercept			0.00470	0.000880
26	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)		0.06070	0.148718
27	1	HbA1c (%)	REGION1	EUROPE		-0.01687	-0.052484
28	1	HbA1c (%)	REGION1	JAPAN		-0.04630	-0.062041
29	1	HbA1c (%)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.01762	-0.021088
30	1	HbA1c (%)	BASE			-0.05089	-0.063765
31	1	HbA1c (%)	visit1400			-0.00872	0.033362
32	1	HbA1c (%)	visit1800			-0.04190	-0.135089
33	1	HbA1c (%)	visit2200			0.13741	0.177348
34	1	HbA1c (%)	visit2600			0.77995	0.748492

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=C64849B Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3400

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
35	1	HbA1c (%)	Intercept			-0.01184	-0.024179
36	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)		-0.02060	-0.106054
37	1	HbA1c (%)	REGION1	EUROPE		0.05186	0.033103
38	1	HbA1c (%)	REGION1	JAPAN		-0.00313	0.021663
39	1	HbA1c (%)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.03422	0.029439
40	1	HbA1c (%)	BASE			-0.02467	-0.057455
41	1	HbA1c (%)	visit1400			0.03224	0.056713
42	1	HbA1c (%)	visit1800			0.06484	0.065119
43	1	HbA1c (%)	visit2200			0.10401	0.062497
44	1	HbA1c (%)	visit2600			0.04016	0.091387
45	1	HbA1c (%)	visit3000			0.69334	0.679997

Parameter Code=C64849B Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
46	1	HbA1c (%)	Intercept			-0.00842	-0.002266
47	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)		0.00681	-0.001836
48	1	HbA1c (%)	REGION1	EUROPE		0.07882	0.069723
49	1	HbA1c (%)	REGION1	JAPAN		-0.02375	-0.051322
50	1	HbA1c (%)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.03279	0.073114
51	1	HbA1c (%)	BASE			-0.00901	-0.004187
52	1	HbA1c (%)	visit1400			-0.05048	0.013687
53	1	HbA1c (%)	visit1800			0.05404	-0.023130
54	1	HbA1c (%)	visit2200			-0.02721	-0.035487
55	1	HbA1c (%)	visit2600			-0.02993	-0.079645
56	1	HbA1c (%)	visit3000			0.19040	0.277138
57	1	HbA1c (%)	visit3400			0.78725	0.782421

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Regression Information

Parameter Code=C64849B Planned Treatment for Period 30 (N)=3 Imputed Variable=visit1800

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
58	1	HbA1c (%)	Intercept			-0.01926	-0.037986
59	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)		-0.10018	-0.206800
60	1	HbA1c (%)	REGION1	EUROPE		0.05007	0.068771
61	1	HbA1c (%)	REGION1	JAPAN		0.00906	0.046104
62	1	HbA1c (%)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.01633	0.028690
63	1	HbA1c (%)	BASE			-0.08755	-0.154644
64	1	HbA1c (%)	visit1400			0.68521	0.699326

Parameter Code=C64849B Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
65	1	HbA1c (%)	Intercept			0.01118	-0.004245
66	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)		-0.01828	0.127569
67	1	HbA1c (%)	REGION1	EUROPE		-0.04982	-0.098054
68	1	HbA1c (%)	REGION1	JAPAN		0.03331	0.049438
69	1	HbA1c (%)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.04842	-0.074866
70	1	HbA1c (%)	BASE			-0.08216	-0.037971
71	1	HbA1c (%)	visit1400			-0.13053	-0.115932
72	1	HbA1c (%)	visit1800			0.88988	0.836075

Parameter Code=C64849B Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
73	1	HbA1c (%)	Intercept			-0.01855	-0.016609
74	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)		-0.11414	-0.185389

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Parameter Code=C64849B Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2600

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Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
75	1	HbA1c (%)	REGION1	EUROPE		0.03606	0.047641
76	1	HbA1c (%)	REGION1	JAPAN		-0.06722	-0.103283
77	1	HbA1c (%)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.00341	-0.013684
78	1	HbA1c (%)	BASE			-0.05109	-0.067962
79	1	HbA1c (%)	visit1400			-0.04207	-0.078865
80	1	HbA1c (%)	visit1800			0.02816	-0.049050
81	1	HbA1c (%)	visit2200			0.81025	0.893071

Parameter Code=C64849B Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3000

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
82	1	HbA1c (%)	Intercept			-0.02544	0.010852
83	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)		-0.09312	-0.066235
84	1	HbA1c (%)	REGION1	EUROPE		0.07868	0.109021
85	1	HbA1c (%)	REGION1	JAPAN		-0.06419	-0.069120
86	1	HbA1c (%)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.01247	-0.017864
87	1	HbA1c (%)	BASE			-0.03156	-0.045564
88	1	HbA1c (%)	visit1400			0.06135	0.077188
89	1	HbA1c (%)	visit1800			0.01278	0.001863
90	1	HbA1c (%)	visit2200			0.07036	-0.038208
91	1	HbA1c (%)	visit2600			0.74615	0.812919

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Parameter Code=C64849B Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3400

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
92	1	HbA1c (%)	Intercept			-0.00912	-0.038805
93	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)		-0.01022	-0.070683
94	1	HbA1c (%)	REGION1	EUROPE		0.11256	0.175551
95	1	HbA1c (%)	REGION1	JAPAN		-0.05792	-0.079030
96	1	HbA1c (%)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.00220	0.073053
97	1	HbA1c (%)	BASE			-0.04134	-0.056567
98	1	HbA1c (%)	visit1400			-0.01477	-0.018580
99	1	HbA1c (%)	visit1800			0.18707	0.195816
100	1	HbA1c (%)	visit2200			-0.10272	-0.069598
101	1	HbA1c (%)	visit2600			-0.11138	-0.105316
102	1	HbA1c (%)	visit3000			0.89811	0.835215

Parameter Code=C64849B Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
103	1	HbA1c (%)	Intercept			-0.00899	-0.006916
104	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)		-0.01275	0.062773
105	1	HbA1c (%)	REGION1	EUROPE		0.00198	0.003285
106	1	HbA1c (%)	REGION1	JAPAN		-0.02795	-0.073792
107	1	HbA1c (%)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.05266	0.064977
108	1	HbA1c (%)	BASE			-0.04517	-0.042993
109	1	HbA1c (%)	visit1400			0.03115	-0.009189
110	1	HbA1c (%)	visit1800			-0.03490	-0.022901
111	1	HbA1c (%)	visit2200			0.07273	-0.001352
112	1	HbA1c (%)	visit2600			-0.01908	0.046345
113	1	HbA1c (%)	visit3000			0.03662	0.054044
114	1	HbA1c (%)	visit3400			0.85656	0.834533

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Regression Information

Parameter Code=C64849B Planned Treatment for Period 30 (N)=4 Imputed Variable=visit1400

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
115	1	HbA1c (%)	Intercept			0.01522	-0.015586
116	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)		0.09959	0.102632
117	1	HbA1c (%)	REGION1	EUROPE		-0.03672	-0.032238
118	1	HbA1c (%)	REGION1	JAPAN		-0.08579	-0.017706
119	1	HbA1c (%)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.02030	0.036323
120	1	HbA1c (%)	BASE			-0.10269	-0.164111

Parameter Code=C64849B Planned Treatment for Period 30 (N)=4 Imputed Variable=visit1800

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
121	1	HbA1c (%)	Intercept			0.00797	0.034318
122	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)		0.10914	0.090631
123	1	HbA1c (%)	REGION1	EUROPE		0.03017	0.109250
124	1	HbA1c (%)	REGION1	JAPAN		-0.15491	-0.161049
125	1	HbA1c (%)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.00445	0.029097
126	1	HbA1c (%)	BASE			-0.22603	-0.214342
127	1	HbA1c (%)	visit1400			0.58150	0.619707

Parameter Code=C64849B Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
128	1	HbA1c (%)	Intercept			0.00829	-0.000052108
129	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)		0.05328	0.165734
130	1	HbA1c (%)	REGION1	EUROPE		-0.01024	-0.068842
131	1	HbA1c (%)	REGION1	JAPAN		-0.06429	-0.114525

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Parameter Code=C64849B Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2200

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Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
132	1	HbA1c (%)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.01740	-0.011108
133	1	HbA1c (%)	BASE			-0.08740	-0.100397
134	1	HbA1c (%)	visit1400			0.09867	0.060593
135	1	HbA1c (%)	visit1800			0.72704	0.796001

Parameter Code=C64849B Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
136	1	HbA1c (%)	Intercept			-0.01115	-0.003917
137	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)		-0.12922	0.076710
138	1	HbA1c (%)	REGION1	EUROPE		0.03637	-0.037402
139	1	HbA1c (%)	REGION1	JAPAN		0.04512	-0.027459
140	1	HbA1c (%)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.00463	-0.083111
141	1	HbA1c (%)	BASE			-0.08299	-0.152316
142	1	HbA1c (%)	visit1400			-0.10860	-0.149011
143	1	HbA1c (%)	visit1800			0.10456	0.093682
144	1	HbA1c (%)	visit2200			0.72642	0.757670

Parameter Code=C64849B Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3000

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
145	1	HbA1c (%)	Intercept			0.0001546	-0.016978
146	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)		-0.03084	-0.062442

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Parameter Code=C64849B Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3000

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Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
147	1	HbA1c (%)	REGION1	EUROPE		0.06877	0.063018
148	1	HbA1c (%)	REGION1	JAPAN		-0.02155	-0.059005
149	1	HbA1c (%)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.04322	-0.032411
150	1	HbA1c (%)	BASE			-0.07482	-0.062503
151	1	HbA1c (%)	visit1400			-0.02267	-0.044616
152	1	HbA1c (%)	visit1800			-0.05705	-0.116188
153	1	HbA1c (%)	visit2200			-0.06825	-0.012577
154	1	HbA1c (%)	visit2600			0.93381	0.937160

Parameter Code=C64849B Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3400

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
155	1	HbA1c (%)	Intercept			-0.02286	-0.046986
156	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)		-0.17052	-0.239583
157	1	HbA1c (%)	REGION1	EUROPE		0.12355	0.116479
158	1	HbA1c (%)	REGION1	JAPAN		0.01871	0.083248
159	1	HbA1c (%)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.01335	-0.046723
160	1	HbA1c (%)	BASE			-0.07124	-0.054810
161	1	HbA1c (%)	visit1400			-0.04304	-0.066256
162	1	HbA1c (%)	visit1800			0.11556	0.066677
163	1	HbA1c (%)	visit2200			0.06533	0.086427
164	1	HbA1c (%)	visit2600			-0.05378	-0.038586
165	1	HbA1c (%)	visit3000			0.80048	0.821662

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Parameter Code=C64849B Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
166	1	HbA1c (%)	Intercept			0.00227	0.024309
167	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)		-0.05406	0.011835
168	1	HbA1c (%)	REGION1	EUROPE		0.06926	0.049095
169	1	HbA1c (%)	REGION1	JAPAN		-0.00797	0.025942
170	1	HbA1c (%)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.03622	-0.010977
171	1	HbA1c (%)	BASE			-0.02834	-0.035294
172	1	HbA1c (%)	visit1400			-0.02136	0.024351
173	1	HbA1c (%)	visit1800			0.01692	0.055269
174	1	HbA1c (%)	visit2200			0.10434	0.019591
175	1	HbA1c (%)	visit2600			-0.03648	-0.051217
176	1	HbA1c (%)	visit3000			-0.20668	-0.263641
177	1	HbA1c (%)	visit3400			1.02457	1.097591

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The MI Procedure with MCMC
Model Information

Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=2

Obs	PARAM	Description	Value
1	HbA1c (mmol/mol)	Data Set	WORK.ENDPOINT_PARAM
2	HbA1c (mmol/mol)	Method	Monotone-data_MCMC
3	HbA1c (mmol/mol)	Multiple Imputation Chain	Multiple Chains
4	HbA1c (mmol/mol)	Initial Estimates for MCMC	EM Posterior Mode
5	HbA1c (mmol/mol)	Start	Starting Value
6	HbA1c (mmol/mol)	Prior	Jeffreys
7	HbA1c (mmol/mol)	Number of Imputations	100
8	HbA1c (mmol/mol)	Number of Burn-in Iterations	200
9	HbA1c (mmol/mol)	Seed for random number generator	73804

Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=3

Obs	PARAM	Description	Value
10	HbA1c (mmol/mol)	Data Set	WORK.ENDPOINT_PARAM
11	HbA1c (mmol/mol)	Method	Monotone-data_MCMC
12	HbA1c (mmol/mol)	Multiple Imputation Chain	Multiple Chains
13	HbA1c (mmol/mol)	Initial Estimates for MCMC	EM Posterior Mode
14	HbA1c (mmol/mol)	Start	Starting Value
15	HbA1c (mmol/mol)	Prior	Jeffreys
16	HbA1c (mmol/mol)	Number of Imputations	100
17	HbA1c (mmol/mol)	Number of Burn-in Iterations	200
18	HbA1c (mmol/mol)	Seed for random number generator	1221371123

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The MI Procedure with MCMC
Model Information

Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=4

Obs	PARAM	Description	Value
19	HbA1c (mmol/mol)	Data Set	WORK.ENDPOINT_PARAM
20	HbA1c (mmol/mol)	Method	Monotone-data_MCMC
21	HbA1c (mmol/mol)	Multiple Imputation Chain	Multiple Chains
22	HbA1c (mmol/mol)	Initial Estimates for MCMC	EM Posterior Mode
23	HbA1c (mmol/mol)	Start	Starting Value
24	HbA1c (mmol/mol)	Prior	Jeffreys
25	HbA1c (mmol/mol)	Number of Imputations	100
26	HbA1c (mmol/mol)	Number of Burn-in Iterations	200
27	HbA1c (mmol/mol)	Seed for random number generator	662262896

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The MI Procedure with MCMC
Missing data pattern

Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=2

Obs	PARAM	Group	BASE_ Miss	visit1400_ Miss	visit1800_ Miss	visit2200_ Miss	visit2600_ Miss	visit3000_ Miss	visit3400_ Miss	visit3600_ Miss	Freq
1	HbA1c (mmol/mol)	1	X	X	X	X	X	X	X	X	330
2	HbA1c (mmol/mol)	2	X	X	X	X	X	X	X	O	1
3	HbA1c (mmol/mol)	3	X	X	X	X	X	X	.	X	3
4	HbA1c (mmol/mol)	4	X	X	X	X	X	.	X	X	1
5	HbA1c (mmol/mol)	5	X	X	X	O	O	O	O	O	1
6	HbA1c (mmol/mol)	6	X	X	.	X	X	X	X	X	2
7	HbA1c (mmol/mol)	7	X	X	.	.	X	X	X	X	1
8	HbA1c (mmol/mol)	8	X	X	O	O	O	O	O	O	2
9	HbA1c (mmol/mol)	9	X	.	X	X	X	.	.	X	1

Obs	Percent	BASE	visit1400	visit1800	visit2200	visit2600	visit3000	visit3400	visit3600
1	96.49	57.974870	-1.169179	-1.460645	-1.884597	-1.255294	-1.410964	-1.066503	-1.357970
2	0.29	49.731000	1.093000	-3.279000	-4.372000	0	0	2.186000	.
3	0.88	60.296667	-1.457333	-1.457333	-3.279000	-3.643333	-5.465000	.	2.914667
4	0.29	56.289000	-10.930000	-18.581000	-19.674000	-27.325000	.	-16.395000	-13.116000
5	0.29	56.289000	0	-2.186000
6	0.58	63.940000	-2.732500	.	1.093000	0.546500	-3.825500	0	1.639500
7	0.29	61.754000	0	.	.	0	-2.186000	-7.651000	-7.651000
8	0.58	61.207500	2.186000
9	0.29	45.359000	.	1.093000	0	-1.093000	.	.	-1.093000

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Missing data pattern

Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=3

Obs	PARAM	Group	BASE_ Miss	visit1400_ Miss	visit1800_ Miss	visit2200_ Miss	visit2600_ Miss	visit3000_ Miss	visit3400_ Miss	visit3600_ Miss	Freq
10	HbA1c (mmol/mol)	1	X	X	X	X	X	X	X	X	325
11	HbA1c (mmol/mol)	2	X	X	X	X	X	X	.	X	3
12	HbA1c (mmol/mol)	3	X	X	X	X	X	X	O	O	1
13	HbA1c (mmol/mol)	4	X	X	X	X	X	.	X	X	2
14	HbA1c (mmol/mol)	5	X	X	X	X	X	O	O	O	1
15	HbA1c (mmol/mol)	6	X	X	X	X	.	X	X	X	1
16	HbA1c (mmol/mol)	7	X	X	X	X	.	.	.	X	1
17	HbA1c (mmol/mol)	8	X	X	X	X	O	O	O	O	3
18	HbA1c (mmol/mol)	9	X	X	X	O	O	O	O	O	1
19	HbA1c (mmol/mol)	10	X	X	.	X	X	X	X	X	1
20	HbA1c (mmol/mol)	11	X	X	O	O	O	O	O	O	1

Obs	Percent	BASE	visit1400	visit1800	visit2200	visit2600	visit3000	visit3400	visit3600
10	95.31	57.492982	-0.534729	-0.191695	-0.433837	0.289225	0.269046	0.353123	-0.114345
11	0.88	49.731000	-1.093000	-1.821667	-3.279000	0.364333	4.007667	.	1.093000
12	0.29	53.010000	-3.279000	-1.093000	-2.186000	-4.372000	-3.279000	.	.
13	0.59	56.835500	1.093000	-2.732500	-2.186000	0	.	8.744000	7.104500
14	0.29	63.940000	-6.558000	-6.558000	-8.744000	-7.651000	.	.	.
15	0.29	54.103000	1.093000	6.558000	10.930000	.	16.395000	17.488000	13.116000
16	0.29	65.033000	-4.372000	5.465000	7.651000	.	.	.	14.209000
17	0.88	58.475000	-1.093000	0.728667	2.550333
18	0.29	57.382000	6.558000	9.837000
19	0.29	57.382000	1.093000	.	1.093000	3.279000	0	1.093000	3.279000
20	0.29	48.638000	2.186000

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The MI Procedure with MCMC
Missing data pattern

Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=3

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Obs	PARAM	Group	BASE_ Miss	visit1400_ Miss	visit1800_ Miss	visit2200_ Miss	visit2600_ Miss	visit3000_ Miss	visit3400_ Miss	visit3600_ Miss	Freq
21	HbA1c (mmol/mol)	12	X	.	X	X	X	X	X	X	1
Obs	Percent	BASE	visit1400	visit1800	visit2200	visit2600	visit3000	visit3400	visit3600		
21	0.29	61.754000	.	-2.186000	-6.558000	-7.651000	-3.279000	-3.279000	-2.186000		

Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=4

Obs	PARAM	Group	BASE_ Miss	visit1400_ Miss	visit1800_ Miss	visit2200_ Miss	visit2600_ Miss	visit3000_ Miss	visit3400_ Miss	visit3600_ Miss	Freq
22	HbA1c (mmol/mol)	1	X	X	X	X	X	X	X	X	328
23	HbA1c (mmol/mol)	2	X	X	X	X	X	X	X	O	1
24	HbA1c (mmol/mol)	3	X	X	X	X	X	X	.	X	2
25	HbA1c (mmol/mol)	4	X	X	X	X	X	.	.	X	1
Obs	Percent	BASE	visit1400	visit1800	visit2200	visit2600	visit3000	visit3400	visit3600		
22	95.91	57.441982	-0.709784	-0.539835	-0.739774	-0.376552	-0.856405	-0.749771	-1.169643		
23	0.29	51.917000	1.093000	-1.093000	-4.372000	-2.186000	-1.093000	-1.093000	.		
24	0.58	63.940000	-1.093000	3.825500	3.279000	3.825500	4.918500	.	0		
25	0.29	71.591000	5.465000	3.279000	-1.093000	-7.651000	.	.	0		

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Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=4

(continued)

Obs	PARAM	Group	BASE_ Miss	visit1400_ Miss	visit1800_ Miss	visit2200_ Miss	visit2600_ Miss	visit3000_ Miss	visit3400_ Miss	visit3600_ Miss	Freq
26	HbA1c (mmol/mol)	5	X	X	X	X	X	O	O	O	1
27	HbA1c (mmol/mol)	6	X	X	X	X	.	X	X	X	1
28	HbA1c (mmol/mol)	7	X	X	X	X	.	.	X	X	1
29	HbA1c (mmol/mol)	8	X	X	X	X	O	O	O	O	2
30	HbA1c (mmol/mol)	9	X	X	X	.	X	X	X	X	1
31	HbA1c (mmol/mol)	10	X	X	.	X	X	X	X	X	1
32	HbA1c (mmol/mol)	11	X	X	O	O	O	O	O	O	1
33	HbA1c (mmol/mol)	12	X	.	X	X	X	X	X	O	1
34	HbA1c (mmol/mol)	13	X	O	O	O	O	O	O	O	1

Obs	Percent	BASE	visit1400	visit1800	visit2200	visit2600	visit3000	visit3400	visit3600
26	0.29	61.754000	3.279000	4.372000	3.279000	2.186000	.	.	.
27	0.29	62.847000	0	-6.558000	0	.	-1.093000	0	0
28	0.29	56.289000	-10.930000	4.372000	2.186000	.	.	15.302000	15.302000
29	0.58	57.382000	3.279000	6.558000	6.011500
30	0.29	54.103000	-3.279000	-2.186000	.	7.651000	5.465000	1.093000	-2.186000
31	0.29	55.196000	-7.651000	.	-7.651000	-7.651000	-8.744000	-8.744000	-8.744000
32	0.29	62.847000	2.186000
33	0.29	51.917000	.	12.023000	15.302000	16.395000	14.209000	12.023000	.
34	0.29	61.754000

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NN1218-4131

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The MI Procedure with Monotone Regression
Model Information

Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM	Description	Value
1	1	HbA1c (mmol/mol)	Data Set	WORK.MONOTONE
2	1	HbA1c (mmol/mol)	Method	Monotone
3	1	HbA1c (mmol/mol)	Number of Imputations	1
4	1	HbA1c (mmol/mol)	Seed for random number generator	73904

Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM	Description	Value
5	1	HbA1c (mmol/mol)	Data Set	WORK.MONOTONE
6	1	HbA1c (mmol/mol)	Method	Monotone
7	1	HbA1c (mmol/mol)	Number of Imputations	1
8	1	HbA1c (mmol/mol)	Seed for random number generator	627673144

Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM	Description	Value
9	1	HbA1c (mmol/mol)	Data Set	WORK.MONOTONE
10	1	HbA1c (mmol/mol)	Method	Monotone
11	1	HbA1c (mmol/mol)	Number of Imputations	1
12	1	HbA1c (mmol/mol)	Seed for random number generator	947009354

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The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM	Group	REGION1_	BOLAD1_	BASE_	visit1400_	visit1800_	visit2200_
				Miss	Miss	Miss	Miss	Miss	Miss
1	1	HbA1c (mmol/mol)	1	X	X	X	X	X	X
2	1	HbA1c (mmol/mol)	2	X	X	X	X	X	X
3	1	HbA1c (mmol/mol)	3	X	X	X	X	X	.
4	1	HbA1c (mmol/mol)	4	X	X	X	X	.	.

Obs	visit2600_	visit3000_	visit3400_	visit3600_	Freq	Percent	BASE	visit1400
	Miss	Miss	Miss	Miss				
1	X	X	X	X	338	98.83	57.999642	-1.204128
2	X	X	X	.	1	0.29	49.731000	1.093000
3	1	0.29	56.289000	0
4	2	0.58	61.207500	2.186000

Obs	visit1800	visit2200	visit2600	visit3000	visit3400	visit3600
1	-1.484479	-1.917245	-1.338763	-1.500881	-1.113985	-1.354932
2	-3.279000	-4.372000	0	0	2.186000	.
3	-2.186000
4

nn1218/nn1218-4131/ctr_20180214_er
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The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM	Group	REGION1_ Miss	BOLAD1_ Miss	BASE_ Miss	visit1400_ Miss	visit1800_ Miss	visit2200_ Miss
5	1	HbA1c (mmol/mol)	1	X	X	X	X	X	X
6	1	HbA1c (mmol/mol)	2	X	X	X	X	X	X
7	1	HbA1c (mmol/mol)	3	X	X	X	X	X	X
8	1	HbA1c (mmol/mol)	4	X	X	X	X	X	X
9	1	HbA1c (mmol/mol)	5	X	X	X	X	X	.
10	1	HbA1c (mmol/mol)	6	X	X	X	X	.	.

Obs	visit2600_ Miss	visit3000_ Miss	visit3400_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit1400
5	X	X	X	X	334	97.95	57.444177	-0.521011
6	X	X	.	.	1	0.29	53.010000	-3.279000
7	X	.	.	.	1	0.29	63.940000	-6.558000
8	3	0.88	58.475000	-1.093000
9	1	0.29	57.382000	6.558000
10	1	0.29	48.638000	2.186000

Obs	visit1800	visit2200	visit2600	visit3000	visit3400	visit3600
5	-0.184436	-0.425419	0.332426	0.382787	0.511050	0.026180
6	-1.093000	-2.186000	-4.372000	-3.279000	.	.
7	-6.558000	-8.744000	-7.651000	.	.	.
8	0.728667	2.550333
9	9.837000
10

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The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM	Group	REGION1_	BOLAD1_	BASE_	visit1400_	visit1800_	visit2200_
				Miss	Miss	Miss	Miss	Miss	Miss
11	1	HbA1c (mmol/mol)	1	X	X	X	X	X	X
12	1	HbA1c (mmol/mol)	2	X	X	X	X	X	X
13	1	HbA1c (mmol/mol)	3	X	X	X	X	X	X
14	1	HbA1c (mmol/mol)	4	X	X	X	X	X	X
15	1	HbA1c (mmol/mol)	5	X	X	X	X	.	.
16	1	HbA1c (mmol/mol)	6	X	X	X	.	.	.

Obs	visit2600_	visit3000_	visit3400_	visit3600_	Freq	Percent	BASE	visit1400
	Miss	Miss	Miss	Miss				
11	X	X	X	X	335	97.95	57.519033	-0.750418
12	X	X	X	.	2	0.58	51.917000	2.771386
13	X	.	.	.	1	0.29	61.754000	3.279000
14	2	0.58	57.382000	3.279000
15	1	0.29	62.847000	2.186000
16	1	0.29	61.754000	.

Obs	visit1800	visit2200	visit2600	visit3000	visit3400	visit3600
11	-0.525743	-0.723113	-0.334093	-0.809317	-0.701729	-1.132152
12	5.465000	5.465000	7.104500	6.558000	5.465000	.
13	4.372000	3.279000	2.186000	.	.	.
14	6.558000	6.011500
15
16

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HbA1c 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=2 Imputed Variable=visit1800

O b s	i n s	P u t a t i o n	P A R A M E T E R	E f f e c t	R E G I O N 1	B O L A D 1	O b s e r v e d	I
1	1	HbA1c	(mmol/mol)	Intercept			0.00528	-0.024152
2	1	HbA1c	(mmol/mol)	REGION1	ASIA (EXCLUDING JAPAN)		-0.00414	-0.174527
3	1	HbA1c	(mmol/mol)	REGION1	EUROPE		-0.01094	0.082624
4	1	HbA1c	(mmol/mol)	REGION1	JAPAN		-0.02761	-0.003080
5	1	HbA1c	(mmol/mol)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.03216	0.000774
6	1	HbA1c	(mmol/mol)	BASE			-0.09533	-0.081146
7	1	HbA1c	(mmol/mol)	visit1400			0.79489	0.801511

HbA1c 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2200

O b s	i	P a r a m e t e r	E f f e c t	R E G I O N	B O L A D	O b s e r v e d	I
8	1	HbA1c (mmol/mol)	Intercept			0.00686	0.040311
9	1	HbA1c (mmol/mol)	REGION1	ASIA (EXCLUDING JAPAN)		0.02897	0.103162
10	1	HbA1c (mmol/mol)	REGION1	EUROPE		0.02996	-0.004806
11	1	HbA1c (mmol/mol)	REGION1	JAPAN		-0.03287	-0.021275
12	1	HbA1c (mmol/mol)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.03100	-0.031332
13	1	HbA1c (mmol/mol)	BASE			-0.08697	-0.099733
14	1	HbA1c (mmol/mol)	visit1400			0.07031	0.149503
15	1	HbA1c (mmol/mol)	visit1800			0.76995	0.681092

HbA1c 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2600

O b s	i n s	P a r a m e t e r	E f f e c t	R e g i o n	B o l u s	O b s e r v e d	I n t e r c e p t
16	1	HbA1c (mmol/mol)	Intercept			-0.03730	-0.067983
17	1	HbA1c (mmol/mol)	REGION1	ASIA (EXCLUDING JAPAN)		-0.16215	-0.264385
18	1	HbA1c (mmol/mol)	REGION1	EUROPE		0.10932	0.149667
19	1	HbA1c (mmol/mol)	REGION1	JAPAN		-0.01231	-0.004004
20	1	HbA1c (mmol/mol)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.0001918	0.024271
21	1	HbA1c (mmol/mol)	BASE			-0.08361	-0.074793
22	1	HbA1c (mmol/mol)	visit1400			-0.01487	-0.038410
23	1	HbA1c (mmol/mol)	visit1800			0.01507	0.122848
24	1	HbA1c (mmol/mol)	visit2200			0.83504	0.758671

HbA1c 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3000

O b s	i n s	P a r a m e t e r	E f f e c t	R e g i o n	B o l u s	O b s e r v e d	I n t e r c e p t
25	1	HbA1c (mmol/mol)	Intercept			0.00470	0.000880
26	1	HbA1c (mmol/mol)	REGION1	ASIA (EXCLUDING JAPAN)		0.06070	0.148718
27	1	HbA1c (mmol/mol)	REGION1	EUROPE		-0.01687	-0.052484
28	1	HbA1c (mmol/mol)	REGION1	JAPAN		-0.04630	-0.062041
29	1	HbA1c (mmol/mol)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.01762	-0.021088
30	1	HbA1c (mmol/mol)	BASE			-0.05089	-0.063765
31	1	HbA1c (mmol/mol)	visit1400			-0.00872	0.033362
32	1	HbA1c (mmol/mol)	visit1800			-0.04190	-0.135089
33	1	HbA1c (mmol/mol)	visit2200			0.13741	0.177348
34	1	HbA1c (mmol/mol)	visit2600			0.77995	0.748492

HbA1c 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3400

O b s	i n s	P a r a m e t e r	E f f e c t	R e g i o n	B o l u s	O b s e r v e d	I m p u t e d
35	1	HbA1c (mmol/mol)	Intercept			-0.01184	-0.024179
36	1	HbA1c (mmol/mol)	REGION1	ASIA (EXCLUDING JAPAN)		-0.02060	-0.106054
37	1	HbA1c (mmol/mol)	REGION1	EUROPE		0.05186	0.033103
38	1	HbA1c (mmol/mol)	REGION1	JAPAN		-0.00313	0.021663
39	1	HbA1c (mmol/mol)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.03422	0.029439
40	1	HbA1c (mmol/mol)	BASE			-0.02467	-0.057455
41	1	HbA1c (mmol/mol)	visit1400			0.03224	0.056713
42	1	HbA1c (mmol/mol)	visit1800			0.06484	0.065119
43	1	HbA1c (mmol/mol)	visit2200			0.10401	0.062497
44	1	HbA1c (mmol/mol)	visit2600			0.04016	0.091387
45	1	HbA1c (mmol/mol)	visit3000			0.69334	0.679997

HbA1c 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

O b s	i n s	P a r a m e t e r	E f f e c t	R e g i o n	B o l u s	O b s e r v e d	I n t e r c e p t
46	1	HbA1c (mmol/mol)	Intercept			-0.00842	-0.002266
47	1	HbA1c (mmol/mol)	REGION1	ASIA (EXCLUDING JAPAN)		0.00681	-0.001836
48	1	HbA1c (mmol/mol)	REGION1	EUROPE		0.07882	0.069723
49	1	HbA1c (mmol/mol)	REGION1	JAPAN		-0.02375	-0.051322
50	1	HbA1c (mmol/mol)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.03279	0.073114
51	1	HbA1c (mmol/mol)	BASE			-0.00901	-0.004187
52	1	HbA1c (mmol/mol)	visit1400			-0.05048	0.013687
53	1	HbA1c (mmol/mol)	visit1800			0.05404	-0.023130
54	1	HbA1c (mmol/mol)	visit2200			-0.02721	-0.035487
55	1	HbA1c (mmol/mol)	visit2600			-0.02993	-0.079645
56	1	HbA1c (mmol/mol)	visit3000			0.19040	0.277138
57	1	HbA1c (mmol/mol)	visit3400			0.78725	0.782421

HbA1c 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=3 Imputed Variable=visit1800

		Imputed		Region		Treatment		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		Base		Visit			
		P		E		B		O							
		A		f		L		b							
		R		e		A		s							
		A		c		D		V							
		M		t		1		a							
								l							
58	1	HbA1c	(mmol/mol)	Intercept										-0.01926	-0.037986
59	1	HbA1c	(mmol/mol)	REGION1	ASIA (EXCLUDING JAPAN)									-0.10018	-0.206800
60	1	HbA1c	(mmol/mol)	REGION1	EUROPE									0.05007	0.068771
61	1	HbA1c	(mmol/mol)	REGION1	JAPAN									0.00906	0.046104
62	1	HbA1c	(mmol/mol)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)								0.01633	0.028690
63	1	HbA1c	(mmol/mol)	BASE										-0.08755	-0.154644
64	1	HbA1c	(mmol/mol)	visit1400										0.68521	0.699326

HbA1c 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2200

O b s	i n s	P a r a m e t e r	E f f e c t	R e g i o n	B o l u s	O b s e r v e d	I n t e r c e p t
65	1	HbA1c (mmol/mol)	Intercept			0.01118	-0.004245
66	1	HbA1c (mmol/mol)	REGION1	ASIA (EXCLUDING JAPAN)		-0.01828	0.127569
67	1	HbA1c (mmol/mol)	REGION1	EUROPE		-0.04982	-0.098054
68	1	HbA1c (mmol/mol)	REGION1	JAPAN		0.03331	0.049438
69	1	HbA1c (mmol/mol)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.04842	-0.074866
70	1	HbA1c (mmol/mol)	BASE			-0.08216	-0.037971
71	1	HbA1c (mmol/mol)	visit1400			-0.13053	-0.115932
72	1	HbA1c (mmol/mol)	visit1800			0.88988	0.836075

HbA1c 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2600

O b s	i n s	P a r a m e t e r	E f f e c t	R e g i o n	B o l u s	O b s e r v e d	I n t e r c e p t
73	1	HbA1c (mmol/mol)	Intercept			-0.01855	-0.016609
74	1	HbA1c (mmol/mol)	REGION1	ASIA (EXCLUDING JAPAN)		-0.11414	-0.185389
75	1	HbA1c (mmol/mol)	REGION1	EUROPE		0.03606	0.047641
76	1	HbA1c (mmol/mol)	REGION1	JAPAN		-0.06722	-0.103283
77	1	HbA1c (mmol/mol)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.00341	-0.013684
78	1	HbA1c (mmol/mol)	BASE			-0.05109	-0.067962
79	1	HbA1c (mmol/mol)	visit1400			-0.04207	-0.078865
80	1	HbA1c (mmol/mol)	visit1800			0.02816	-0.049050
81	1	HbA1c (mmol/mol)	visit2200			0.81025	0.893071

HbA1c 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3000

O b s		P A R A M E T E R S		R E G I O N S		B O L U S		O b s e r v e d		I m p u t e d	
—		M		t		1		1		1	
82	1	HbA1c	(mmol/mol)	Intercept				-0.02544		0.010852	
83	1	HbA1c	(mmol/mol)	REGION1	ASIA (EXCLUDING JAPAN)			-0.09312		-0.066235	
84	1	HbA1c	(mmol/mol)	REGION1	EUROPE			0.07868		0.109021	
85	1	HbA1c	(mmol/mol)	REGION1	JAPAN			-0.06419		-0.069120	
86	1	HbA1c	(mmol/mol)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.01247		-0.017864	
87	1	HbA1c	(mmol/mol)	BASE				-0.03156		-0.045564	
88	1	HbA1c	(mmol/mol)	visit1400				0.06135		0.077188	
89	1	HbA1c	(mmol/mol)	visit1800				0.01278		0.001863	
90	1	HbA1c	(mmol/mol)	visit2200				0.07036		-0.038208	
91	1	HbA1c	(mmol/mol)	visit2600				0.74615		0.812919	

HbA1c 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3400

O b s	i n s	P a r a m e t e r	E f f e c t	R e g i o n	B o l u s	O b s e r v e d	I n t e r c e p t
92	1	HbA1c (mmol/mol)	Intercept			-0.00912	-0.038805
93	1	HbA1c (mmol/mol)	REGION1	ASIA (EXCLUDING JAPAN)		-0.01022	-0.070683
94	1	HbA1c (mmol/mol)	REGION1	EUROPE		0.11256	0.175551
95	1	HbA1c (mmol/mol)	REGION1	JAPAN		-0.05792	-0.079030
96	1	HbA1c (mmol/mol)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.00220	0.073053
97	1	HbA1c (mmol/mol)	BASE			-0.04134	-0.056567
98	1	HbA1c (mmol/mol)	visit1400			-0.01477	-0.018580
99	1	HbA1c (mmol/mol)	visit1800			0.18707	0.195816
100	1	HbA1c (mmol/mol)	visit2200			-0.10272	-0.069598
101	1	HbA1c (mmol/mol)	visit2600			-0.11138	-0.105316
102	1	HbA1c (mmol/mol)	visit3000			0.89811	0.835215

HbA1c 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression Regression Information

Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

Obs	Id	Unit	Parameter	Region	Model	Obs	Est
103	1	HbA1c	(mmol/mol)	Intercept			-0.00899
104	1	HbA1c	(mmol/mol)	REGION1	ASIA (EXCLUDING JAPAN)		0.062773
105	1	HbA1c	(mmol/mol)	REGION1	EUROPE		0.00198
106	1	HbA1c	(mmol/mol)	REGION1	JAPAN		-0.02795
107	1	HbA1c	(mmol/mol)	BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.05266
108	1	HbA1c	(mmol/mol)	BASE			-0.04517
109	1	HbA1c	(mmol/mol)	visit1400			0.03115
110	1	HbA1c	(mmol/mol)	visit1800			-0.03490
111	1	HbA1c	(mmol/mol)	visit2200			0.07273
112	1	HbA1c	(mmol/mol)	visit2600			-0.01908
113	1	HbA1c	(mmol/mol)	visit3000			0.03662
114	1	HbA1c	(mmol/mol)	visit3400			0.85656

HbA1c 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2200

Imputed		Region		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		Observations	
O	b	P	E	B	O		
s	n	A	f	O	b		
—	M	A	e	N	s		
			c	1	V		
			t		a		
					l		
128	1	HbA1c	(mmol/mol)	Intercept		0.00829	-0.000052108
129	1	HbA1c	(mmol/mol)	REGION1 ASIA (EXCLUDING JAPAN)		0.05328	0.165734
130	1	HbA1c	(mmol/mol)	REGION1 EUROPE		-0.01024	-0.068842
131	1	HbA1c	(mmol/mol)	REGION1 JAPAN		-0.06429	-0.114525
132	1	HbA1c	(mmol/mol)	BOLAD1		-0.01740	-0.011108
133	1	HbA1c	(mmol/mol)	BASE		-0.08740	-0.100397
134	1	HbA1c	(mmol/mol)	visit1400		0.09867	0.060593
135	1	HbA1c	(mmol/mol)	visit1800		0.72704	0.796001

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2600

Obs	N	HbA1c	(mmol/mol)	Intercept	REGION1	EUROPE	JAPAN	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	BASE	visit1400	visit1800	visit2200	visit2600	visit2600	visit2600
136	1	HbA1c	(mmol/mol)	Intercept										-0.01115	-0.003917
137	1	HbA1c	(mmol/mol)	REGION1	ASIA (EXCLUDING JAPAN)									-0.12922	0.076710
138	1	HbA1c	(mmol/mol)	REGION1	EUROPE									0.03637	-0.037402
139	1	HbA1c	(mmol/mol)	REGION1	JAPAN									0.04512	-0.027459
140	1	HbA1c	(mmol/mol)	BOLAD1				BOLUS INSULIN ALGORITHM (SLIDING SCALE)						-0.00463	-0.083111
141	1	HbA1c	(mmol/mol)	BASE										-0.08299	-0.152316
142	1	HbA1c	(mmol/mol)	visit1400										-0.10860	-0.149011
143	1	HbA1c	(mmol/mol)	visit1800										0.10456	0.093682
144	1	HbA1c	(mmol/mol)	visit2200										0.72642	0.757670

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3400

O b s —		P A R A M E T E R	E F F E C T	R E G I O N	B O L U S	O b s V a l	\bar{I}
155	1	HbA1c (mmol/mol)	Intercept			-0.02286	-0.046986
156	1	HbA1c (mmol/mol)	REGION1	ASIA (EXCLUDING JAPAN)		-0.17052	-0.239583
157	1	HbA1c (mmol/mol)	REGION1	EUROPE		0.12355	0.116479
158	1	HbA1c (mmol/mol)	REGION1	JAPAN		0.01871	0.083248
159	1	HbA1c (mmol/mol)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.01335	-0.046723
160	1	HbA1c (mmol/mol)	BASE			-0.07124	-0.054810
161	1	HbA1c (mmol/mol)	visit1400			-0.04304	-0.066256
162	1	HbA1c (mmol/mol)	visit1800			0.11556	0.066677
163	1	HbA1c (mmol/mol)	visit2200			0.06533	0.086427
164	1	HbA1c (mmol/mol)	visit2600			-0.05378	-0.038586
165	1	HbA1c (mmol/mol)	visit3000			0.80048	0.821662

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The Mixed procedure
Model Information

Parameter Code=C64849B Parameter=HbA1c (%)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Data Set	WORK.IMPUTE
2	1	NN1218-4131	Dependent Variable	eotVisit
3	1	NN1218-4131	Covariance Structure	Diagonal
4	1	NN1218-4131	Estimation Method	REML
5	1	NN1218-4131	Residual Variance Method	Profile
6	1	NN1218-4131	Fixed Effects SE Method	Model-Based
7	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=HBA1CONV Parameter=HbA1c (mmol/mol)

Obs	_Imputation_	STUDYID	Descr	Value
8	1	NN1218-4131	Data Set	WORK.IMPUTE
9	1	NN1218-4131	Dependent Variable	eotVisit
10	1	NN1218-4131	Covariance Structure	Diagonal
11	1	NN1218-4131	Estimation Method	REML
12	1	NN1218-4131	Residual Variance Method	Profile
13	1	NN1218-4131	Fixed Effects SE Method	Model-Based
14	1	NN1218-4131	Degrees of Freedom Method	Residual

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The Mixed procedure
Dimensions

Parameter Code=C64849B Parameter=HbA1c (%)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Covariance Parameters	1
2	1	NN1218-4131	Columns in X	10
3	1	NN1218-4131	Columns in Z	0
4	1	NN1218-4131	Subjects	1
5	1	NN1218-4131	Max Obs per Subject	1025

Parameter Code=HBA1CONV Parameter=HbA1c (mmol/mol)

Obs	_Imputation_	STUDYID	Descr	Value
6	1	NN1218-4131	Covariance Parameters	1
7	1	NN1218-4131	Columns in X	10
8	1	NN1218-4131	Columns in Z	0
9	1	NN1218-4131	Subjects	1
10	1	NN1218-4131	Max Obs per Subject	1025

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HbA1c 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Number of Observations

Parameter Code=C64849B Parameter=HbA1c (%)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
1	1	NN1218-4131	Number of Observations Read	1025	1025	1025	1025	1025
2	1	NN1218-4131	Number of Observations Used	1025	1025	1025	1025	1025
3	1	NN1218-4131	Number of Observations Not Used	0	1025	1025	1025	1025

Parameter Code=HBA1CONV Parameter=HbA1c (mmol/mol)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
4	1	NN1218-4131	Number of Observations Read	1025	1025	1025	1025	1025
5	1	NN1218-4131	Number of Observations Used	1025	1025	1025	1025	1025
6	1	NN1218-4131	Number of Observations Not Used	0	1025	1025	1025	1025

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The Mixed procedure
Covariance Parameter Estimates

Parameter Code=C64849B Parameter=HbA1c (%)

Obs	_Imputation_	STUDYID	CovParm	Estimate
1	1	NN1218-4131	Residual	0.3689

Parameter Code=HBA1CONV Parameter=HbA1c (mmol/mol)

Obs	_Imputation_	STUDYID	CovParm	Estimate
101	1	NN1218-4131	Residual	44.0760

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The Mixed procedure
Fit Statistics

Parameter Code=C64849B Parameter=HbA1c (%)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	-2 Res Log Likelihood	1916.1
2	1	NN1218-4131	AIC (Smaller is Better)	1918.1
3	1	NN1218-4131	AICC (Smaller is Better)	1918.1
4	1	NN1218-4131	BIC (Smaller is Better)	1923.0

Parameter Code=HBA1CONV Parameter=HbA1c (mmol/mol)

Obs	_Imputation_	STUDYID	Descr	Value
5	1	NN1218-4131	-2 Res Log Likelihood	6785.2
6	1	NN1218-4131	AIC (Smaller is Better)	6787.2
7	1	NN1218-4131	AICC (Smaller is Better)	6787.2
8	1	NN1218-4131	BIC (Smaller is Better)	6792.1

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HbA1c 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Solution for Fixed Effects

Parameter Code=C64849B Parameter=HbA1c (%)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
1	1	NN1218-4131	TRTPN	2				
2	1	NN1218-4131	TRTPN	3				
3	1	NN1218-4131	TRTPN	4				
4	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
5	1	NN1218-4131	REGION1	—	EUROPE			
6	1	NN1218-4131	REGION1	—	JAPAN			
7	1	NN1218-4131	REGION1	—	NORTH AMERICA			
8	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
9	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
10	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	2.0840	0.2116	1017	9.85	<.0001	0.05	1.6688	2.4992
2	2.1951	0.2105	1017	10.43	<.0001	0.05	1.7820	2.6081
3	2.1040	0.2106	1017	9.99	<.0001	0.05	1.6907	2.5173
4	-0.1583	0.06931	1017	-2.28	0.0226	0.05	-0.2943	-0.02229
5	0.07658	0.04889	1017	1.57	0.1176	0.05	-0.01936	0.1725
6	-0.1124	0.05470	1017	-2.05	0.0402	0.05	-0.2197	-0.00503
7	0
8	-0.01805	0.04257	1017	-0.42	0.6717	0.05	-0.1016	0.06549
9	0
10	-0.2919	0.02744	1017	-10.64	<.0001	0.05	-0.3457	-0.2380

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HbA1c 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Solution for Fixed Effects

Parameter Code=HBA1CONV Parameter=HbA1c (mmol/mol)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
11	1	NN1218-4131	TRTPN	2				
12	1	NN1218-4131	TRTPN	3				
13	1	NN1218-4131	TRTPN	4				
14	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
15	1	NN1218-4131	REGION1	—	EUROPE			
16	1	NN1218-4131	REGION1	—	JAPAN			
17	1	NN1218-4131	REGION1	—	NORTH AMERICA			
18	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
19	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
20	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
11	15.9191	1.6890	1017	9.43	<.0001	0.05	12.6049	19.2334
12	17.1337	1.6777	1017	10.21	<.0001	0.05	13.8415	20.4258
13	16.1382	1.6795	1017	9.61	<.0001	0.05	12.8425	19.4338
14	-1.7302	0.7576	1017	-2.28	0.0226	0.05	-3.2168	-0.2437
15	0.8370	0.5344	1017	1.57	0.1176	0.05	-0.2116	1.8857
16	-1.2282	0.5979	1017	-2.05	0.0402	0.05	-2.4014	-0.05502
17	0
18	-0.1972	0.4653	1017	-0.42	0.6717	0.05	-1.1103	0.7158
19	0
20	-0.2919	0.02744	1017	-10.64	<.0001	0.05	-0.3457	-0.2380

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HbA1c 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Least Squares Means

Obs	_Imputation_	PARAMCD	PARAM	STUDYID	Effect	TRTPN	Margins
1	1	C64849B	HbA1c (%)	NN1218-4131	TRTPN	2	WORK.IMPUTE
2	1	C64849B	HbA1c (%)	NN1218-4131	TRTPN	3	WORK.IMPUTE
3	1	C64849B	HbA1c (%)	NN1218-4131	TRTPN	4	WORK.IMPUTE
4	1	HBA1CONV	HbA1c (mmol/mol)	NN1218-4131	TRTPN	2	WORK.IMPUTE
5	1	HBA1CONV	HbA1c (mmol/mol)	NN1218-4131	TRTPN	3	WORK.IMPUTE
6	1	HBA1CONV	HbA1c (mmol/mol)	NN1218-4131	TRTPN	4	WORK.IMPUTE

Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	-0.1152	0.03290	1017	-3.50	0.0005	0.05	-0.1797	-0.05062
2	-0.00406	0.03293	1017	-0.12	0.9018	0.05	-0.06868	0.06056
3	-0.09514	0.03288	1017	-2.89	0.0039	0.05	-0.1597	-0.03062
4	-1.2589	0.3596	1017	-3.50	0.0005	0.05	-1.9646	-0.5533
5	-0.04441	0.3599	1017	-0.12	0.9018	0.05	-0.7507	0.6619
6	-1.0399	0.3594	1017	-2.89	0.0039	0.05	-1.7451	-0.3347

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The Mixed procedure
Least Squares Means Estimate

Parameter Code=C64849B Parameter=HbA1c (%)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
1	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
2	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	WORK.IMPUTE	-0.02004	0.04655	1017	-0.43	0.6669	0.05	-0.1114	0.07130
2	WORK.IMPUTE	0.09108	0.04655	1017	1.96	0.0507	0.05	-0.00026	0.1824

Parameter Code=HBA1CONV Parameter=HbA1c (mmol/mol)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
3	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
4	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
3	WORK.IMPUTE	-0.2190	0.5088	1017	-0.43	0.6669	0.05	-1.2174	0.7793
4	WORK.IMPUTE	0.9955	0.5088	1017	1.96	0.0507	0.05	-0.00289	1.9939

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HbA1c 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=C64849B Parameter=HbA1c (%) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	100

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000007747	0.001080	0.001088	1.91E6	0.007247	0.007196	0.999928

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.119220	0.032978	-0.18386	-0.05458	1.91E6	-0.126874	-0.111778

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-3.62	0.0003

HbA1c 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=HBA1CONV Parameter=HbA1c (mmol/mol) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	100

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000926	0.128989	0.129923	1.91E6	0.007247	0.007196	0.999928

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-1.303077	0.360449	-2.00954	-0.59661	1.91E6	-1.386734	-1.221737

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-3.62	0.0003

HbA1c 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=C64849B Parameter=HbA1c (%) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	100

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000017393	0.001082	0.001099	387758	0.016238	0.015984	0.999840

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.001696	0.033157	-0.06668	0.063291	387758	-0.011651	0.009902

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-0.05	0.9592

HbA1c 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=HBA1CONV Parameter=HbA1c (mmol/mol) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	100

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.002078	0.129239	0.131337	387758	0.016238	0.015984	0.999840

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.018532	0.362405	-0.72883	0.691771	387758	-0.127343	0.108230

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-0.05	0.9592

HbA1c 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=C64849B Parameter=HbA1c (%) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	100

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000011606	0.001078	0.001090	856286	0.010869	0.010755	0.999892

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.096918	0.033018	-0.16163	-0.03220	856286	-0.105648	-0.090602

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-2.94	0.0033

HbA1c 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=HBA1CONV Parameter=HbA1c (mmol/mol) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	100

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.001387	0.128839	0.130240	856286	0.010869	0.010755	0.999892

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-1.059318	0.360887	-1.76664	-0.35199	856286	-1.154737	-0.990284

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-2.94	0.0033

HbA1c 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=C64849B Label=Faster aspart (meal) - NovoRapid (meal) Parameter=HbA1c (%) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	100

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000016903	0.002162	0.002179	1.61E6	0.007898	0.007837	0.999922

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.022302	0.046676	-0.11379	0.069181	1.61E6	-0.031446	-0.013050

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-0.48	0.6328

HbA1c 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=C64849B Label=Faster aspart (post) - NovoRapid (meal) Parameter=HbA1c (%) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	100

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000027186	0.002162	0.002189	629210	0.012703	0.012547	0.999875

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.095223	0.046786	0.003523	0.186923	629210	0.083815	0.110874

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	2.04	0.0418

HbA1c 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=HBA1CONV Label=Faster aspart (meal) - NovoRapid (meal) Parameter=HbA1c (mmol/mol) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	100

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.002019	0.258232	0.260272	1.61E6	0.007898	0.007837	0.999922

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.243760	0.510168	-1.24367	0.756152	1.61E6	-0.343710	-0.142633

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-0.48	0.6328

HbA1c 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=HBA1CONV Label=Faster aspart (post) - NovoRapid (meal) Parameter=HbA1c (mmol/mol) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	100

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.003248	0.258225	0.261505	629210	0.012703	0.012547	0.999875

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits	DF	Minimum	Maximum
Estimate	1.040785	0.511376	0.038505 2.043066	629210	0.916098	1.211849

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	2.04	0.0418

HbA1c 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=C64849B Label=Faster aspart (meal) - NovoRapid (meal) Parameter=HbA1c (%) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	100

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000016903	0.002162	0.002179	1.61E6	0.007898	0.007837	0.999922

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.022302	0.046676	-0.11379	0.069181	1.61E6	-0.031446	-0.013050

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0.400000	-9.05	<.0001

HbA1c 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=C64849B Label=Faster aspart (post) - NovoRapid (meal) Parameter=HbA1c (%) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	100

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000027186	0.002162	0.002189	629210	0.012703	0.012547	0.999875

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.095223	0.046786	0.003523	0.186923	629210	0.083815	0.110874

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0.400000	-6.51	<.0001

HbA1c 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=HBA1CONV Label=Faster aspart (meal) - NovoRapid (meal) Parameter=HbA1c (mmol/mol) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	100

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.002019	0.258232	0.260272	1.61E6	0.007898	0.007837	0.999922

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.243760	0.510168	-1.24367	0.756152	1.61E6	-0.343710	-0.142633

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	4.372000	-9.05	<.0001

HbA1c 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=HBA1CONV Label=Faster aspart (post) - NovoRapid (meal) Parameter=HbA1c (mmol/mol) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	100

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.003248	0.258225	0.261505	629210	0.012703	0.012547	0.999875

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits	DF	Minimum	Maximum
Estimate	1.040785	0.511376	0.038505 2.043066	629210	0.916098	1.211849

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	4.372000	-6.51	<.0001

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The Mixed procedure
Model Information

Parameter Code=C64849B Parameter=HbA1c (%)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Data Set	WORK.IMPUTE_ABS
2	1	NN1218-4131	Dependent Variable	eotVisitAbs
3	1	NN1218-4131	Covariance Structure	Diagonal
4	1	NN1218-4131	Estimation Method	REML
5	1	NN1218-4131	Residual Variance Method	Profile
6	1	NN1218-4131	Fixed Effects SE Method	Model-Based
7	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=HBA1CONV Parameter=HbA1c (mmol/mol)

Obs	_Imputation_	STUDYID	Descr	Value
8	1	NN1218-4131	Data Set	WORK.IMPUTE_ABS
9	1	NN1218-4131	Dependent Variable	eotVisitAbs
10	1	NN1218-4131	Covariance Structure	Diagonal
11	1	NN1218-4131	Estimation Method	REML
12	1	NN1218-4131	Residual Variance Method	Profile
13	1	NN1218-4131	Fixed Effects SE Method	Model-Based
14	1	NN1218-4131	Degrees of Freedom Method	Residual

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HbA1c 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Dimensions

Parameter Code=C64849B Parameter=HbA1c (%)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Covariance Parameters	1
2	1	NN1218-4131	Columns in X	10
3	1	NN1218-4131	Columns in Z	0
4	1	NN1218-4131	Subjects	1
5	1	NN1218-4131	Max Obs per Subject	1025

Parameter Code=HBA1CONV Parameter=HbA1c (mmol/mol)

Obs	_Imputation_	STUDYID	Descr	Value
6	1	NN1218-4131	Covariance Parameters	1
7	1	NN1218-4131	Columns in X	10
8	1	NN1218-4131	Columns in Z	0
9	1	NN1218-4131	Subjects	1
10	1	NN1218-4131	Max Obs per Subject	1025

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HbA1c 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Number of Observations

Parameter Code=C64849B Parameter=HbA1c (%)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
1	1	NN1218-4131	Number of Observations Read	1025	1025	1025	1025	1025
2	1	NN1218-4131	Number of Observations Used	1025	1025	1025	1025	1025
3	1	NN1218-4131	Number of Observations Not Used	0	1025	1025	1025	1025

Parameter Code=HBA1CONV Parameter=HbA1c (mmol/mol)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
4	1	NN1218-4131	Number of Observations Read	1025	1025	1025	1025	1025
5	1	NN1218-4131	Number of Observations Used	1025	1025	1025	1025	1025
6	1	NN1218-4131	Number of Observations Not Used	0	1025	1025	1025	1025

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The Mixed procedure
Covariance Parameter Estimates

Parameter Code=C64849B Parameter=HbA1c (%)

Obs	_Imputation_	STUDYID	CovParm	Estimate
1	1	NN1218-4131	Residual	0.3689

Parameter Code=HBA1CONV Parameter=HbA1c (mmol/mol)

Obs	_Imputation_	STUDYID	CovParm	Estimate
101	1	NN1218-4131	Residual	44.0760

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The Mixed procedure
Fit Statistics

Parameter Code=C64849B Parameter=HbA1c (%)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	-2 Res Log Likelihood	1916.1
2	1	NN1218-4131	AIC (Smaller is Better)	1918.1
3	1	NN1218-4131	AICC (Smaller is Better)	1918.1
4	1	NN1218-4131	BIC (Smaller is Better)	1923.0

Parameter Code=HBA1CONV Parameter=HbA1c (mmol/mol)

Obs	_Imputation_	STUDYID	Descr	Value
5	1	NN1218-4131	-2 Res Log Likelihood	6785.2
6	1	NN1218-4131	AIC (Smaller is Better)	6787.2
7	1	NN1218-4131	AICC (Smaller is Better)	6787.2
8	1	NN1218-4131	BIC (Smaller is Better)	6792.1

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HbA1c 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Solution for Fixed Effects

Parameter Code=C64849B Parameter=HbA1c (%)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
1	1	NN1218-4131	TRTPN	2				
2	1	NN1218-4131	TRTPN	3				
3	1	NN1218-4131	TRTPN	4				
4	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
5	1	NN1218-4131	REGION1	—	EUROPE			
6	1	NN1218-4131	REGION1	—	JAPAN			
7	1	NN1218-4131	REGION1	—	NORTH AMERICA			
8	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
9	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
10	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	2.0840	0.2116	1017	9.85	<.0001	0.05	1.6688	2.4992
2	2.1951	0.2105	1017	10.43	<.0001	0.05	1.7820	2.6081
3	2.1040	0.2106	1017	9.99	<.0001	0.05	1.6907	2.5173
4	-0.1583	0.06931	1017	-2.28	0.0226	0.05	-0.2943	-0.02229
5	0.07658	0.04889	1017	1.57	0.1176	0.05	-0.01936	0.1725
6	-0.1124	0.05470	1017	-2.05	0.0402	0.05	-0.2197	-0.00503
7	0
8	-0.01805	0.04257	1017	-0.42	0.6717	0.05	-0.1016	0.06549
9	0
10	0.7081	0.02744	1017	25.81	<.0001	0.05	0.6543	0.7620

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HbA1c 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Solution for Fixed Effects

Parameter Code=HBA1CONV Parameter=HbA1c (mmol/mol)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
11	1	NN1218-4131	TRTPN	2				
12	1	NN1218-4131	TRTPN	3				
13	1	NN1218-4131	TRTPN	4				
14	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
15	1	NN1218-4131	REGION1	—	EUROPE			
16	1	NN1218-4131	REGION1	—	JAPAN			
17	1	NN1218-4131	REGION1	—	NORTH AMERICA			
18	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
19	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
20	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
11	15.9191	1.6890	1017	9.43	<.0001	0.05	12.6049	19.2334
12	17.1337	1.6777	1017	10.21	<.0001	0.05	13.8415	20.4258
13	16.1382	1.6795	1017	9.61	<.0001	0.05	12.8425	19.4338
14	-1.7302	0.7576	1017	-2.28	0.0226	0.05	-3.2168	-0.2437
15	0.8370	0.5344	1017	1.57	0.1176	0.05	-0.2116	1.8857
16	-1.2282	0.5979	1017	-2.05	0.0402	0.05	-2.4014	-0.05502
17	0
18	-0.1972	0.4653	1017	-0.42	0.6717	0.05	-1.1103	0.7158
19	0
20	0.7081	0.02744	1017	25.81	<.0001	0.05	0.6543	0.7620

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HbA1c 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Least Squares Means

Obs	_Imputation_	PARAMCD	PARAM	STUDYID	Effect	TRTPN	Margins
1	1	C64849B	HbA1c (%)	NN1218-4131	TRTPN	2	WORK.IMPUTE
101	1	HBA1CONV	HbA1c (mmol/mol)	NN1218-4131	TRTPN	2	WORK.IMPUTE
201	1	C64849B	HbA1c (%)	NN1218-4131	TRTPN	3	WORK.IMPUTE
301	1	HBA1CONV	HbA1c (mmol/mol)	NN1218-4131	TRTPN	3	WORK.IMPUTE
401	1	C64849B	HbA1c (%)	NN1218-4131	TRTPN	4	WORK.IMPUTE
501	1	HBA1CONV	HbA1c (mmol/mol)	NN1218-4131	TRTPN	4	WORK.IMPUTE

Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	-0.1152	0.03290	1017	-3.50	0.0005	0.05	-0.1797	-0.05062
101	-1.2589	0.3596	1017	-3.50	0.0005	0.05	-1.9646	-0.5533
201	-0.00406	0.03293	1017	-0.12	0.9018	0.05	-0.06868	0.06056
301	-0.04441	0.3599	1017	-0.12	0.9018	0.05	-0.7507	0.6619
401	-0.09514	0.03288	1017	-2.89	0.0039	0.05	-0.1597	-0.03062
501	-1.0399	0.3594	1017	-2.89	0.0039	0.05	-1.7451	-0.3347

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HbA1c 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Least Squares Means Estimate

Parameter Code=C64849B Parameter=HbA1c (%)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
1	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
101	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	WORK.IMPUTE	-0.02004	0.04655	1017	-0.43	0.6669	0.05	-0.1114	0.07130
101	WORK.IMPUTE	0.09108	0.04655	1017	1.96	0.0507	0.05	-0.00026	0.1824

Parameter Code=HBA1CONV Parameter=HbA1c (mmol/mol)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
201	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
301	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
201	WORK.IMPUTE	-0.2190	0.5088	1017	-0.43	0.6669	0.05	-1.2174	0.7793
301	WORK.IMPUTE	0.9955	0.5088	1017	1.96	0.0507	0.05	-0.00289	1.9939

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HbA1c 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=C64849B Parameter=HbA1c (%) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	100

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000007747	0.001080	0.001088	1.91E6	0.007247	0.007196	0.999928

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	7.305268	0.032978	7.240632	7.369903	1.91E6	7.297614	7.312709

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	221.52	<.0001

HbA1c 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=HBA1CONV Parameter=HbA1c (mmol/mol) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	100

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000926	0.128989	0.129923	1.91E6	0.007247	0.007196	0.999928

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	56.346574	0.360449	55.64011	57.05304	1.91E6	56.262917	56.427914

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	156.32	<.0001

HbA1c 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=C64849B Parameter=HbA1c (%) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	100

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000017393	0.001082	0.001099	387758	0.016238	0.015984	0.999840

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	7.422792	0.033157	7.357806	7.487779	387758	7.412837	7.434390

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	223.87	<.0001

HbA1c 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=HBA1CONV Parameter=HbA1c (mmol/mol) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	100

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.002078	0.129239	0.131337	387758	0.016238	0.015984	0.999840

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	57.631120	0.362405	56.92082	58.34142	387758	57.522309	57.757882

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	159.02	<.0001

HbA1c 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=C64849B Parameter=HbA1c (%) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	100

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000011606	0.001078	0.001090	856286	0.010869	0.010755	0.999892

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	7.327569	0.033018	7.262855	7.392284	856286	7.318839	7.333885

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	221.93	<.0001

HbA1c 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=HBA1CONV Parameter=HbA1c (mmol/mol) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	100

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.001387	0.128839	0.130240	856286	0.010869	0.010755	0.999892

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	56.590334	0.360887	55.88301	57.29766	856286	56.494915	56.659367

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	156.81	<.0001

2: HbA1c 26 weeks after randomisation - statistical sensitivity analysis - reduced model - in-trial - full analysis set

The MI Procedure with MCMC
 Model Information

Parameter Code=C64849B Planned Treatment for Period 30 (N)=2

Obs	PARAM	Description	Value
1	HbA1c (%)	Data Set	WORK.ENDPOINT_PARAM
2	HbA1c (%)	Method	Monotone-data_MCMC
3	HbA1c (%)	Multiple Imputation Chain	Multiple Chains
4	HbA1c (%)	Initial Estimates for MCMC	EM Posterior Mode
5	HbA1c (%)	Start	Starting Value
6	HbA1c (%)	Prior	Jeffreys
7	HbA1c (%)	Number of Imputations	100
8	HbA1c (%)	Number of Burn-in Iterations	200
9	HbA1c (%)	Seed for random number generator	6805

Parameter Code=C64849B Planned Treatment for Period 30 (N)=3

Obs	PARAM	Description	Value
10	HbA1c (%)	Data Set	WORK.ENDPOINT_PARAM
11	HbA1c (%)	Method	Monotone-data_MCMC
12	HbA1c (%)	Multiple Imputation Chain	Multiple Chains
13	HbA1c (%)	Initial Estimates for MCMC	EM Posterior Mode
14	HbA1c (%)	Start	Starting Value
15	HbA1c (%)	Prior	Jeffreys
16	HbA1c (%)	Number of Imputations	100
17	HbA1c (%)	Number of Burn-in Iterations	200
18	HbA1c (%)	Seed for random number generator	676244766

Parameter Code=C64849B Planned Treatment for Period 30 (N)=4

Obs	PARAM	Description	Value
19	HbA1c (%)	Data Set	WORK.ENDPOINT_PARAM
20	HbA1c (%)	Method	Monotone-data_MCMC
21	HbA1c (%)	Multiple Imputation Chain	Multiple Chains
22	HbA1c (%)	Initial Estimates for MCMC	EM Posterior Mode
23	HbA1c (%)	Start	Starting Value
24	HbA1c (%)	Prior	Jeffreys
25	HbA1c (%)	Number of Imputations	100
26	HbA1c (%)	Number of Burn-in Iterations	200
27	HbA1c (%)	Seed for random number generator	309283557

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - reduced model - in-trial - full analysis set

The MI Procedure with MCMC
Missing data pattern

Parameter Code=C64849B Planned Treatment for Period 30 (N)=2

Obs	PARAM	Group	BASE_ Miss	visit1400_ Miss	visit1800_ Miss	visit2200_ Miss	visit2600_ Miss	visit3000_ Miss
1	HbA1c (%)	1	X	X	X	X	X	X
2	HbA1c (%)	2	X	X	X	X	X	X
3	HbA1c (%)	3	X	X	X	X	X	X
4	HbA1c (%)	4	X	X	X	X	X	.
5	HbA1c (%)	5	X	X	X	O	O	O
6	HbA1c (%)	6	X	X	.	X	X	X
7	HbA1c (%)	7	X	X	.	.	X	X
8	HbA1c (%)	8	X	X	O	O	O	O
9	HbA1c (%)	9	X	.	X	X	X	.

Obs	visit3400_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit1400	visit1800
1	X	X	330	96.49	7.454242	-0.106970	-0.133636
2	X	O	1	0.29	6.700000	0.100000	-0.300000
3	.	X	3	0.88	7.666667	-0.133333	-0.133333
4	X	X	1	0.29	7.300000	-1.000000	-1.700000
5	O	O	1	0.29	7.300000	0	-0.200000
6	X	X	2	0.58	8.000000	-0.250000	.
7	X	X	1	0.29	7.800000	0	.
8	O	O	2	0.58	7.750000	0.200000	.
9	.	X	1	0.29	6.300000	.	0.100000

Obs	visit2200	visit2600	visit3000	visit3400	visit3600
1	-0.172424	-0.114848	-0.129091	-0.097576	-0.124242
2	-0.400000	0	0	0.200000	.
3	-0.300000	-0.333333	-0.500000	.	0.266667
4	-1.800000	-2.500000	.	-1.500000	-1.200000
5
6	0.100000	0.050000	-0.350000	0	0.150000
7	.	0	-0.200000	-0.700000	-0.700000
8
9	0	-0.100000	.	.	-0.100000

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - reduced model - in-trial - full analysis set

The MI Procedure with MCMC
Missing data pattern

Parameter Code=C64849B Planned Treatment for Period 30 (N)=3

Obs	PARAM	Group	BASE_ Miss	visit1400_ Miss	visit1800_ Miss	visit2200_ Miss	visit2600_ Miss	visit3000_ Miss
10	HbA1c (%)	1	X	X	X	X	X	X
11	HbA1c (%)	2	X	X	X	X	X	X
12	HbA1c (%)	3	X	X	X	X	X	X
13	HbA1c (%)	4	X	X	X	X	X	.
14	HbA1c (%)	5	X	X	X	X	X	O
15	HbA1c (%)	6	X	X	X	X	.	X
16	HbA1c (%)	7	X	X	X	X	.	.
17	HbA1c (%)	8	X	X	X	X	O	O
18	HbA1c (%)	9	X	X	X	O	O	O
19	HbA1c (%)	10	X	X	.	X	X	X
20	HbA1c (%)	11	X	X	O	O	O	O
21	HbA1c (%)	12	X	.	X	X	X	X

Obs	visit3400_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit1400	visit1800
10	X	X	325	95.31	7.410154	-0.048923	-0.017538
11	.	X	3	0.88	6.700000	-0.100000	-0.166667
12	O	O	1	0.29	7.000000	-0.300000	-0.100000
13	X	X	2	0.59	7.350000	0.100000	-0.250000
14	O	O	1	0.29	8.000000	-0.600000	-0.600000
15	X	X	1	0.29	7.100000	0.100000	0.600000
16	.	X	1	0.29	8.100000	-0.400000	0.500000
17	O	O	3	0.88	7.500000	-0.100000	0.066667
18	O	O	1	0.29	7.400000	0.600000	0.900000
19	X	X	1	0.29	7.400000	0.100000	.
20	O	O	1	0.29	6.600000	0.200000	.
21	X	X	1	0.29	7.800000	.	-0.200000

Obs	visit2200	visit2600	visit3000	visit3400	visit3600
10	-0.039692	0.026462	0.024615	0.032308	-0.010462
11	-0.300000	0.033333	0.366667	.	0.100000
12	-0.200000	-0.400000	-0.300000	.	.
13	-0.200000	0	.	0.800000	0.650000
14	-0.800000	-0.700000	.	.	.
15	1.000000	.	1.500000	1.600000	1.200000
16	0.700000	.	.	.	1.300000
17	0.233333
18
19	0.100000	0.300000	0	0.100000	0.300000
20
21	-0.600000	-0.700000	-0.300000	-0.300000	-0.200000

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - reduced model - in-trial - full analysis set

The MI Procedure with MCMC
Missing data pattern

Parameter Code=C64849B Planned Treatment for Period 30 (N)=4

Obs	PARAM	Group	BASE_ Miss	visit1400_ Miss	visit1800_ Miss	visit2200_ Miss	visit2600_ Miss	visit3000_ Miss
22	HbA1c (%)	1	X	X	X	X	X	X
23	HbA1c (%)	2	X	X	X	X	X	X
24	HbA1c (%)	3	X	X	X	X	X	X
25	HbA1c (%)	4	X	X	X	X	X	.
26	HbA1c (%)	5	X	X	X	X	X	O
27	HbA1c (%)	6	X	X	X	X	.	X
28	HbA1c (%)	7	X	X	X	X	.	.
29	HbA1c (%)	8	X	X	X	X	O	O
30	HbA1c (%)	9	X	X	X	.	X	X
31	HbA1c (%)	10	X	X	.	X	X	X
32	HbA1c (%)	11	X	X	O	O	O	O
33	HbA1c (%)	12	X	.	X	X	X	X
34	HbA1c (%)	13	X	O	O	O	O	O

Obs	visit3400_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit1400	visit1800
22	X	X	328	95.91	7.405488	-0.064939	-0.049390
23	X	O	1	0.29	6.900000	0.100000	-0.100000
24	.	X	2	0.58	8.000000	-0.100000	0.350000
25	.	X	1	0.29	8.700000	0.500000	0.300000
26	O	O	1	0.29	7.800000	0.300000	0.400000
27	X	X	1	0.29	7.900000	0	-0.600000
28	X	X	1	0.29	7.300000	-1.000000	0.400000
29	O	O	2	0.58	7.400000	0.300000	0.600000
30	X	X	1	0.29	7.100000	-0.300000	-0.200000
31	X	X	1	0.29	7.200000	-0.700000	.
32	O	O	1	0.29	7.900000	0.200000	.
33	X	O	1	0.29	6.900000	.	1.100000
34	O	O	1	0.29	7.800000	.	.

Obs	visit2200	visit2600	visit3000	visit3400	visit3600
22	-0.067683	-0.034451	-0.078354	-0.068598	-0.107012
23	-0.400000	-0.200000	-0.100000	-0.100000	.
24	0.300000	0.350000	0.450000	.	0
25	-0.100000	-0.700000	.	.	0
26	0.300000	0.200000	.	.	.
27	0	.	-0.100000	0	0
28	0.200000	.	.	1.400000	1.400000
29	0.550000
30	.	0.700000	0.500000	0.100000	-0.200000
31	-0.700000	-0.700000	-0.800000	-0.800000	-0.800000
32
33	1.400000	1.500000	1.300000	1.100000	.
34

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - reduced model -
 in-trial - full analysis set

The MI Procedure with Monotone Regression
 Model Information

Parameter Code=C64849B Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM	Description	Value
1	1	HbA1c (%)	Data Set	WORK.MONOTONE
2	1	HbA1c (%)	Method	Monotone
3	1	HbA1c (%)	Number of Imputations	1
4	1	HbA1c (%)	Seed for random number generator	9892

Parameter Code=C64849B Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM	Description	Value
5	1	HbA1c (%)	Data Set	WORK.MONOTONE
6	1	HbA1c (%)	Method	Monotone
7	1	HbA1c (%)	Number of Imputations	1
8	1	HbA1c (%)	Seed for random number generator	1981707483

Parameter Code=C64849B Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM	Description	Value
9	1	HbA1c (%)	Data Set	WORK.MONOTONE
10	1	HbA1c (%)	Method	Monotone
11	1	HbA1c (%)	Number of Imputations	1
12	1	HbA1c (%)	Seed for random number generator	272978947

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - reduced model - in-trial - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=C64849B Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM	Group	BASE_ Miss	visit1400_ Miss	visit1800_ Miss	visit2200_ Miss	visit2600_ Miss
1	1	HbA1c (%)	1	X	X	X	X	X
2	1	HbA1c (%)	2	X	X	X	X	X
3	1	HbA1c (%)	3	X	X	X	.	.
4	1	HbA1c (%)	4	X	X	.	.	.

Obs	visit3000_ Miss	visit3400_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit1400
1	X	X	X	338	98.83	7.456509	-0.109921
2	X	X	.	1	0.29	6.700000	0.100000
3	.	.	.	1	0.29	7.300000	0
4	.	.	.	2	0.58	7.750000	0.200000

Obs	visit1800	visit2200	visit2600	visit3000	visit3400	visit3600
1	-0.138407	-0.176385	-0.122485	-0.138826	-0.100107	-0.123964
2	-0.300000	-0.400000	0	0	0.200000	.
3	-0.200000
4

Parameter Code=C64849B Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM	Group	BASE_ Miss	visit1400_ Miss	visit1800_ Miss	visit2200_ Miss	visit2600_ Miss
5	1	HbA1c (%)	1	X	X	X	X	X
6	1	HbA1c (%)	2	X	X	X	X	X
7	1	HbA1c (%)	3	X	X	X	X	X
8	1	HbA1c (%)	4	X	X	X	X	.

Obs	visit3000_ Miss	visit3400_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit1400
5	X	X	X	334	97.95	7.405689	-0.049145
6	X	.	.	1	0.29	7.000000	-0.300000
7	.	.	.	1	0.29	8.000000	-0.600000
8	.	.	.	3	0.88	7.500000	-0.100000

Obs	visit1800	visit2200	visit2600	visit3000	visit3400	visit3600
5	-0.015699	-0.038922	0.032501	0.036442	0.046049	0.002395
6	-0.100000	-0.200000	-0.400000	-0.300000	.	.
7	-0.600000	-0.800000	-0.700000	.	.	.
8	0.066667	0.233333

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - reduced model - in-trial - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=C64849B Planned Treatment for Period 30 (N)=3

(continued)

Obs	_Imputation_	PARAM	Group	BASE_ Miss	visit1400_ Miss	visit1800_ Miss	visit2200_ Miss	visit2600_ Miss
9	1	HbA1c (%)	5	X	X	X	.	.
10	1	HbA1c (%)	6	X	X	.	.	.

Obs	visit3000_ Miss	visit3400_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit1400
9	.	.	.	1	0.29	7.400000	0.600000
10	.	.	.	1	0.29	6.600000	0.200000

Obs	visit1800	visit2200	visit2600	visit3000	visit3400	visit3600
9	0.900000
10

Parameter Code=C64849B Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM	Group	BASE_ Miss	visit1400_ Miss	visit1800_ Miss	visit2200_ Miss	visit2600_ Miss
11	1	HbA1c (%)	1	X	X	X	X	X
12	1	HbA1c (%)	2	X	X	X	X	X
13	1	HbA1c (%)	3	X	X	X	X	X
14	1	HbA1c (%)	4	X	X	X	X	.
15	1	HbA1c (%)	5	X	X	.	.	.
16	1	HbA1c (%)	6	X

Obs	visit3000_ Miss	visit3400_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit1400
11	X	X	X	335	97.95	7.412537	-0.068657
12	X	X	.	2	0.58	6.900000	0.481749
13	.	.	.	1	0.29	7.800000	0.300000
14	.	.	.	2	0.58	7.400000	0.300000
15	.	.	.	1	0.29	7.900000	0.200000
16	.	.	.	1	0.29	7.800000	.

Obs	visit1800	visit2200	visit2600	visit3000	visit3400	visit3600
11	-0.048942	-0.066697	-0.032765	-0.071403	-0.064734	-0.103582
12	0.500000	0.500000	0.650000	0.600000	0.500000	.
13	0.400000	0.300000	0.200000	.	.	.
14	0.600000	0.550000
15
16

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - reduced model - in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=C64849B Planned Treatment for Period 30 (N)=2 Imputed Variable=visit1800

Obs	_Imputation_	PARAM	Effect	ObsVal	_1
1	1	HbA1c (%)	Intercept	0.00328	0.075043
2	1	HbA1c (%)	BASE	-0.09267	-0.061284
3	1	HbA1c (%)	visit1400	0.79731	0.741689

Parameter Code=C64849B Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	ObsVal	_1
4	1	HbA1c (%)	Intercept	-0.0000635	0.007695
5	1	HbA1c (%)	BASE	-0.08472	-0.079385
6	1	HbA1c (%)	visit1400	0.06819	-0.001732
7	1	HbA1c (%)	visit1800	0.76994	0.894606

Parameter Code=C64849B Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2600

Obs	_Imputation_	PARAM	Effect	ObsVal	_1
8	1	HbA1c (%)	Intercept	-0.0002419	-0.003769
9	1	HbA1c (%)	BASE	-0.07964	-0.062086
10	1	HbA1c (%)	visit1400	-0.01670	-0.005944
11	1	HbA1c (%)	visit1800	0.01742	-0.001808
12	1	HbA1c (%)	visit2200	0.83844	0.849788

Parameter Code=C64849B Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3000

Obs	_Imputation_	PARAM	Effect	ObsVal	_1
13	1	HbA1c (%)	Intercept	-0.0001519	-0.000644
14	1	HbA1c (%)	BASE	-0.04855	-0.120131
15	1	HbA1c (%)	visit1400	-0.01373	0.049333
16	1	HbA1c (%)	visit1800	-0.03105	-0.051628
17	1	HbA1c (%)	visit2200	0.13453	0.190813
18	1	HbA1c (%)	visit2600	0.77802	0.671467

Parameter Code=C64849B Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3400

Obs	_Imputation_	PARAM	Effect	ObsVal	_1
19	1	HbA1c (%)	Intercept	0.0000590	0.038718
20	1	HbA1c (%)	BASE	-0.02605	-0.043954
21	1	HbA1c (%)	visit1400	0.02571	-0.047460
22	1	HbA1c (%)	visit1800	0.07606	0.129272
23	1	HbA1c (%)	visit2200	0.10190	0.149563
24	1	HbA1c (%)	visit2600	0.03133	-0.011826
25	1	HbA1c (%)	visit3000	0.69500	0.676859

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - reduced model -
 in-trial - full analysis set

The MI Procedure with Monotone Regression
 Regression Information

Parameter Code=C64849B Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	ObsVal	_1
26	1	HbA1c (%)	Intercept	0.0008464	0.015329
27	1	HbA1c (%)	BASE	-0.01718	-0.053776
28	1	HbA1c (%)	visit1400	-0.05072	-0.074471
29	1	HbA1c (%)	visit1800	0.04794	0.081839
30	1	HbA1c (%)	visit2200	-0.03004	-0.087343
31	1	HbA1c (%)	visit2600	-0.03436	-0.036922
32	1	HbA1c (%)	visit3000	0.18406	0.140958
33	1	HbA1c (%)	visit3400	0.80524	0.859710

Parameter Code=C64849B Planned Treatment for Period 30 (N)=3 Imputed Variable=visit1800

Obs	_Imputation_	PARAM	Effect	ObsVal	_1
34	1	HbA1c (%)	Intercept	0.00177	-0.042414
35	1	HbA1c (%)	BASE	-0.08672	-0.073353
36	1	HbA1c (%)	visit1400	0.68464	0.689746

Parameter Code=C64849B Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	ObsVal	_1
37	1	HbA1c (%)	Intercept	0.00477	-0.015725
38	1	HbA1c (%)	BASE	-0.08511	-0.132168
39	1	HbA1c (%)	visit1400	-0.12217	-0.165538
40	1	HbA1c (%)	visit1800	0.88327	0.896885

Parameter Code=C64849B Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2600

Obs	_Imputation_	PARAM	Effect	ObsVal	_1
41	1	HbA1c (%)	Intercept	0.00383	0.007268
42	1	HbA1c (%)	BASE	-0.04704	-0.010289
43	1	HbA1c (%)	visit1400	-0.05626	-0.043562
44	1	HbA1c (%)	visit1800	0.03194	0.021429
45	1	HbA1c (%)	visit2200	0.81723	0.800368

Parameter Code=C64849B Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3000

Obs	_Imputation_	PARAM	Effect	ObsVal	_1
46	1	HbA1c (%)	Intercept	-0.00301	-0.000625
47	1	HbA1c (%)	BASE	-0.02723	-0.062918
48	1	HbA1c (%)	visit1400	0.04961	0.049933
49	1	HbA1c (%)	visit1800	0.01770	0.023474
50	1	HbA1c (%)	visit2200	0.05685	-0.000723
51	1	HbA1c (%)	visit2600	0.76867	0.808119

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - reduced model -
 in-trial - full analysis set

The MI Procedure with Monotone Regression
 Regression Information

Parameter Code=C64849B Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3400

Obs	_Imputation_	PARAM	Effect	ObsVal	_1
52	1	HbA1c (%)	Intercept	-0.0000913	0.018985
53	1	HbA1c (%)	BASE	-0.04169	-0.077284
54	1	HbA1c (%)	visit1400	-0.00948	-0.045170
55	1	HbA1c (%)	visit1800	0.18850	0.237402
56	1	HbA1c (%)	visit2200	-0.11362	-0.164427
57	1	HbA1c (%)	visit2600	-0.10844	-0.124698
58	1	HbA1c (%)	visit3000	0.90296	0.910936

Parameter Code=C64849B Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	ObsVal	_1
59	1	HbA1c (%)	Intercept	0.0000436	0.009937
60	1	HbA1c (%)	BASE	-0.04740	-0.066561
61	1	HbA1c (%)	visit1400	0.02340	0.069198
62	1	HbA1c (%)	visit1800	-0.02068	-0.066545
63	1	HbA1c (%)	visit2200	0.05601	0.103050
64	1	HbA1c (%)	visit2600	-0.02321	-0.019461
65	1	HbA1c (%)	visit3000	0.04347	-0.005719
66	1	HbA1c (%)	visit3400	0.85746	0.856435

Parameter Code=C64849B Planned Treatment for Period 30 (N)=4 Imputed Variable=visit1400

Obs	_Imputation_	PARAM	Effect	ObsVal	_1
67	1	HbA1c (%)	Intercept	-0.0001298	0.115432
68	1	HbA1c (%)	BASE	-0.09092	-0.110741

Parameter Code=C64849B Planned Treatment for Period 30 (N)=4 Imputed Variable=visit1800

Obs	_Imputation_	PARAM	Effect	ObsVal	_1
69	1	HbA1c (%)	Intercept	0.0006558	-0.013842
70	1	HbA1c (%)	BASE	-0.20990	-0.153406
71	1	HbA1c (%)	visit1400	0.59208	0.583609

Parameter Code=C64849B Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	ObsVal	_1
72	1	HbA1c (%)	Intercept	-0.0000269	0.002774
73	1	HbA1c (%)	BASE	-0.07849	-0.068116
74	1	HbA1c (%)	visit1400	0.10066	0.101585
75	1	HbA1c (%)	visit1800	0.73075	0.703727

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - reduced model - in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=C64849B Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2600

Obs	_Imputation_	PARAM	Effect	ObsVal	_1
76	1	HbA1c (%)	Intercept	0.00405	0.027388
77	1	HbA1c (%)	BASE	-0.09876	-0.036335
78	1	HbA1c (%)	visit1400	-0.09168	-0.124795
79	1	HbA1c (%)	visit1800	0.09509	0.019416
80	1	HbA1c (%)	visit2200	0.72027	0.857365

Parameter Code=C64849B Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3000

Obs	_Imputation_	PARAM	Effect	ObsVal	_1
81	1	HbA1c (%)	Intercept	-0.0007542	0.025105
82	1	HbA1c (%)	BASE	-0.07366	-0.075114
83	1	HbA1c (%)	visit1400	-0.04029	-0.027534
84	1	HbA1c (%)	visit1800	-0.03800	-0.048963
85	1	HbA1c (%)	visit2200	-0.06901	-0.019128
86	1	HbA1c (%)	visit2600	0.93017	0.894041

Parameter Code=C64849B Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3400

Obs	_Imputation_	PARAM	Effect	ObsVal	_1
87	1	HbA1c (%)	Intercept	0.0005711	0.004076
88	1	HbA1c (%)	BASE	-0.09412	-0.104017
89	1	HbA1c (%)	visit1400	-0.04167	-0.008247
90	1	HbA1c (%)	visit1800	0.10980	0.068323
91	1	HbA1c (%)	visit2200	0.05562	0.067331
92	1	HbA1c (%)	visit2600	-0.06468	-0.076097
93	1	HbA1c (%)	visit3000	0.82446	0.852036

Parameter Code=C64849B Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	ObsVal	_1
94	1	HbA1c (%)	Intercept	0.00499	-0.006633
95	1	HbA1c (%)	BASE	-0.02924	-0.064677
96	1	HbA1c (%)	visit1400	-0.02013	-0.017556
97	1	HbA1c (%)	visit1800	0.01583	-0.011189
98	1	HbA1c (%)	visit2200	0.10602	0.076442
99	1	HbA1c (%)	visit2600	-0.05426	-0.003905
100	1	HbA1c (%)	visit3000	-0.19770	-0.198477
101	1	HbA1c (%)	visit3400	1.04360	0.993604

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - reduced model -
in-trial - full analysis set

The Mixed procedure
Model Information

Parameter Code=C64849B Parameter=HbA1c (%)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Data Set	WORK.IMPUTE
2	1	NN1218-4131	Dependent Variable	eotVisit
3	1	NN1218-4131	Covariance Structure	Diagonal
4	1	NN1218-4131	Estimation Method	REML
5	1	NN1218-4131	Residual Variance Method	Profile
6	1	NN1218-4131	Fixed Effects SE Method	Model-Based
7	1	NN1218-4131	Degrees of Freedom Method	Residual

Fast-acting insulin aspart
NN1218-4131
Clinical Trial Report
Statistical document

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HbA1c 26 weeks after randomisation - statistical sensitivity analysis - reduced model -
in-trial - full analysis set

The Mixed procedure
Class Level Information

Parameter Code=C64849B Parameter=HbA1c (%)

Obs	_Imputation_	STUDYID	Class	Levels	Values	min_ length
1	1	NN1218-4131	TRTPN	3	2 3 4	5

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - reduced model -
in-trial - full analysis set

The Mixed procedure
Dimensions

Parameter Code=C64849B Parameter=HbA1c (%)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Covariance Parameters	1
2	1	NN1218-4131	Columns in X	4
3	1	NN1218-4131	Columns in Z	0
4	1	NN1218-4131	Subjects	1
5	1	NN1218-4131	Max Obs per Subject	1025

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - reduced model -
 in-trial - full analysis set

The Mixed procedure
 Number of Observations

Parameter Code=C64849B Parameter=HbA1c (%)

O b s	I m p u t a t i o n s	S T U D Y I D	L a b e l	N	N O b s R e a d	N O b s U s e d	S u m F r e q s R e a d	S u m F r e q s U s e d
1	1	NN1218-4131	Number of Observations Read	1025	1025	1025	1025	1025
2	1	NN1218-4131	Number of Observations Used	1025	1025	1025	1025	1025
3	1	NN1218-4131	Number of Observations Not Used	0	1025	1025	1025	1025

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - reduced model -
in-trial - full analysis set

The Mixed procedure
Covariance Parameter Estimates

Parameter Code=C64849B Parameter=HbA1c (%)

Obs	_Imputation_	STUDYID	CovParm	Estimate
1	1	NN1218-4131	Residual	0.3743

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - reduced model -
in-trial - full analysis set

The Mixed procedure
Fit Statistics

Parameter Code=C64849B Parameter=HbA1c (%)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	-2 Res Log Likelihood	1917.7
2	1	NN1218-4131	AIC (Smaller is Better)	1919.7
3	1	NN1218-4131	AICC (Smaller is Better)	1919.7
4	1	NN1218-4131	BIC (Smaller is Better)	1924.7

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - reduced model -
 in-trial - full analysis set

The Mixed procedure
 Solution for Fixed Effects

Parameter Code=C64849B Parameter=HbA1c (%)

O b s	I m p u t a t i o n s		S T U D I D	E f f i c i e n t	T R T P N	E s t i m a t e	S t d E r	D F	t V a l u e	P r o b a b i l i t y	A l l o w e d	L o w e r	U p p e r
1	1	NN1218-4131	TRTPN	2		2.0674	0.2071	1021	9.98	<.0001	0.05	1.6611	2.4738
2	1	NN1218-4131	TRTPN	3		2.1844	0.2057	1021	10.62	<.0001	0.05	1.7807	2.5881
3	1	NN1218-4131	TRTPN	4		2.0832	0.2059	1021	10.12	<.0001	0.05	1.6791	2.4873
4	1	NN1218-4131	BASE			-0.2942	0.02742	1021	-10.73	<.0001	0.05	-0.3480	-0.2404

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - reduced model -
 in-trial - full analysis set

The Mixed procedure
 Least Squares Means

Obs	_Imputation_	PARAMCD	PARAM	STUDYID	Effect	TRTPN	Margins	
1	1	C64849B	HbA1c (%)	NN1218-4131	TRTPN	2	WORK.IMPUTE	
2	1	C64849B	HbA1c (%)	NN1218-4131	TRTPN	3	WORK.IMPUTE	
3	1	C64849B	HbA1c (%)	NN1218-4131	TRTPN	4	WORK.IMPUTE	

Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	-0.1169	0.03309	1021	-3.53	0.0004	0.05	-0.1819	-0.05200
2	-5.72E-6	0.03313	1021	-0.00	0.9999	0.05	-0.06502	0.06501
3	-0.1012	0.03308	1021	-3.06	0.0023	0.05	-0.1661	-0.03626

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - reduced model -
in-trial - full analysis set

The Mixed procedure
Least Squares Means Estimate

Parameter Code=C64849B Parameter=HbA1c (%)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
1	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
2	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	WORK.IMPUTE	-0.01576	0.04680	1021	-0.34	0.7364	0.05	-0.1076	0.07607
2	WORK.IMPUTE	0.1012	0.04682	1021	2.16	0.0309	0.05	0.009298	0.1930

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - reduced model -
 in-trial - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=C64849B Parameter=HbA1c (%)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	100

Variance Information

Parameter	-----Variance-----			
	Between	Within	Total	DF
Estimate	0.000007331	0.001099	0.001106	2.21E6

Variance Information

Parameter	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
Estimate	0.006737	0.006693	0.999933

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF
Estimate	-0.112649	0.033263	-0.17784	-0.04745	2.21E6

Parameter Estimates

Parameter	Minimum	Maximum	Theta0	t for H0: Parameter=Theta0	Pr > t
Estimate	-0.118507	-0.106513	0	-3.39	0.0007

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - reduced model -
 in-trial - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=C64849B Parameter=HbA1c (%)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	100

Variance Information

Parameter	-----Variance-----			
	Between	Within	Total	DF
Estimate	0.000018034	0.001102	0.001120	374345

Variance Information

Parameter	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
Estimate	0.016531	0.016268	0.999837

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF
Estimate	-0.001319	0.033467	-0.06691	0.064274	374345

Parameter Estimates

Parameter	Minimum	Maximum	Theta0	t for H0: Parameter=Theta0	Pr > t
Estimate	-0.012740	0.008187	0	-0.04	0.9686

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - reduced model -
 in-trial - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=C64849B Parameter=HbA1c (%)

The MIANALYZE Procedure

Model Information

Data Set WORK.MI_MEANS
 Number of Imputations 100

Variance Information

Parameter	Between	Within	Total	DF
Estimate	0.000015724	0.001098	0.001114	487339

Variance Information

Parameter	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
Estimate	0.014459	0.014257	0.999857

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits	DF
Estimate	-0.101653	0.033381	-0.16708 -0.03623	487339

Parameter Estimates

Parameter	Minimum	Maximum	Theta0	t for H0: Parameter=Theta0	Pr > t
Estimate	-0.111531	-0.091215	0	-3.05	0.0023

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - reduced model -
 in-trial - full analysis set

Parameter Code=C64849B Label=Faster aspart (meal) - NovoRapid (meal) Parameter=HbA1c (%)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	100

Variance Information

Parameter	-----Variance-----			
	Between	Within	Total	DF
Estimate	0.000020983	0.002198	0.002219	1.09E6

Variance Information

Parameter	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
Estimate	0.009642	0.009552	0.999904

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF
Estimate	-0.010995	0.047108	-0.10332	0.081334	1.09E6

Parameter Estimates

Parameter	Minimum	Maximum	Theta0	t for H0: Parameter=Theta0	Pr > t
Estimate	-0.022771	-0.000580	0	-0.23	0.8154

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - reduced model -
 in-trial - full analysis set

Parameter Code=C64849B Label=Faster aspart (post) - NovoRapid (meal) Parameter=HbA1c (%)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	100

Variance Information

Parameter	-----Variance-----			
	Between	Within	Total	DF
Estimate	0.000031668	0.002200	0.002232	482040

Variance Information

Parameter	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
Estimate	0.014539	0.014335	0.999857

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF
Estimate	0.100334	0.047242	0.007741	0.192927	482040

Parameter Estimates

Parameter	Minimum	Maximum	Theta0	t for H0: Parameter=Theta0	Pr > t
Estimate	0.082436	0.113847	0	2.12	0.0337

3: HbA1c 26 weeks after randomisation - statistical sensitivity analysis - switch to inferior treatment - in-trial - full analysis set

The MI Procedure with MCMC
 Model Information

Parameter Code=C64849B Planned Treatment for Period 30 (N)=2

Obs	PARAM	Description	Value
1	HbA1c (%)	Data Set	WORK.ENDPOINT_PARAM
2	HbA1c (%)	Method	Monotone-data_MCMC
3	HbA1c (%)	Multiple Imputation Chain	Multiple Chains
4	HbA1c (%)	Initial Estimates for MCMC	EM Posterior Mode
5	HbA1c (%)	Start	Starting Value
6	HbA1c (%)	Prior	Jeffreys
7	HbA1c (%)	Number of Imputations	100
8	HbA1c (%)	Number of Burn-in Iterations	200
9	HbA1c (%)	Seed for random number generator	6837

Parameter Code=C64849B Planned Treatment for Period 30 (N)=3

Obs	PARAM	Description	Value
10	HbA1c (%)	Data Set	WORK.ENDPOINT_PARAM
11	HbA1c (%)	Method	Monotone-data_MCMC
12	HbA1c (%)	Multiple Imputation Chain	Multiple Chains
13	HbA1c (%)	Initial Estimates for MCMC	EM Posterior Mode
14	HbA1c (%)	Start	Starting Value
15	HbA1c (%)	Prior	Jeffreys
16	HbA1c (%)	Number of Imputations	100
17	HbA1c (%)	Number of Burn-in Iterations	200
18	HbA1c (%)	Seed for random number generator	520941473

Parameter Code=C64849B Planned Treatment for Period 30 (N)=4

Obs	PARAM	Description	Value
19	HbA1c (%)	Data Set	WORK.ENDPOINT_PARAM
20	HbA1c (%)	Method	Monotone-data_MCMC
21	HbA1c (%)	Multiple Imputation Chain	Multiple Chains
22	HbA1c (%)	Initial Estimates for MCMC	EM Posterior Mode
23	HbA1c (%)	Start	Starting Value
24	HbA1c (%)	Prior	Jeffreys
25	HbA1c (%)	Number of Imputations	100
26	HbA1c (%)	Number of Burn-in Iterations	200
27	HbA1c (%)	Seed for random number generator	796883322

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - switch to inferior treatment - in-trial - full analysis set

The MI Procedure with MCMC
Missing data pattern

Parameter Code=C64849B Planned Treatment for Period 30 (N)=2

Obs	PARAM	Group	BASE_ Miss	visit1400_ Miss	visit1800_ Miss	visit2200_ Miss	visit2600_ Miss	visit3000_ Miss
1	HbA1c (%)	1	X	X	X	X	X	X
2	HbA1c (%)	2	X	X	X	X	X	X
3	HbA1c (%)	3	X	X	X	X	X	X
4	HbA1c (%)	4	X	X	X	X	X	.
5	HbA1c (%)	5	X	X	X	O	O	O
6	HbA1c (%)	6	X	X	.	X	X	X
7	HbA1c (%)	7	X	X	.	.	X	X
8	HbA1c (%)	8	X	X	O	O	O	O
9	HbA1c (%)	9	X	.	X	X	X	.

Obs	visit3400_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit1400	visit1800
1	X	X	330	96.49	7.454242	-0.106970	-0.133636
2	X	O	1	0.29	6.700000	0.100000	-0.300000
3	.	X	3	0.88	7.666667	-0.133333	-0.133333
4	X	X	1	0.29	7.300000	-1.000000	-1.700000
5	O	O	1	0.29	7.300000	0	-0.200000
6	X	X	2	0.58	8.000000	-0.250000	.
7	X	X	1	0.29	7.800000	0	.
8	O	O	2	0.58	7.750000	0.200000	.
9	.	X	1	0.29	6.300000	.	0.100000

Obs	visit2200	visit2600	visit3000	visit3400	visit3600
1	-0.172424	-0.114848	-0.129091	-0.097576	-0.124242
2	-0.400000	0	0	0.200000	.
3	-0.300000	-0.333333	-0.500000	.	0.266667
4	-1.800000	-2.500000	.	-1.500000	-1.200000
5
6	0.100000	0.050000	-0.350000	0	0.150000
7	.	0	-0.200000	-0.700000	-0.700000
8
9	0	-0.100000	.	.	-0.100000

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - switch to inferior treatment - in-trial - full analysis set

The MI Procedure with MCMC
Missing data pattern

Parameter Code=C64849B Planned Treatment for Period 30 (N)=3

Obs	PARAM	Group	BASE_ Miss	visit1400_ Miss	visit1800_ Miss	visit2200_ Miss	visit2600_ Miss	visit3000_ Miss
10	HbA1c (%)	1	X	X	X	X	X	X
11	HbA1c (%)	2	X	X	X	X	X	X
12	HbA1c (%)	3	X	X	X	X	X	X
13	HbA1c (%)	4	X	X	X	X	X	.
14	HbA1c (%)	5	X	X	X	X	X	O
15	HbA1c (%)	6	X	X	X	X	.	X
16	HbA1c (%)	7	X	X	X	X	.	.
17	HbA1c (%)	8	X	X	X	X	O	O
18	HbA1c (%)	9	X	X	X	O	O	O
19	HbA1c (%)	10	X	X	.	X	X	X
20	HbA1c (%)	11	X	X	O	O	O	O
21	HbA1c (%)	12	X	.	X	X	X	X

Obs	visit3400_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit1400	visit1800
10	X	X	325	95.31	7.410154	-0.048923	-0.017538
11	.	X	3	0.88	6.700000	-0.100000	-0.166667
12	O	O	1	0.29	7.000000	-0.300000	-0.100000
13	X	X	2	0.59	7.350000	0.100000	-0.250000
14	O	O	1	0.29	8.000000	-0.600000	-0.600000
15	X	X	1	0.29	7.100000	0.100000	0.600000
16	.	X	1	0.29	8.100000	-0.400000	0.500000
17	O	O	3	0.88	7.500000	-0.100000	0.066667
18	O	O	1	0.29	7.400000	0.600000	0.900000
19	X	X	1	0.29	7.400000	0.100000	.
20	O	O	1	0.29	6.600000	0.200000	.
21	X	X	1	0.29	7.800000	.	-0.200000

Obs	visit2200	visit2600	visit3000	visit3400	visit3600
10	-0.039692	0.026462	0.024615	0.032308	-0.010462
11	-0.300000	0.033333	0.366667	.	0.100000
12	-0.200000	-0.400000	-0.300000	.	.
13	-0.200000	0	.	0.800000	0.650000
14	-0.800000	-0.700000	.	.	.
15	1.000000	.	1.500000	1.600000	1.200000
16	0.700000	.	.	.	1.300000
17	0.233333
18
19	0.100000	0.300000	0	0.100000	0.300000
20
21	-0.600000	-0.700000	-0.300000	-0.300000	-0.200000

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - switch to inferior treatment - in-trial - full analysis set

The MI Procedure with MCMC
 Missing data pattern

Parameter Code=C64849B Planned Treatment for Period 30 (N)=4

Obs	PARAM	Group	BASE_ Miss	visit1400_ Miss	visit1800_ Miss	visit2200_ Miss	visit2600_ Miss	visit3000_ Miss
22	HbA1c (%)	1	X	X	X	X	X	X
23	HbA1c (%)	2	X	X	X	X	X	X
24	HbA1c (%)	3	X	X	X	X	X	X
25	HbA1c (%)	4	X	X	X	X	X	.
26	HbA1c (%)	5	X	X	X	X	X	O
27	HbA1c (%)	6	X	X	X	X	.	X
28	HbA1c (%)	7	X	X	X	X	.	.
29	HbA1c (%)	8	X	X	X	X	O	O
30	HbA1c (%)	9	X	X	X	.	X	X
31	HbA1c (%)	10	X	X	.	X	X	X
32	HbA1c (%)	11	X	X	O	O	O	O
33	HbA1c (%)	12	X	.	X	X	X	X
34	HbA1c (%)	13	X	O	O	O	O	O

Obs	visit3400_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit1400	visit1800
22	X	X	328	95.91	7.405488	-0.064939	-0.049390
23	X	O	1	0.29	6.900000	0.100000	-0.100000
24	.	X	2	0.58	8.000000	-0.100000	0.350000
25	.	X	1	0.29	8.700000	0.500000	0.300000
26	O	O	1	0.29	7.800000	0.300000	0.400000
27	X	X	1	0.29	7.900000	0	-0.600000
28	X	X	1	0.29	7.300000	-1.000000	0.400000
29	O	O	2	0.58	7.400000	0.300000	0.600000
30	X	X	1	0.29	7.100000	-0.300000	-0.200000
31	X	X	1	0.29	7.200000	-0.700000	.
32	O	O	1	0.29	7.900000	0.200000	.
33	X	O	1	0.29	6.900000	.	1.100000
34	O	O	1	0.29	7.800000	.	.

Obs	visit2200	visit2600	visit3000	visit3400	visit3600
22	-0.067683	-0.034451	-0.078354	-0.068598	-0.107012
23	-0.400000	-0.200000	-0.100000	-0.100000	.
24	0.300000	0.350000	0.450000	.	0
25	-0.100000	-0.700000	.	.	0
26	0.300000	0.200000	.	.	.
27	0	.	-0.100000	0	0
28	0.200000	.	.	1.400000	1.400000
29	0.550000
30	.	0.700000	0.500000	0.100000	-0.200000
31	-0.700000	-0.700000	-0.800000	-0.800000	-0.800000
32
33	1.400000	1.500000	1.300000	1.100000	.
34

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - switch to inferior treatment - in-trial - full analysis set

The MI Procedure with Monotone Regression
 Model Information

Parameter Code=C64849B Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM	Description	Value
1	1	HbA1c (%)	Data Set	WORK.MONOTONE
2	1	HbA1c (%)	Method	Monotone
3	1	HbA1c (%)	Number of Imputations	1
4	1	HbA1c (%)	Seed for random number generator	9924

Parameter Code=C64849B Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM	Description	Value
5	1	HbA1c (%)	Data Set	WORK.MONOTONE
6	1	HbA1c (%)	Method	Monotone
7	1	HbA1c (%)	Number of Imputations	1
8	1	HbA1c (%)	Seed for random number generator	369748696

Parameter Code=C64849B Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM	Description	Value
9	1	HbA1c (%)	Data Set	WORK.MONOTONE
10	1	HbA1c (%)	Method	Monotone
11	1	HbA1c (%)	Number of Imputations	1
12	1	HbA1c (%)	Seed for random number generator	670427086

Parameter Code=C64849B Planned Treatment for Period 30 (N)=2

	Obs	Input atom	PORAM	Groupp	VVVVVVVV	Freq	Percent	BASIS	visit
				R	i i i i i i				
			E B	s s s s s s					
			G O	i i i i i i					
			I L B	t t t t t t					
			O A A	1 1 2 2 3 3					v
			N D S	4 8 2 6 0 4					i
			1 1 E	0 0 0 0 0 0					s
			M M M M M M M M M						i
			i i i i i i i i i						t
			s s s s s s s s s						l
			s s s s s s s s s						4
1 1 HbA1c (%)	338	98.83	7.456509	-0.110292					
2 1 HbA1c (%)	1	0.29	6.700000	0.100000					
3 1 HbA1c (%)	1	0.29	7.300000	0					
4 1 HbA1c (%)	2	0.58	7.750000	0.200000					

	v	v	v	v	v	v
	i	i	i	i	i	i
	s	s	s	s	s	s
	i	i	i	i	i	i
	t	t	t	t	t	t
	1	2	2	3	3	3
O	8	2	6	0	4	6
b	0	0	0	0	0	0
s	0	0	0	0	0	0
1	-0.134889	-0.174046	-0.122485	-0.139541	-0.100947	-0.123964
2	-0.300000	-0.400000	0	0	0.200000	.
3	-0.200000
4

```
nn1218/nn1218-4131/ctr_20180214_er
13FEB2018:22:00:44 - s stat diff.sas/s hba sens2 stat in_fas app.txt
```

```
nn1218/nn1218-4131/ctr_20180214_er
13FEB2018:22:00:44 - s stat diff.sas/s hba sens2 stat in_fas app.txt
```

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - switch to inferior treatment - in-trial - full analysis set

The MI Procedure with Monotone Regression
 Regression Information

Parameter Code=C64849B Planned Treatment for Period 30 (N)=2 Imputed Variable=visit1800

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	HbA1c (%)	Intercept	
2	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	HbA1c (%)	REGION1	EUROPE
4	1	HbA1c (%)	REGION1	JAPAN
5	1	HbA1c (%)	BOLAD1	
6	1	HbA1c (%)	BASE	
7	1	HbA1c (%)	visit1400	

Obs		BOLAD1	ObsVal	_1
1			0.00559	0.002791
2			-0.00455	0.002680
3			-0.01107	-0.064233
4			-0.02685	-0.066458
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.03400	-0.014279
6			-0.09463	-0.101116
7			0.79400	0.768406

Parameter Code=C64849B Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
8	1	HbA1c (%)	Intercept	
9	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)
10	1	HbA1c (%)	REGION1	EUROPE
11	1	HbA1c (%)	REGION1	JAPAN
12	1	HbA1c (%)	BOLAD1	
13	1	HbA1c (%)	BASE	
14	1	HbA1c (%)	visit1400	
15	1	HbA1c (%)	visit1800	

Obs		BOLAD1	ObsVal	_1
8			0.00677	-0.063430
9			0.02931	-0.065482
10			0.03418	0.096651
11			-0.03483	-0.083919
12	BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.03203	-0.051076
13			-0.08622	-0.130112
14			0.06919	0.051740
15			0.77158	0.753246

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - switch to inferior treatment - in-trial - full analysis set

The MI Procedure with Monotone Regression
 Regression Information

Parameter Code=C64849B Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2600

Obs	_Imputation_	PARAM	Effect	REGION1
16	1	HbA1c (%)	Intercept	
17	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)
18	1	HbA1c (%)	REGION1	EUROPE
19	1	HbA1c (%)	REGION1	JAPAN
20	1	HbA1c (%)	BOLAD1	
21	1	HbA1c (%)	BASE	
22	1	HbA1c (%)	visit1400	
23	1	HbA1c (%)	visit1800	
24	1	HbA1c (%)	visit2200	

Obs		BOLAD1	ObsVal	_1
16			-0.03751	-0.061996
17			-0.16235	-0.116629
18			0.10591	0.113195
19			-0.01154	0.003165
20	BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.00230	-0.029329
21			-0.08550	-0.104406
22			-0.01132	0.027122
23			0.01442	-0.109095
24			0.83136	0.892550

Parameter Code=C64849B Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3000

Obs	_Imputation_	PARAM	Effect	REGION1
25	1	HbA1c (%)	Intercept	
26	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)
27	1	HbA1c (%)	REGION1	EUROPE
28	1	HbA1c (%)	REGION1	JAPAN
29	1	HbA1c (%)	BOLAD1	
30	1	HbA1c (%)	BASE	
31	1	HbA1c (%)	visit1400	
32	1	HbA1c (%)	visit1800	
33	1	HbA1c (%)	visit2200	
34	1	HbA1c (%)	visit2600	

Obs		BOLAD1	ObsVal	_1
25			0.00617	0.061137
26			0.06936	0.110512
27			-0.01636	-0.112893
28			-0.05301	-0.035241
29	BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.01517	-0.036935
30			-0.04584	-0.054141
31			-0.00721	-0.042671
32			-0.03854	-0.066882
33			0.12421	0.213601
34			0.79406	0.715441

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - switch to inferior treatment - in-trial - full analysis set

The MI Procedure with Monotone Regression
 Regression Information

Parameter Code=C64849B Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3400

Obs	_Imputation_	PARAM	Effect	REGION1
35	1	HbA1c (%)	Intercept	
36	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)
37	1	HbA1c (%)	REGION1	EUROPE
38	1	HbA1c (%)	REGION1	JAPAN
39	1	HbA1c (%)	BOLAD1	
40	1	HbA1c (%)	BASE	
41	1	HbA1c (%)	visit1400	
42	1	HbA1c (%)	visit1800	
43	1	HbA1c (%)	visit2200	
44	1	HbA1c (%)	visit2600	
45	1	HbA1c (%)	visit3000	

Obs		BOLAD1	ObsVal	_1
35			-0.01332	-0.035643
36			-0.02662	0.008578
37			0.05742	0.050112
38			0.00109	-0.016945
39	BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.03743	0.047723
40			-0.02347	0.010039
41			0.03547	-0.021256
42			0.06929	0.167022
43			0.08926	0.048621
44			0.03545	-0.106331
45			0.70368	0.867363

Parameter Code=C64849B Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1
46	1	HbA1c (%)	Intercept	
47	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)
48	1	HbA1c (%)	REGION1	EUROPE
49	1	HbA1c (%)	REGION1	JAPAN
50	1	HbA1c (%)	BOLAD1	
51	1	HbA1c (%)	BASE	
52	1	HbA1c (%)	visit1400	
53	1	HbA1c (%)	visit1800	

Obs		BOLAD1	ObsVal	_1
46			-0.00793	-0.009731
47			0.00646	0.015743
48			0.07240	0.103587
49			-0.02176	-0.077128
50	BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.03192	0.019387
51			-0.01347	-0.008265
52			-0.05165	-0.013190
53			0.05224	0.048554

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - switch to inferior treatment - in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=C64849B Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
54	1	HbA1c (%)	visit2200			-0.02465	-0.039448
55	1	HbA1c (%)	visit2600			-0.03447	-0.018170
56	1	HbA1c (%)	visit3000			0.18751	0.188813
57	1	HbA1c (%)	visit3400			0.79371	0.775037

Parameter Code=C64849B Planned Treatment for Period 30 (N)=3 Imputed Variable=visit1800

Obs	_Imputation_	PARAM	Effect	REGION1		ObsVal	_1
58	1	HbA1c (%)	Intercept				
59	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)			
60	1	HbA1c (%)	REGION1	EUROPE			
61	1	HbA1c (%)	REGION1	JAPAN			
62	1	HbA1c (%)	BOLAD1				
63	1	HbA1c (%)	BASE				
64	1	HbA1c (%)	visit1400				

Obs		BOLAD1	ObsVal	_1
58			-0.01726	0.020780
59			-0.08955	0.002374
60			0.05473	-0.027432
61			0.00357	0.052544
62	BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.01102	-0.033872
63			-0.08452	-0.099131
64			0.68718	0.650916

Parameter Code=C64849B Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1		ObsVal	_1
65	1	HbA1c (%)	Intercept				
66	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)			
67	1	HbA1c (%)	REGION1	EUROPE			
68	1	HbA1c (%)	REGION1	JAPAN			
69	1	HbA1c (%)	BOLAD1				
70	1	HbA1c (%)	BASE				

Obs		BOLAD1	ObsVal	_1
65			0.00927	0.059426
66			-0.02871	-0.048088
67			-0.04780	-0.074802
68			0.03667	0.059161
69	BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.04701	-0.016356
70			-0.08233	-0.035138

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - switch to inferior treatment - in-trial - full analysis set

The MI Procedure with Monotone Regression
 Regression Information

Parameter Code=C64849B Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2200

(continued)

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
71	1	HbA1c (%)	visit1400			-0.12203	-0.133783
72	1	HbA1c (%)	visit1800			0.88380	0.864656

Parameter Code=C64849B Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
73	1	HbA1c (%)	Intercept				
74	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)			
75	1	HbA1c (%)	REGION1	EUROPE			
76	1	HbA1c (%)	REGION1	JAPAN			
77	1	HbA1c (%)	BOLAD1				
78	1	HbA1c (%)	BASE				
79	1	HbA1c (%)	visit1400				
80	1	HbA1c (%)	visit1800				
81	1	HbA1c (%)	visit2200				

Obs	BOLAD1	ObsVal	_1
73		-0.01816	0.005241
74		-0.11317	-0.176020
75		0.03761	-0.001575
76		-0.06721	-0.057126
77	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.0007508	0.008086
78		-0.04830	-0.005198
79		-0.04284	-0.049138
80		0.03114	0.060496
81		0.80912	0.786013

Parameter Code=C64849B Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3000

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
82	1	HbA1c (%)	Intercept				
83	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)			
84	1	HbA1c (%)	REGION1	EUROPE			
85	1	HbA1c (%)	REGION1	JAPAN			
86	1	HbA1c (%)	BOLAD1				

Obs	BOLAD1	ObsVal	_1
82		-0.02590	-0.059990
83		-0.09413	-0.212587
84		0.07810	0.067978
85		-0.06278	-0.047735
86	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.01578	0.018447

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - switch to inferior treatment - in-trial - full analysis set

The MI Procedure with Monotone Regression
 Regression Information

Parameter Code=C64849B Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3000

(continued)

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
87	1	HbA1c (%)	BASE			-0.03373	-0.054038
88	1	HbA1c (%)	visit1400			0.06593	0.080074
89	1	HbA1c (%)	visit1800			0.00596	0.051099
90	1	HbA1c (%)	visit2200			0.08363	0.051733
91	1	HbA1c (%)	visit2600			0.73872	0.756848

Parameter Code=C64849B Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3400

Obs	_Imputation_	PARAM	Effect	REGION1		ObsVal	_1
92	1	HbA1c (%)	Intercept				
93	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)			
94	1	HbA1c (%)	REGION1	EUROPE			
95	1	HbA1c (%)	REGION1	JAPAN			
96	1	HbA1c (%)	BOLAD1				
97	1	HbA1c (%)	BASE				
98	1	HbA1c (%)	visit1400				
99	1	HbA1c (%)	visit1800				
100	1	HbA1c (%)	visit2200				
101	1	HbA1c (%)	visit2600				
102	1	HbA1c (%)	visit3000				

Obs		BOLAD1	ObsVal	_1
92			-0.01101	-0.005708
93			-0.01668	0.025592
94			0.11673	0.133879
95			-0.06313	-0.168907
96	BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.0006082	0.018268
97			-0.04033	-0.035580
98			-0.01404	-0.045942
99			0.18855	0.231223
100			-0.10985	-0.031629
101			-0.08283	-0.189353
102			0.87101	0.921689

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - switch to inferior treatment - in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=C64849B Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

Obs	Imputed	PARAM	Effect	REGION1	BOLAD1	ObsVal	Intercept
103	1	HbA1c (%)	Intercept				-0.00793
104	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)			-0.01017
105	1	HbA1c (%)	REGION1	EUROPE			-0.0001534
Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1		
106	1	HbA1c (%)	REGION1	JAPAN			
107	1	HbA1c (%)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
108	1	HbA1c (%)	BASE				
109	1	HbA1c (%)	visit1400				
110	1	HbA1c (%)	visit1800				
111	1	HbA1c (%)	visit2200				
112	1	HbA1c (%)	visit2600				
113	1	HbA1c (%)	visit3000				
114	1	HbA1c (%)	visit3400				
Obs	ObsVal		_1				
106	-0.02511		-0.015351				
107	0.04869		0.028725				
108	-0.04603		-0.061309				
109	0.02602		-0.004698				
110	-0.02908		-0.043915				
111	0.06606		0.045923				
112	-0.00848		0.047829				
113	0.01850		0.000771				
114	0.86780		0.871523				

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - switch to inferior treatment - in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=C64849B Planned Treatment for Period 30 (N)=4 Imputed Variable=visit1400

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	I
115	1	HbA1c (%)	Intercept			0.083245
116	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)		0.212997
117	1	HbA1c (%)	REGION1	EUROPE		-0.116566
118	1	HbA1c (%)	REGION1	JAPAN		
119	1	HbA1c (%)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	
120	1	HbA1c (%)	BASE			
118		ObsVal	_1			
118		-0.08853	-0.086221			
119		-0.02291	-0.031802			
120		-0.10478	0.016443			

Parameter Code=C64849B Planned Treatment for Period 30 (N)=4 Imputed Variable=visit1800

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
121	1	HbA1c (%)	Intercept			0.00878	-0.037072
122	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)		0.11171	0.114422
123	1	HbA1c (%)	REGION1	EUROPE		0.02712	0.059676
124	1	HbA1c (%)	REGION1	JAPAN		-0.15015	-0.211051
125	1	HbA1c (%)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.00516	0.036310
126	1	HbA1c (%)	BASE			-0.22322	-0.314087
127	1	HbA1c (%)	visit1400			0.58741	0.658815

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - switch to inferior treatment - in-trial - full analysis set

The MI Procedure with Monotone Regression
 Regression Information

Parameter Code=C64849B Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
128	1	HbA1c (%)	Intercept	
129	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)
130	1	HbA1c (%)	REGION1	EUROPE
131	1	HbA1c (%)	REGION1	JAPAN
132	1	HbA1c (%)	BOLAD1	
133	1	HbA1c (%)	BASE	
134	1	HbA1c (%)	visit1400	
135	1	HbA1c (%)	visit1800	

Obs		BOLAD1	ObsVal	_1
128			0.00757	-0.026873
129			0.05202	0.030788
130			-0.00565	0.086529
131			-0.06572	-0.025685
132	BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.01601	0.067653
133			-0.08800	-0.048448
134			0.09967	0.097652
135			0.72581	0.694900

Parameter Code=C64849B Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2600

Obs	_Imputation_	PARAM	Effect	REGION1
136	1	HbA1c (%)	Intercept	
137	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)
138	1	HbA1c (%)	REGION1	EUROPE
139	1	HbA1c (%)	REGION1	JAPAN
140	1	HbA1c (%)	BOLAD1	
141	1	HbA1c (%)	BASE	
142	1	HbA1c (%)	visit1400	
143	1	HbA1c (%)	visit1800	
144	1	HbA1c (%)	visit2200	

Obs		BOLAD1	ObsVal	_1
136			-0.01218	-0.022341
137			-0.14027	-0.175414
138			0.03750	0.024396
139			0.04926	-0.005186
140	BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.00556	0.022138
141			-0.08423	-0.005625
142			-0.10428	-0.140565
143			0.11251	0.168748
144			0.71725	0.733599

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - switch to inferior treatment - in-trial - full analysis set

The MI Procedure with Monotone Regression
 Regression Information

Parameter Code=C64849B Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3000

Obs	_Imputation_	PARAM	Effect	REGION1
145	1	HbA1c (%)	Intercept	
146	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)
147	1	HbA1c (%)	REGION1	EUROPE
148	1	HbA1c (%)	REGION1	JAPAN
149	1	HbA1c (%)	BOLAD1	
150	1	HbA1c (%)	BASE	
151	1	HbA1c (%)	visit1400	
152	1	HbA1c (%)	visit1800	
153	1	HbA1c (%)	visit2200	
154	1	HbA1c (%)	visit2600	
Obs		BOLAD1	ObsVal	_1
145			0.0007303	0.033067
146			-0.02433	-0.071574
147			0.06439	0.080180
148			-0.02556	-0.014230
149	BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.04138	0.011442
150			-0.07374	-0.086017
151			-0.01755	-0.024303
152			-0.06327	-0.030634
153			-0.05833	-0.034759
154			0.92696	0.853651

Parameter Code=C64849B Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3400

Obs	_Imputation_	PARAM	Effect	REGION1
155	1	HbA1c (%)	Intercept	
156	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)
157	1	HbA1c (%)	REGION1	EUROPE
158	1	HbA1c (%)	REGION1	JAPAN
159	1	HbA1c (%)	BOLAD1	
160	1	HbA1c (%)	BASE	
161	1	HbA1c (%)	visit1400	
162	1	HbA1c (%)	visit1800	
163	1	HbA1c (%)	visit2200	
Obs		BOLAD1	ObsVal	_1
155			-0.02206	-0.013814
156			-0.16821	-0.107085
157			0.12597	0.078717
158			0.01873	-0.001886
159	BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.01671	-0.019830
160			-0.07260	-0.065299
161			-0.05431	-0.074925
162			0.12444	0.235611
163			0.06437	0.019474

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - switch to inferior treatment - in-trial - full analysis set

The MI Procedure with Monotone Regression
 Regression Information

Parameter Code=C64849B Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3400

(continued)

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
164	1	HbA1c (%)	visit2600			-0.06162	-0.136801
165	1	HbA1c (%)	visit3000			0.80455	0.849512

Parameter Code=C64849B Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
166	1	HbA1c (%)	Intercept				
167	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)			
168	1	HbA1c (%)	REGION1	EUROPE			
169	1	HbA1c (%)	REGION1	JAPAN			
170	1	HbA1c (%)	BOLAD1				
171	1	HbA1c (%)	BASE				
172	1	HbA1c (%)	visit1400				
173	1	HbA1c (%)	visit1800				
174	1	HbA1c (%)	visit2200				
175	1	HbA1c (%)	visit2600				
176	1	HbA1c (%)	visit3000				
177	1	HbA1c (%)	visit3400				

Obs	BOLAD1	ObsVal	_1
166		0.00120	-0.037123
167		-0.05753	-0.156805
168		0.06913	0.139813
169		-0.00737	0.016261
170	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.03293	-0.021816
171		-0.02735	0.025693
172		-0.01802	0.001890
173		0.01521	0.023215
174		0.10820	0.170341
175		-0.04030	-0.101828
176		-0.20370	-0.204431
177		1.02385	1.052547

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - switch to
inferior treatment - in-trial - full analysis set

The Mixed procedure
Model Information

Parameter Code=C64849B Parameter=HbA1c (%)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Data Set	WORK.IMPUTE
2	1	NN1218-4131	Dependent Variable	eotVisit
3	1	NN1218-4131	Covariance Structure	Diagonal
4	1	NN1218-4131	Estimation Method	REML
5	1	NN1218-4131	Residual Variance Method	Profile
6	1	NN1218-4131	Fixed Effects SE Method	Model-Based
7	1	NN1218-4131	Degrees of Freedom Method	Residual

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - switch to inferior treatment - in-trial - full analysis set

The Mixed procedure
 Class Level Information

Parameter Code=C64849B Parameter=HbA1c (%)

Obs	_Imputation_	STUDYID	Class	Levels
1	1	NN1218-4131	TRTPN	3
2	1	NN1218-4131	REGION1	4
3	1	NN1218-4131	BOLAD1	2

Obs Values

1	2	3	4
2	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA		
3	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULI		

min_
 Obs legth

1	5
2	49
3	85

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - switch to
inferior treatment - in-trial - full analysis set

The Mixed procedure
Dimensions

Parameter Code=C64849B Parameter=HbA1c (%)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Covariance Parameters	1
2	1	NN1218-4131	Columns in X	10
3	1	NN1218-4131	Columns in Z	0
4	1	NN1218-4131	Subjects	1
5	1	NN1218-4131	Max Obs per Subject	1025

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - switch to inferior treatment - in-trial - full analysis set

The Mixed procedure
 Number of Observations

Parameter Code=C64849B Parameter=HbA1c (%)

O b s	I m p u t i o n s	S T U D Y I D	L a b e l	N	N O b s R e a d	N O b s U s e d	S u m F r e q s R e a d	S u m F r e q s U s e d
1	1	NN1218-4131	Number of Observations Read	1025	1025	1025	1025	1025
2	1	NN1218-4131	Number of Observations Used	1025	1025	1025	1025	1025
3	1	NN1218-4131	Number of Observations Not Used	0	1025	1025	1025	1025

Fast-acting insulin aspart
NN1218-4131
Clinical Trial Report
Statistical document

~~CONFIDENTIAL~~

Date: 14 February 2018
Version: 1.0
Status: Final
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Novo Nordisk

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - switch to
inferior treatment - in-trial - full analysis set

The Mixed procedure
Covariance Parameter Estimates

Parameter Code=C64849B Parameter=HbA1c (%)

Obs	_Imputation_	STUDYID	CovParm	Estimate
1	1	NN1218-4131	Residual	0.3702

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - switch to
inferior treatment - in-trial - full analysis set

The Mixed procedure
Fit Statistics

Parameter Code=C64849B Parameter=HbA1c (%)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	-2 Res Log Likelihood	1919.4
2	1	NN1218-4131	AIC (Smaller is Better)	1921.4
3	1	NN1218-4131	AICC (Smaller is Better)	1921.4
4	1	NN1218-4131	BIC (Smaller is Better)	1926.3

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - switch to inferior treatment - in-trial - full analysis set

The Mixed procedure
 Solution for Fixed Effects

Parameter Code=C64849B Parameter=HbA1c (%)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1
1	1	NN1218-4131	TRTPN	2	
2	1	NN1218-4131	TRTPN	3	
3	1	NN1218-4131	TRTPN	4	
4	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)
5	1	NN1218-4131	REGION1	—	EUROPE
6	1	NN1218-4131	REGION1	—	JAPAN
7	1	NN1218-4131	REGION1	—	NORTH AMERICA
8	1	NN1218-4131	BOLAD1	—	
9	1	NN1218-4131	BOLAD1	—	
10	1	NN1218-4131	BASE	—	

Obs		BOLAD1	Estimate
1			2.0948
2			2.2129
3			2.1101
4			-0.1523
5			0.07914
6			-0.1160
7			0
8	BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.01511
9	CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0
10			-0.2929

Obs	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	0.2119	1017	9.88	<.0001	0.05	1.6789	2.5107
2	0.2108	1017	10.50	<.0001	0.05	1.7992	2.6266
3	0.2110	1017	10.00	<.0001	0.05	1.6961	2.5241
4	0.06942	1017	-2.19	0.0284	0.05	-0.2886	-0.01610
5	0.04897	1017	1.62	0.1064	0.05	-0.01695	0.1752
6	0.05479	1017	-2.12	0.0344	0.05	-0.2235	-0.00852
7
8	0.04264	1017	-0.35	0.7232	0.05	-0.09878	0.06857
9
10	0.02749	1017	-10.66	<.0001	0.05	-0.3469	-0.2390

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - switch to inferior treatment - in-trial - full analysis set

The Mixed procedure
 Least Squares Means

Obs	_Imputation_	PARAMCD	PARAM	STUDYID	Effect	TRTPN	Margins	
1	1	C64849B	HbA1c (%)	NN1218-4131	TRTPN	2	WORK.IMPUTE	
2	1	C64849B	HbA1c (%)	NN1218-4131	TRTPN	3	WORK.IMPUTE	
3	1	C64849B	HbA1c (%)	NN1218-4131	TRTPN	4	WORK.IMPUTE	

Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	-0.1100	0.03295	1017	-3.34	0.0009	0.05	-0.1746	-0.04529
2	0.008122	0.03298	1017	0.25	0.8055	0.05	-0.05660	0.07285
3	-0.09463	0.03293	1017	-2.87	0.0041	0.05	-0.1593	-0.03001

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - switch to inferior treatment - in-trial - full analysis set

The Mixed procedure
 Least Squares Means Estimate

Parameter Code=C64849B Parameter=HbA1c (%)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
1	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
2	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	WORK.IMPUTE	-0.01532	0.04663	1017	-0.33	0.7425	0.05	-0.1068	0.07617
2	WORK.IMPUTE	0.1028	0.04662	1017	2.20	0.0278	0.05	0.01126	0.1942

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - switch to inferior treatment - in-trial - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=C64849B Parameter=HbA1c (%)

The MIANALYZE Procedure

Model Information

Data Set WORK.MI_MEANS
 Number of Imputations 100

Variance Information

Parameter	Between	Within	Total	DF
Estimate	0.000009241	0.001087	0.001096	1.36E6

Variance Information

Parameter	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
Estimate	0.008590	0.008518	0.999915

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits	DF
Estimate	-0.114862	0.033104	-0.17975 -0.04998	1.36E6

Parameter Estimates

Parameter	Minimum	Maximum	Theta0	t for H0: Parameter=Theta0	Pr > t
Estimate	-0.124221	-0.108418	0	-3.47	0.0005

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - switch to inferior treatment - in-trial - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=C64849B Parameter=HbA1c (%)

The MIANALYZE Procedure

Model Information

Data Set WORK.MI_MEANS
 Number of Imputations 100

Variance Information

Parameter	Between	Within	Total	DF
Estimate	0.000014161	0.001089	0.001103	588749

Variance Information

Parameter	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
Estimate	0.013138	0.012971	0.999870

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits	DF
Estimate	0.006793	0.033211	-0.05830 0.071885	588749

Parameter Estimates

Parameter	Minimum	Maximum	Theta0	t for H0: Parameter=Theta0	Pr > t
Estimate	-0.000658	0.016258	0	0.20	0.8379

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - switch to inferior treatment - in-trial - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=C64849B Parameter=HbA1c (%)

The MIANALYZE Procedure

Model Information

Data Set WORK.MI_MEANS
 Number of Imputations 100

Variance Information

Parameter	Between	Within	Total	DF
Estimate	0.000013528	0.001085	0.001099	640476

Variance Information

Parameter	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
Estimate	0.012589	0.012436	0.999876

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits	DF
Estimate	-0.097294	0.033151	-0.16227 -0.03232	640476

Parameter Estimates

Parameter	Minimum	Maximum	Theta0	t for H0: Parameter=Theta0	Pr > t
Estimate	-0.109461	-0.088642	0	-2.93	0.0033

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - switch to inferior treatment - in-trial - full analysis set

Parameter Code=C64849B Label=Faster aspart (meal) - NovoRapid (meal) Parameter=HbA1c (%)

The MIANALYZE Procedure

Model Information

Data Set WORK.MI_ESTIMATE
 Number of Imputations 100

Variance Information

Parameter	Between	Within	Total	DF
Estimate	0.000022532	0.002175	0.002198	923589

Variance Information

Parameter	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
Estimate	0.010462	0.010355	0.999896

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits	DF
Estimate	-0.017568	0.046883	-0.10946 0.074322	923589

Parameter Estimates

Parameter	Minimum	Maximum	Theta0	t for H0: Parameter=Theta0	Pr > t
Estimate	-0.032534	-0.006820	0	-0.37	0.7079

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - switch to inferior treatment - in-trial - full analysis set

Parameter Code=C64849B Label=Faster aspart (post) - NovoRapid (meal) Parameter=HbA1c (%)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	100

Variance Information

Parameter	Between	Within	Total	DF
Estimate	0.000029972	0.002175	0.002206	525521

Variance Information

Parameter	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
Estimate	0.013916	0.013729	0.999863

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits	DF
Estimate	0.104086	0.046963	0.012041 0.196132	525521

Parameter Estimates

Parameter	Minimum	Maximum	Theta0	t for H0: Parameter=Theta0	Pr > t
Estimate	0.092650	0.120916	0	2.22	0.0267

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - switch to inferior treatment - in-trial - full analysis set

Parameter Code=C64849B Label=Faster aspart (meal) - NovoRapid (meal) Parameter=HbA1c (%)

The MIANALYZE Procedure

Model Information

Data Set WORK.MI_ESTIMATE
 Number of Imputations 100

Variance Information

Parameter	Between	Within	Total	DF
Estimate	0.000022532	0.002175	0.002198	923589

Variance Information

Parameter	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
Estimate	0.010462	0.010355	0.999896

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits	DF
Estimate	-0.017568	0.046883	-0.10946 0.074322	923589

Parameter Estimates

Parameter	Minimum	Maximum	Theta0	t for H0: Parameter=Theta0	Pr > t
Estimate	-0.032534	-0.006820	0.400000	-8.91	<.0001

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - switch to inferior treatment - in-trial - full analysis set

Parameter Code=C64849B Label=Faster aspart (post) - NovoRapid (meal) Parameter=HbA1c (%)

The MIANALYZE Procedure

Model Information

Data Set WORK.MI_ESTIMATE
 Number of Imputations 100

Variance Information

Parameter	Between	Within	Total	DF
Estimate	0.000029972	0.002175	0.002206	525521

Variance Information

Parameter	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
Estimate	0.013916	0.013729	0.999863

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits	DF
Estimate	0.104086	0.046963	0.012041 0.196132	525521

Parameter Estimates

Parameter	Minimum	Maximum	Theta0	t for H0: Parameter=Theta0	Pr > t
Estimate	0.092650	0.120916	0.400000	-6.30	<.0001

4: HbA1c 26 weeks after randomisation - statistical sensitivity analysis - conditional switch to NovoRapid - in-trial - full analysis set

The MI Procedure with MCMC
 Model Information

Parameter Code=C64849B Planned Treatment for Period 30 (N)=2

Obs	PARAM	Description	Value
1	HbA1c (%)	Data Set	WORK.ENDPOINT_PARAM
2	HbA1c (%)	Method	Monotone-data_MCMC
3	HbA1c (%)	Multiple Imputation Chain	Multiple Chains
4	HbA1c (%)	Initial Estimates for MCMC	EM Posterior Mode
5	HbA1c (%)	Start	Starting Value
6	HbA1c (%)	Prior	Jeffreys
7	HbA1c (%)	Number of Imputations	100
8	HbA1c (%)	Number of Burn-in Iterations	200
9	HbA1c (%)	Seed for random number generator	6829

Parameter Code=C64849B Planned Treatment for Period 30 (N)=3

Obs	PARAM	Description	Value
10	HbA1c (%)	Data Set	WORK.ENDPOINT_PARAM
11	HbA1c (%)	Method	Monotone-data_MCMC
12	HbA1c (%)	Multiple Imputation Chain	Multiple Chains
13	HbA1c (%)	Initial Estimates for MCMC	EM Posterior Mode
14	HbA1c (%)	Start	Starting Value
15	HbA1c (%)	Prior	Jeffreys
16	HbA1c (%)	Number of Imputations	100
17	HbA1c (%)	Number of Burn-in Iterations	200
18	HbA1c (%)	Seed for random number generator	1373923523

Parameter Code=C64849B Planned Treatment for Period 30 (N)=4

Obs	PARAM	Description	Value
19	HbA1c (%)	Data Set	WORK.ENDPOINT_PARAM
20	HbA1c (%)	Method	Monotone-data_MCMC
21	HbA1c (%)	Multiple Imputation Chain	Multiple Chains
22	HbA1c (%)	Initial Estimates for MCMC	EM Posterior Mode
23	HbA1c (%)	Start	Starting Value
24	HbA1c (%)	Prior	Jeffreys
25	HbA1c (%)	Number of Imputations	100
26	HbA1c (%)	Number of Burn-in Iterations	200
27	HbA1c (%)	Seed for random number generator	718762417

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - conditional switch to NovoRapid - in-trial - full analysis set

The MI Procedure with MCMC
Missing data pattern

Parameter Code=C64849B Planned Treatment for Period 30 (N)=2

Obs	PARAM	Group	BASE_ Miss	visit1400_ Miss	visit1800_ Miss	visit2200_ Miss	visit2600_ Miss	visit3000_ Miss
1	HbA1c (%)	1	X	X	X	X	X	X
2	HbA1c (%)	2	X	X	X	X	X	X
3	HbA1c (%)	3	X	X	X	X	X	X
4	HbA1c (%)	4	X	X	X	X	X	.
5	HbA1c (%)	5	X	X	X	O	O	O
6	HbA1c (%)	6	X	X	.	X	X	X
7	HbA1c (%)	7	X	X	.	.	X	X
8	HbA1c (%)	8	X	X	O	O	O	O
9	HbA1c (%)	9	X	.	X	X	X	.

Obs	visit3400_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit1400	visit1800
1	X	X	330	96.49	7.454242	-0.106970	-0.133636
2	X	O	1	0.29	6.700000	0.100000	-0.300000
3	.	X	3	0.88	7.666667	-0.133333	-0.133333
4	X	X	1	0.29	7.300000	-1.000000	-1.700000
5	O	O	1	0.29	7.300000	0	-0.200000
6	X	X	2	0.58	8.000000	-0.250000	.
7	X	X	1	0.29	7.800000	0	.
8	O	O	2	0.58	7.750000	0.200000	.
9	.	X	1	0.29	6.300000	.	0.100000

Obs	visit2200	visit2600	visit3000	visit3400	visit3600
1	-0.172424	-0.114848	-0.129091	-0.097576	-0.124242
2	-0.400000	0	0	0.200000	.
3	-0.300000	-0.333333	-0.500000	.	0.266667
4	-1.800000	-2.500000	.	-1.500000	-1.200000
5
6	0.100000	0.050000	-0.350000	0	0.150000
7	.	0	-0.200000	-0.700000	-0.700000
8
9	0	-0.100000	.	.	-0.100000

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - conditional switch to NovoRapid - in-trial - full analysis set

The MI Procedure with MCMC
Missing data pattern

Parameter Code=C64849B Planned Treatment for Period 30 (N)=3

Obs	PARAM	Group	BASE_ Miss	visit1400_ Miss	visit1800_ Miss	visit2200_ Miss	visit2600_ Miss	visit3000_ Miss
10	HbA1c (%)	1	X	X	X	X	X	X
11	HbA1c (%)	2	X	X	X	X	X	X
12	HbA1c (%)	3	X	X	X	X	X	X
13	HbA1c (%)	4	X	X	X	X	X	.
14	HbA1c (%)	5	X	X	X	X	X	O
15	HbA1c (%)	6	X	X	X	X	.	X
16	HbA1c (%)	7	X	X	X	X	.	.
17	HbA1c (%)	8	X	X	X	X	O	O
18	HbA1c (%)	9	X	X	X	O	O	O
19	HbA1c (%)	10	X	X	.	X	X	X
20	HbA1c (%)	11	X	X	O	O	O	O
21	HbA1c (%)	12	X	.	X	X	X	X

Obs	visit3400_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit1400	visit1800
10	X	X	325	95.31	7.410154	-0.048923	-0.017538
11	.	X	3	0.88	6.700000	-0.100000	-0.166667
12	O	O	1	0.29	7.000000	-0.300000	-0.100000
13	X	X	2	0.59	7.350000	0.100000	-0.250000
14	O	O	1	0.29	8.000000	-0.600000	-0.600000
15	X	X	1	0.29	7.100000	0.100000	0.600000
16	.	X	1	0.29	8.100000	-0.400000	0.500000
17	O	O	3	0.88	7.500000	-0.100000	0.066667
18	O	O	1	0.29	7.400000	0.600000	0.900000
19	X	X	1	0.29	7.400000	0.100000	.
20	O	O	1	0.29	6.600000	0.200000	.
21	X	X	1	0.29	7.800000	.	-0.200000

Obs	visit2200	visit2600	visit3000	visit3400	visit3600
10	-0.039692	0.026462	0.024615	0.032308	-0.010462
11	-0.300000	0.033333	0.366667	.	0.100000
12	-0.200000	-0.400000	-0.300000	.	.
13	-0.200000	0	.	0.800000	0.650000
14	-0.800000	-0.700000	.	.	.
15	1.000000	.	1.500000	1.600000	1.200000
16	0.700000	.	.	.	1.300000
17	0.233333
18
19	0.100000	0.300000	0	0.100000	0.300000
20
21	-0.600000	-0.700000	-0.300000	-0.300000	-0.200000

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - conditional switch to NovoRapid - in-trial - full analysis set

The MI Procedure with MCMC
Missing data pattern

Parameter Code=C64849B Planned Treatment for Period 30 (N)=4

Obs	PARAM	Group	BASE_ Miss	visit1400_ Miss	visit1800_ Miss	visit2200_ Miss	visit2600_ Miss	visit3000_ Miss
22	HbA1c (%)	1	X	X	X	X	X	X
23	HbA1c (%)	2	X	X	X	X	X	X
24	HbA1c (%)	3	X	X	X	X	X	X
25	HbA1c (%)	4	X	X	X	X	X	.
26	HbA1c (%)	5	X	X	X	X	X	O
27	HbA1c (%)	6	X	X	X	X	.	X
28	HbA1c (%)	7	X	X	X	X	.	.
29	HbA1c (%)	8	X	X	X	X	O	O
30	HbA1c (%)	9	X	X	X	.	X	X
31	HbA1c (%)	10	X	X	.	X	X	X
32	HbA1c (%)	11	X	X	O	O	O	O
33	HbA1c (%)	12	X	.	X	X	X	X
34	HbA1c (%)	13	X	O	O	O	O	O

Obs	visit3400_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit1400	visit1800
22	X	X	328	95.91	7.405488	-0.064939	-0.049390
23	X	O	1	0.29	6.900000	0.100000	-0.100000
24	.	X	2	0.58	8.000000	-0.100000	0.350000
25	.	X	1	0.29	8.700000	0.500000	0.300000
26	O	O	1	0.29	7.800000	0.300000	0.400000
27	X	X	1	0.29	7.900000	0	-0.600000
28	X	X	1	0.29	7.300000	-1.000000	0.400000
29	O	O	2	0.58	7.400000	0.300000	0.600000
30	X	X	1	0.29	7.100000	-0.300000	-0.200000
31	X	X	1	0.29	7.200000	-0.700000	.
32	O	O	1	0.29	7.900000	0.200000	.
33	X	O	1	0.29	6.900000	.	1.100000
34	O	O	1	0.29	7.800000	.	.

Obs	visit2200	visit2600	visit3000	visit3400	visit3600
22	-0.067683	-0.034451	-0.078354	-0.068598	-0.107012
23	-0.400000	-0.200000	-0.100000	-0.100000	.
24	0.300000	0.350000	0.450000	.	0
25	-0.100000	-0.700000	.	.	0
26	0.300000	0.200000	.	.	.
27	0	.	-0.100000	0	0
28	0.200000	.	.	1.400000	1.400000
29	0.550000
30	.	0.700000	0.500000	0.100000	-0.200000
31	-0.700000	-0.700000	-0.800000	-0.800000	-0.800000
32
33	1.400000	1.500000	1.300000	1.100000	.
34

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - conditional switch to NovoRapid - in-trial - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=C64849B

Obs	_Imputation_	PARAM	Description	Value
1	1	HbA1c (%)	Data Set	WORK.MONOTONE
2	1	HbA1c (%)	Method	Monotone
3	1	HbA1c (%)	Number of Imputations	1
4	1	HbA1c (%)	Seed for random number generator	9916

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - conditional switch to NovoRapid - in-trial - full analysis set

The MI Procedure with Monotone Regression
 Regression Information

Parameter Code=C64849B Imputed Variable=visit1400

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	HbA1c (%)	Intercept	
2	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	HbA1c (%)	REGION1	EUROPE
4	1	HbA1c (%)	REGION1	JAPAN
5	1	HbA1c (%)	BOLAD1	
6	1	HbA1c (%)	BASE	

Obs		BOLAD1	ObsVal	_1
1			0.03994	0.057382
2			0.09159	0.035254
3			-0.03184	-0.022908
4			-0.07728	-0.000431
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.01729	-0.046658
6			-0.08171	-0.051299

Parameter Code=C64849B Imputed Variable=visit1800

Obs	_Imputation_	PARAM	Effect	REGION1
7	1	HbA1c (%)	Intercept	
8	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)
9	1	HbA1c (%)	REGION1	EUROPE
10	1	HbA1c (%)	REGION1	JAPAN
11	1	HbA1c (%)	BOLAD1	
12	1	HbA1c (%)	BASE	
13	1	HbA1c (%)	visit1400	

Obs		BOLAD1	ObsVal	_1
7			0.03577	0.081920
8			0.11116	0.243057
9			0.02702	0.028847
10			-0.15615	-0.193770
11	BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.00630	-0.028598
12			-0.20036	-0.225497
13			0.63603	0.570334

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - conditional switch to NovoRapid - in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=C64849B Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
14	1	HbA1c (%)	Intercept			0.02612	0.100165
15	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)		0.05449	0.003362
16	1	HbA1c (%)	REGION1	EUROPE		-0.00903	-0.047643
Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1		
17	1	HbA1c (%)	REGION1	JAPAN			
18	1	HbA1c (%)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
19	1	HbA1c (%)	BASE				
20	1	HbA1c (%)	visit1400				
21	1	HbA1c (%)	visit1800				
Obs	ObsVal		_1				
17	-0.06643		-0.083304				
18	-0.01797		0.046827				
19	-0.07877		-0.078757				
20	0.10712		0.081568				
21	0.74486		0.698621				

Parameter Code=C64849B Imputed Variable=visit2600

Obs	_Imputation_	PARAM	Effect	REGION1		
22	1	HbA1c (%)	Intercept			
23	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)		
24	1	HbA1c (%)	REGION1	EUROPE		
25	1	HbA1c (%)	REGION1	JAPAN		
26	1	HbA1c (%)	BOLAD1			
27	1	HbA1c (%)	BASE			
Obs		BOLAD1			ObsVal	_1
22					-0.03119	-0.027141
23					-0.13362	-0.243369
24					0.03882	0.112868
25					0.04539	0.079139
26		BOLUS INSULIN ALGORITHM (SLIDING SCALE)			-0.00340	0.005800
27					-0.07639	-0.054530

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - conditional switch to NovoRapid - in-trial - full analysis set

The MI Procedure with Monotone Regression
 Regression Information

Parameter Code=C64849B Imputed Variable=visit2600

(continued)

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
28	1	HbA1c (%)	visit1400			-0.12923	-0.157118
29	1	HbA1c (%)	visit1800			0.11083	0.199633
30	1	HbA1c (%)	visit2200			0.74537	0.651104

Parameter Code=C64849B Imputed Variable=visit3000

Obs	_Imputation_	PARAM	Effect	REGION1		ObsVal	_1
31	1	HbA1c (%)	Intercept				
32	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)			
33	1	HbA1c (%)	REGION1	EUROPE			
34	1	HbA1c (%)	REGION1	JAPAN			
35	1	HbA1c (%)	BOLAD1				
36	1	HbA1c (%)	BASE				
37	1	HbA1c (%)	visit1400				
38	1	HbA1c (%)	visit1800				
39	1	HbA1c (%)	visit2200				
40	1	HbA1c (%)	visit2600				

Obs		BOLAD1	ObsVal	_1
31			-0.03701	-0.008094
32			-0.03965	-0.013917
33			0.07697	-0.034258
34			-0.02231	-0.010218
35	BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.04676	-0.026328
36			-0.07158	-0.053572
37			-0.02721	-0.089395
38			-0.05758	0.063489
39			-0.07567	-0.093613
40			0.97366	0.962119

Parameter Code=C64849B Imputed Variable=visit3400

Obs	_Imputation_	PARAM	Effect	REGION1		ObsVal	_1
41	1	HbA1c (%)	Intercept				
42	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)			
43	1	HbA1c (%)	REGION1	EUROPE			
44	1	HbA1c (%)	REGION1	JAPAN			

Obs		BOLAD1	ObsVal	_1
41			-0.05036	-0.038369
42			-0.16944	-0.228908
43			0.12876	0.126671
44			0.02076	0.016768

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - conditional switch to NovoRapid - in-trial - full analysis set

The MI Procedure with Monotone Regression
 Regression Information

Parameter Code=C64849B Imputed Variable=visit3400

(continued)

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1
45	1	HbA1c (%)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)
46	1	HbA1c (%)	BASE		
47	1	HbA1c (%)	visit1400		
48	1	HbA1c (%)	visit1800		
49	1	HbA1c (%)	visit2200		
50	1	HbA1c (%)	visit2600		
51	1	HbA1c (%)	visit3000		

Obs	ObsVal	_1
45	-0.01665	-0.011251
46	-0.06808	-0.079915
47	-0.04273	-0.067548
48	0.11281	0.088094
49	0.06385	0.120575
50	-0.04970	-0.050205
51	0.74520	0.737310

Parameter Code=C64849B Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1
52	1	HbA1c (%)	Intercept	
53	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)
54	1	HbA1c (%)	REGION1	EUROPE
55	1	HbA1c (%)	REGION1	JAPAN
56	1	HbA1c (%)	BOLAD1	
57	1	HbA1c (%)	BASE	
58	1	HbA1c (%)	visit1400	
59	1	HbA1c (%)	visit1800	
60	1	HbA1c (%)	visit2200	
61	1	HbA1c (%)	visit2600	
62	1	HbA1c (%)	visit3000	

Obs	BOLAD1	ObsVal	_1
52		-0.01774	0.006269
53		-0.05954	0.051811
54		0.06811	0.026315
55		-0.00953	-0.114362
56	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.03438	-0.040403
57		-0.02206	-0.019933
58		-0.02770	0.050177
59		0.02125	-0.031111
60		0.10300	0.127861
61		-0.03550	-0.084923
62		-0.18521	-0.173005

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - conditional
switch to NovoRapid - in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=C64849B Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM	Effect	REGION1
63	1	HbA1c (%)	visit3400	
Obs		BOLAD1		ObsVal
63				1.00369
				1.055112

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - conditional switch to NovoRapid - in-trial - full analysis set

The MI Procedure with Monotone Regression
MNAR Information

Parameter Code=C64849B Imputed Variable=visit1400

Obs	_Imputation_	PARAM	Obs
1	1	HbA1c (%)	TRTPN = 4

Parameter Code=C64849B Imputed Variable=visit1800

Obs	_Imputation_	PARAM	Obs
2	1	HbA1c (%)	TRTPN = 4

Parameter Code=C64849B Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Obs
3	1	HbA1c (%)	TRTPN = 4

Parameter Code=C64849B Imputed Variable=visit2600

Obs	_Imputation_	PARAM	Obs
4	1	HbA1c (%)	TRTPN = 4

Parameter Code=C64849B Imputed Variable=visit3000

Obs	_Imputation_	PARAM	Obs
5	1	HbA1c (%)	TRTPN = 4

Parameter Code=C64849B Imputed Variable=visit3400

Obs	_Imputation_	PARAM	Obs
6	1	HbA1c (%)	TRTPN = 4

Parameter Code=C64849B Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Obs
7	1	HbA1c (%)	TRTPN = 4

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - conditional
switch to NovoRapid - in-trial - full analysis set

The Mixed procedure
Model Information

Parameter Code=C64849B Parameter=HbA1c (%)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Data Set	WORK.IMPUTE
2	1	NN1218-4131	Dependent Variable	eotVisit
3	1	NN1218-4131	Covariance Structure	Diagonal
4	1	NN1218-4131	Estimation Method	REML
5	1	NN1218-4131	Residual Variance Method	Profile
6	1	NN1218-4131	Fixed Effects SE Method	Model-Based
7	1	NN1218-4131	Degrees of Freedom Method	Residual

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - conditional switch to NovoRapid - in-trial - full analysis set

The Mixed procedure
 Class Level Information

Parameter Code=C64849B Parameter=HbA1c (%)

Obs	_Imputation_	STUDYID	Class	Levels
1	1	NN1218-4131	TRTPN	3
2	1	NN1218-4131	REGION1	4
3	1	NN1218-4131	BOLAD1	2

Obs Values

1	2	3	4
2	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA		
3	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULI		

min_
 Obs length

1	5
2	49
3	85

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - conditional
switch to NovoRapid - in-trial - full analysis set

The Mixed procedure
Dimensions

Parameter Code=C64849B Parameter=HbA1c (%)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Covariance Parameters	1
2	1	NN1218-4131	Columns in X	10
3	1	NN1218-4131	Columns in Z	0
4	1	NN1218-4131	Subjects	1
5	1	NN1218-4131	Max Obs per Subject	1025

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - conditional switch to NovoRapid - in-trial - full analysis set

The Mixed procedure
 Number of Observations

Parameter Code=C64849B Parameter=HbA1c (%)

O b s	I m p u t i o n s	S T U D Y I D	L a b e l	N	N O b s R e a d	N O b s U s e d	S u m F r e q s R e a d	S u m F r e q s U s e d
1	1	NN1218-4131	Number of Observations Read	1025	1025	1025	1025	1025
2	1	NN1218-4131	Number of Observations Used	1025	1025	1025	1025	1025
3	1	NN1218-4131	Number of Observations Not Used	0	1025	1025	1025	1025

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - conditional
switch to NovoRapid - in-trial - full analysis set

The Mixed procedure
Covariance Parameter Estimates

Parameter Code=C64849B Parameter=HbA1c (%)

Obs	_Imputation_	STUDYID	CovParm	Estimate
1	1	NN1218-4131	Residual	0.3687

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - conditional switch to NovoRapid - in-trial - full analysis set

The Mixed procedure
Fit Statistics

Parameter Code=C64849B Parameter=HbA1c (%)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	-2 Res Log Likelihood	1915.5
2	1	NN1218-4131	AIC (Smaller is Better)	1917.5
3	1	NN1218-4131	AICC (Smaller is Better)	1917.5
4	1	NN1218-4131	BIC (Smaller is Better)	1922.4

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - conditional switch to NovoRapid - in-trial - full analysis set

The Mixed procedure
 Solution for Fixed Effects

Parameter Code=C64849B Parameter=HbA1c (%)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1
1	1	NN1218-4131	TRTPN	2	
2	1	NN1218-4131	TRTPN	3	
3	1	NN1218-4131	TRTPN	4	
4	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)
5	1	NN1218-4131	REGION1	—	EUROPE
6	1	NN1218-4131	REGION1	—	JAPAN
7	1	NN1218-4131	REGION1	—	NORTH AMERICA
8	1	NN1218-4131	BOLAD1	—	
9	1	NN1218-4131	BOLAD1	—	
10	1	NN1218-4131	BASE	—	

Obs	BOLAD1	Estimate
1		2.1108
2		2.2287
3		2.1320
4		-0.1536
5		0.07617
6		-0.1165
7		0
8	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.01899
9	CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY	0
10		-0.2962

Obs	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	0.2115	1017	9.98	<.0001	0.05	1.6957	2.5259
2	0.2104	1017	10.59	<.0001	0.05	1.8158	2.6416
3	0.2106	1017	10.13	<.0001	0.05	1.7188	2.5451
4	0.06929	1017	-2.22	0.0269	0.05	-0.2895	-0.01758
5	0.04888	1017	1.56	0.1195	0.05	-0.01974	0.1721
6	0.05468	1017	-2.13	0.0333	0.05	-0.2238	-0.00923
7
8	0.04256	1017	-0.45	0.6556	0.05	-0.1025	0.06453
9
10	0.02743	1017	-10.80	<.0001	0.05	-0.3500	-0.2424

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - conditional switch to NovoRapid - in-trial - full analysis set

The Mixed procedure
 Least Squares Means

Obs	_Imputation_	PARAMCD	PARAM	STUDYID	Effect	TRTPN	Margins	
1	1	C64849B	HbA1c (%)	NN1218-4131	TRTPN	2	WORK.IMPUTE	
2	1	C64849B	HbA1c (%)	NN1218-4131	TRTPN	3	WORK.IMPUTE	
3	1	C64849B	HbA1c (%)	NN1218-4131	TRTPN	4	WORK.IMPUTE	
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	-0.1216	0.03289	1017	-3.70	0.0002	0.05	-0.1861	-0.05704
2	-0.00367	0.03292	1017	-0.11	0.9114	0.05	-0.06827	0.06094
3	-0.1004	0.03287	1017	-3.06	0.0023	0.05	-0.1649	-0.03592

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - conditional switch to NovoRapid - in-trial - full analysis set

The Mixed procedure
Least Squares Means Estimate

Parameter Code=C64849B Parameter=HbA1c (%)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
1	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
2	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	WORK.IMPUTE	-0.02116	0.04654	1017	-0.45	0.6495	0.05	-0.1125	0.07016
2	WORK.IMPUTE	0.09676	0.04654	1017	2.08	0.0379	0.05	0.005439	0.1881

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - conditional switch to NovoRapid - in-trial - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=C64849B Parameter=HbA1c (%)

The MIANALYZE Procedure

Model Information

Data Set WORK.MI_MEANS
 Number of Imputations 100

Variance Information

Parameter	Between	Within	Total	DF
Estimate	0.000010492	0.001078	0.001089	1.05E6

Variance Information

Parameter	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
Estimate	0.009826	0.009732	0.999903

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits	DF
Estimate	-0.119404	0.033001	-0.18409 -0.05472	1.05E6

Parameter Estimates

Parameter	Minimum	Maximum	Theta0	t for H0: Parameter=Theta0	Pr > t
Estimate	-0.127070	-0.110525	0	-3.62	0.0003

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - conditional switch to NovoRapid - in-trial - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=C64849B Parameter=HbA1c (%)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	100

Variance Information

Parameter	-----Variance-----			DF
	Between	Within	Total	
Estimate	0.000012874	0.001081	0.001094	700271

Variance Information

Parameter	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
Estimate	0.012033	0.011893	0.999881

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF
Estimate	-0.002276	0.033069	-0.06709	0.062539	700271

Parameter Estimates

Parameter	Minimum	Maximum	Theta0	t for H0: Parameter=Theta0	Pr > t
Estimate	-0.013839	0.006907	0	-0.07	0.9451

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - conditional switch to NovoRapid - in-trial - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=C64849B Parameter=HbA1c (%)

The MIANALYZE Procedure

Model Information

Data Set WORK.MI_MEANS
 Number of Imputations 100

Variance Information

Parameter	Between	Within	Total	DF
Estimate	0.000012698	0.001077	0.001090	715227

Variance Information

Parameter	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
Estimate	0.011905	0.011768	0.999882

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits	DF
Estimate	-0.096493	0.033016	-0.16120 -0.03178	715227

Parameter Estimates

Parameter	Minimum	Maximum	Theta0	t for H0: Parameter=Theta0	Pr > t
Estimate	-0.105056	-0.087824	0	-2.92	0.0035

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - conditional switch to NovoRapid - in-trial - full analysis set

Parameter Code=C64849B Label=Faster aspart (meal) - NovoRapid (meal) Parameter=HbA1c (%)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	100

Variance Information

Parameter	-----Variance-----			DF
	Between	Within	Total	
Estimate	0.000025266	0.002159	0.002185	725584

Variance Information

Parameter	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
Estimate	0.011819	0.011684	0.999883

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF
Estimate	-0.022911	0.046740	-0.11452	0.068698	725584

Parameter Estimates

Parameter	Minimum	Maximum	Theta0	t for H0: Parameter=Theta0	Pr > t
Estimate	-0.037445	-0.008417	0	-0.49	0.6240

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - conditional switch to NovoRapid - in-trial - full analysis set

Parameter Code=C64849B Label=Faster aspart (post) - NovoRapid (meal) Parameter=HbA1c (%)

The MIANALYZE Procedure

Model Information

Data Set WORK.MI_ESTIMATE
 Number of Imputations 100

Variance Information

Parameter	Between	Within	Total	DF
Estimate	0.000024634	0.002159	0.002184	762776

Variance Information

Parameter	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
Estimate	0.011524	0.011395	0.999886

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits	DF
Estimate	0.094217	0.046733	0.002623 0.185811	762776

Parameter Estimates

Parameter	Minimum	Maximum	Theta0	t for H0: Parameter=Theta0	Pr > t
Estimate	0.081219	0.106035	0	2.02	0.0438

5: HbA1c 26 weeks after randomisation - statistical sensitivity analysis - unconditional switch to NovoRapid - in-trial - full analysis set

The MI Procedure with MCMC
 Model Information

Parameter Code=C64849B Planned Treatment for Period 30 (N)=2

Obs	PARAM	Description	Value
1	HbA1c (%)	Data Set	WORK.ENDPOINT_PARAM
2	HbA1c (%)	Method	Monotone-data_MCMC
3	HbA1c (%)	Multiple Imputation Chain	Multiple Chains
4	HbA1c (%)	Initial Estimates for MCMC	EM Posterior Mode
5	HbA1c (%)	Start	Starting Value
6	HbA1c (%)	Prior	Jeffreys
7	HbA1c (%)	Number of Imputations	100
8	HbA1c (%)	Number of Burn-in Iterations	200
9	HbA1c (%)	Seed for random number generator	6968

Parameter Code=C64849B Planned Treatment for Period 30 (N)=3

Obs	PARAM	Description	Value
10	HbA1c (%)	Data Set	WORK.ENDPOINT_PARAM
11	HbA1c (%)	Method	Monotone-data_MCMC
12	HbA1c (%)	Multiple Imputation Chain	Multiple Chains
13	HbA1c (%)	Initial Estimates for MCMC	EM Posterior Mode
14	HbA1c (%)	Start	Starting Value
15	HbA1c (%)	Prior	Jeffreys
16	HbA1c (%)	Number of Imputations	100
17	HbA1c (%)	Number of Burn-in Iterations	200
18	HbA1c (%)	Seed for random number generator	1623357457

Parameter Code=C64849B Planned Treatment for Period 30 (N)=4

Obs	PARAM	Description	Value
19	HbA1c (%)	Data Set	WORK.ENDPOINT_PARAM
20	HbA1c (%)	Method	Monotone-data_MCMC
21	HbA1c (%)	Multiple Imputation Chain	Multiple Chains
22	HbA1c (%)	Initial Estimates for MCMC	EM Posterior Mode
23	HbA1c (%)	Start	Starting Value
24	HbA1c (%)	Prior	Jeffreys
25	HbA1c (%)	Number of Imputations	100
26	HbA1c (%)	Number of Burn-in Iterations	200
27	HbA1c (%)	Seed for random number generator	1068829301

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - unconditional switch to NovoRapid - in-trial - full analysis set

The MI Procedure with MCMC
 Missing data pattern

Parameter Code=C64849B Planned Treatment for Period 30 (N)=2

Obs	PARAM	Group	BASE_ Miss	visit1400_ Miss	visit1800_ Miss	visit2200_ Miss	visit2600_ Miss	visit3000_ Miss
1	HbA1c (%)	1	X	X	X	X	X	X
2	HbA1c (%)	2	X	X	X	X	X	X
3	HbA1c (%)	3	X	X	X	X	X	X
4	HbA1c (%)	4	X	X	X	X	X	.
5	HbA1c (%)	5	X	X	X	O	O	O
6	HbA1c (%)	6	X	X	.	X	X	X
7	HbA1c (%)	7	X	X	.	.	X	X
8	HbA1c (%)	8	X	X	O	O	O	O
9	HbA1c (%)	9	X	.	X	X	X	.

Obs	visit3400_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit1400	visit1800
1	X	X	330	96.49	7.454242	-0.106970	-0.133636
2	X	O	1	0.29	6.700000	0.100000	-0.300000
3	.	X	3	0.88	7.666667	-0.133333	-0.133333
4	X	X	1	0.29	7.300000	-1.000000	-1.700000
5	O	O	1	0.29	7.300000	0	-0.200000
6	X	X	2	0.58	8.000000	-0.250000	.
7	X	X	1	0.29	7.800000	0	.
8	O	O	2	0.58	7.750000	0.200000	.
9	.	X	1	0.29	6.300000	.	0.100000

Obs	visit2200	visit2600	visit3000	visit3400	visit3600
1	-0.172424	-0.114848	-0.129091	-0.097576	-0.124242
2	-0.400000	0	0	0.200000	.
3	-0.300000	-0.333333	-0.500000	.	0.266667
4	-1.800000	-2.500000	.	-1.500000	-1.200000
5
6	0.100000	0.050000	-0.350000	0	0.150000
7	.	0	-0.200000	-0.700000	-0.700000
8
9	0	-0.100000	.	.	-0.100000

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - unconditional switch to NovoRapid - in-trial - full analysis set

The MI Procedure with MCMC
 Missing data pattern

Parameter Code=C64849B Planned Treatment for Period 30 (N)=3

Obs	PARAM	Group	BASE_ Miss	visit1400_ Miss	visit1800_ Miss	visit2200_ Miss	visit2600_ Miss	visit3000_ Miss
10	HbA1c (%)	1	X	X	X	X	X	X
11	HbA1c (%)	2	X	X	X	X	X	X
12	HbA1c (%)	3	X	X	X	X	X	X
13	HbA1c (%)	4	X	X	X	X	X	.
14	HbA1c (%)	5	X	X	X	X	X	O
15	HbA1c (%)	6	X	X	X	X	.	X
16	HbA1c (%)	7	X	X	X	X	.	.
17	HbA1c (%)	8	X	X	X	X	O	O
18	HbA1c (%)	9	X	X	X	O	O	O
19	HbA1c (%)	10	X	X	.	X	X	X
20	HbA1c (%)	11	X	X	O	O	O	O
21	HbA1c (%)	12	X	.	X	X	X	X

Obs	visit3400_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit1400	visit1800
10	X	X	325	95.31	7.410154	-0.048923	-0.017538
11	.	X	3	0.88	6.700000	-0.100000	-0.166667
12	O	O	1	0.29	7.000000	-0.300000	-0.100000
13	X	X	2	0.59	7.350000	0.100000	-0.250000
14	O	O	1	0.29	8.000000	-0.600000	-0.600000
15	X	X	1	0.29	7.100000	0.100000	0.600000
16	.	X	1	0.29	8.100000	-0.400000	0.500000
17	O	O	3	0.88	7.500000	-0.100000	0.066667
18	O	O	1	0.29	7.400000	0.600000	0.900000
19	X	X	1	0.29	7.400000	0.100000	.
20	O	O	1	0.29	6.600000	0.200000	.
21	X	X	1	0.29	7.800000	.	-0.200000

Obs	visit2200	visit2600	visit3000	visit3400	visit3600
10	-0.039692	0.026462	0.024615	0.032308	-0.010462
11	-0.300000	0.033333	0.366667	.	0.100000
12	-0.200000	-0.400000	-0.300000	.	.
13	-0.200000	0	.	0.800000	0.650000
14	-0.800000	-0.700000	.	.	.
15	1.000000	.	1.500000	1.600000	1.200000
16	0.700000	.	.	.	1.300000
17	0.233333
18
19	0.100000	0.300000	0	0.100000	0.300000
20
21	-0.600000	-0.700000	-0.300000	-0.300000	-0.200000

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - unconditional switch to NovoRapid - in-trial - full analysis set

The MI Procedure with MCMC
Missing data pattern

Parameter Code=C64849B Planned Treatment for Period 30 (N)=4

Obs	PARAM	Group	BASE_ Miss	visit1400_ Miss	visit1800_ Miss	visit2200_ Miss	visit2600_ Miss	visit3000_ Miss
22	HbA1c (%)	1	X	X	X	X	X	X
23	HbA1c (%)	2	X	X	X	X	X	X
24	HbA1c (%)	3	X	X	X	X	X	X
25	HbA1c (%)	4	X	X	X	X	X	.
26	HbA1c (%)	5	X	X	X	X	X	O
27	HbA1c (%)	6	X	X	X	X	.	X
28	HbA1c (%)	7	X	X	X	X	.	.
29	HbA1c (%)	8	X	X	X	X	O	O
30	HbA1c (%)	9	X	X	X	.	X	X
31	HbA1c (%)	10	X	X	.	X	X	X
32	HbA1c (%)	11	X	X	O	O	O	O
33	HbA1c (%)	12	X	.	X	X	X	X
34	HbA1c (%)	13	X	O	O	O	O	O

Obs	visit3400_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit1400	visit1800
22	X	X	328	95.91	7.405488	-0.064939	-0.049390
23	X	O	1	0.29	6.900000	0.100000	-0.100000
24	.	X	2	0.58	8.000000	-0.100000	0.350000
25	.	X	1	0.29	8.700000	0.500000	0.300000
26	O	O	1	0.29	7.800000	0.300000	0.400000
27	X	X	1	0.29	7.900000	0	-0.600000
28	X	X	1	0.29	7.300000	-1.000000	0.400000
29	O	O	2	0.58	7.400000	0.300000	0.600000
30	X	X	1	0.29	7.100000	-0.300000	-0.200000
31	X	X	1	0.29	7.200000	-0.700000	.
32	O	O	1	0.29	7.900000	0.200000	.
33	X	O	1	0.29	6.900000	.	1.100000
34	O	O	1	0.29	7.800000	.	.

Obs	visit2200	visit2600	visit3000	visit3400	visit3600
22	-0.067683	-0.034451	-0.078354	-0.068598	-0.107012
23	-0.400000	-0.200000	-0.100000	-0.100000	.
24	0.300000	0.350000	0.450000	.	0
25	-0.100000	-0.700000	.	.	0
26	0.300000	0.200000	.	.	.
27	0	.	-0.100000	0	0
28	0.200000	.	.	1.400000	1.400000
29	0.550000
30	.	0.700000	0.500000	0.100000	-0.200000
31	-0.700000	-0.700000	-0.800000	-0.800000	-0.800000
32
33	1.400000	1.500000	1.300000	1.100000	.
34

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - unconditional
switch to NovoRapid - in-trial - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=C64849B

Obs	_Imputation_	PARAM	Description	Value
1	1	HbA1c (%)	Data Set	WORK.MONOTONE_J2R
2	1	HbA1c (%)	Method	Monotone
3	1	HbA1c (%)	Number of Imputations	1
4	1	HbA1c (%)	Seed for random number generator	10055

```
nn1218/nn1218-4131/ctr_20180214_er
13FEB2018:22:02:35 - s stat diff.sas/s hba sens4 stat in_fas app.txt
```

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - unconditional switch to NovoRapid - in-trial - full analysis set

The MI Procedure with Monotone Regression
 Regression Information

Parameter Code=C64849B Imputed Variable=visit1400

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	HbA1c (%)	Intercept	
2	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	HbA1c (%)	REGION1	EUROPE
4	1	HbA1c (%)	REGION1	JAPAN
5	1	HbA1c (%)	BOLAD1	
6	1	HbA1c (%)	BASE	

Obs		BOLAD1	ObsVal	_1
1			0.04132	0.039411
2			0.09145	0.162970
3			-0.03245	-0.016886
4			-0.07772	-0.148542
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.01774	-0.103651
6			-0.08199	-0.108908

Parameter Code=C64849B Imputed Variable=visit1800

Obs	_Imputation_	PARAM	Effect	REGION1
7	1	HbA1c (%)	Intercept	
8	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)
9	1	HbA1c (%)	REGION1	EUROPE
10	1	HbA1c (%)	REGION1	JAPAN
11	1	HbA1c (%)	BOLAD1	
12	1	HbA1c (%)	BASE	
13	1	HbA1c (%)	visit1400	

Obs		BOLAD1	ObsVal	_1
7			0.03685	0.095144
8			0.11417	0.214242
9			0.02234	0.066051
10			-0.15364	-0.273960
11	BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.00831	0.015718
12			-0.19992	-0.181043
13			0.64369	0.611560

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - unconditional switch to NovoRapid - in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=C64849B Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
14	1	HbA1c (%)	Intercept			0.02444	0.020277
15	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)		0.05408	0.028389
16	1	HbA1c (%)	REGION1	EUROPE		-0.00441	0.063482
Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1		
17	1	HbA1c (%)	REGION1	JAPAN			
18	1	HbA1c (%)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
19	1	HbA1c (%)	BASE				
20	1	HbA1c (%)	visit1400				
21	1	HbA1c (%)	visit1800				
Obs	ObsVal		_1				
17	-0.06765		-0.086176				
18	-0.01756		-0.001035				
19	-0.07933		-0.109298				
20	0.10698		0.177861				
21	0.74030		0.699556				

Parameter Code=C64849B Imputed Variable=visit2600

Obs	_Imputation_	PARAM	Effect	REGION1		
22	1	HbA1c (%)	Intercept			
23	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)		
24	1	HbA1c (%)	REGION1	EUROPE		
25	1	HbA1c (%)	REGION1	JAPAN		
26	1	HbA1c (%)	BOLAD1			
27	1	HbA1c (%)	BASE			
Obs		BOLAD1			ObsVal	_1
22					-0.03197	-0.074845
23					-0.11499	-0.119902
24					0.02543	0.024580
25					0.04191	0.086314
26		BOLUS INSULIN ALGORITHM (SLIDING SCALE)			-0.00671	-0.039381
27					-0.07946	-0.074002

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - unconditional switch to NovoRapid - in-trial - full analysis set

The MI Procedure with Monotone Regression
 Regression Information

Parameter Code=C64849B Imputed Variable=visit2600

(continued)

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
28	1	HbA1c (%)	visit1400			-0.10289	-0.090910
29	1	HbA1c (%)	visit1800			0.08710	0.052479
30	1	HbA1c (%)	visit2200			0.74555	0.765483

Parameter Code=C64849B Imputed Variable=visit3000

Obs	_Imputation_	PARAM	Effect	REGION1		ObsVal	_1
31	1	HbA1c (%)	Intercept				
32	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)			
33	1	HbA1c (%)	REGION1	EUROPE			
34	1	HbA1c (%)	REGION1	JAPAN			
35	1	HbA1c (%)	BOLAD1				
36	1	HbA1c (%)	BASE				
37	1	HbA1c (%)	visit1400				
38	1	HbA1c (%)	visit1800				
39	1	HbA1c (%)	visit2200				
40	1	HbA1c (%)	visit2600				

Obs		BOLAD1	ObsVal	_1
31			-0.03600	-0.009638
32			-0.05353	-0.005248
33			0.08399	0.115587
34			-0.01778	-0.003379
35	BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.04631	-0.066320
36			-0.07152	-0.048632
37			-0.04124	-0.034224
38			-0.03949	-0.054021
39			-0.07532	-0.043999
40			0.96592	0.965913

Parameter Code=C64849B Imputed Variable=visit3400

Obs	_Imputation_	PARAM	Effect	REGION1		ObsVal	_1
41	1	HbA1c (%)	Intercept				
42	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)			
43	1	HbA1c (%)	REGION1	EUROPE			
44	1	HbA1c (%)	REGION1	JAPAN			

Obs		BOLAD1	ObsVal	_1
41			-0.05100	-0.032574
42			-0.17716	-0.165259
43			0.13069	0.103564
44			0.01808	0.029698

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - unconditional switch to NovoRapid - in-trial - full analysis set

The MI Procedure with Monotone Regression
 Regression Information

Parameter Code=C64849B Imputed Variable=visit3400

(continued)

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1
45	1	HbA1c (%)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)
46	1	HbA1c (%)	BASE		
47	1	HbA1c (%)	visit1400		
48	1	HbA1c (%)	visit1800		
49	1	HbA1c (%)	visit2200		
50	1	HbA1c (%)	visit2600		
51	1	HbA1c (%)	visit3000		

Obs	ObsVal	_1
45	-0.01176	0.027869
46	-0.06360	-0.061387
47	-0.05551	-0.037168
48	0.12313	0.092609
49	0.06439	0.033212
50	-0.04986	-0.027325
51	0.74658	0.781301

Parameter Code=C64849B Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1
52	1	HbA1c (%)	Intercept	
53	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)
54	1	HbA1c (%)	REGION1	EUROPE
55	1	HbA1c (%)	REGION1	JAPAN
56	1	HbA1c (%)	BOLAD1	
57	1	HbA1c (%)	BASE	
58	1	HbA1c (%)	visit1400	
59	1	HbA1c (%)	visit1800	
60	1	HbA1c (%)	visit2200	
61	1	HbA1c (%)	visit2600	
62	1	HbA1c (%)	visit3000	

Obs	BOLAD1	ObsVal	_1
52		-0.01743	-0.001133
53		-0.05386	-0.001031
54		0.06857	0.030370
55		-0.00823	-0.000466
56	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.03709	-0.036586
57		-0.02545	-0.004433
58		-0.02212	-0.029537
59		0.01587	0.088919
60		0.10370	0.065081
61		-0.03563	-0.096593
62		-0.19168	-0.186509

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - unconditional
switch to NovoRapid - in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=C64849B Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM	Effect	REGION1		
63	1	HbA1c (%)	visit3400			
Obs		BOLAD1		ObsVal		_1
63				1.00843		1.070473

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - unconditional switch to NovoRapid - in-trial - full analysis set

The MI Procedure with Monotone Regression
MNAR Information

Parameter Code=C64849B Imputed Variable=visit1400

Obs	_Imputation_	PARAM	Obs
1	1	HbA1c (%)	TRTPN = 4

Parameter Code=C64849B Imputed Variable=visit1800

Obs	_Imputation_	PARAM	Obs
2	1	HbA1c (%)	TRTPN = 4

Parameter Code=C64849B Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Obs
3	1	HbA1c (%)	TRTPN = 4

Parameter Code=C64849B Imputed Variable=visit2600

Obs	_Imputation_	PARAM	Obs
4	1	HbA1c (%)	TRTPN = 4

Parameter Code=C64849B Imputed Variable=visit3000

Obs	_Imputation_	PARAM	Obs
5	1	HbA1c (%)	TRTPN = 4

Parameter Code=C64849B Imputed Variable=visit3400

Obs	_Imputation_	PARAM	Obs
6	1	HbA1c (%)	TRTPN = 4

Parameter Code=C64849B Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Obs
7	1	HbA1c (%)	TRTPN = 4

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - unconditional
switch to NovoRapid - in-trial - full analysis set

The Mixed procedure
Model Information

Parameter Code=C64849B Parameter=HbA1c (%)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Data Set	WORK.IMPUTE
2	1	NN1218-4131	Dependent Variable	eotVisit
3	1	NN1218-4131	Covariance Structure	Diagonal
4	1	NN1218-4131	Estimation Method	REML
5	1	NN1218-4131	Residual Variance Method	Profile
6	1	NN1218-4131	Fixed Effects SE Method	Model-Based
7	1	NN1218-4131	Degrees of Freedom Method	Residual

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - unconditional switch to NovoRapid - in-trial - full analysis set

The Mixed procedure
 Class Level Information

Parameter Code=C64849B Parameter=HbA1c (%)

Obs	_Imputation_	STUDYID	Class	Levels
1	1	NN1218-4131	TRTPN	3
2	1	NN1218-4131	REGION1	4
3	1	NN1218-4131	BOLAD1	2

Obs Values

1	2	3	4
2	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA		
3	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULI		

min_
 Obs legth

1	5
2	49
3	85

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - unconditional
switch to NovoRapid - in-trial - full analysis set

The Mixed procedure
Dimensions

Parameter Code=C64849B Parameter=HbA1c (%)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Covariance Parameters	1
2	1	NN1218-4131	Columns in X	10
3	1	NN1218-4131	Columns in Z	0
4	1	NN1218-4131	Subjects	1
5	1	NN1218-4131	Max Obs per Subject	1025

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - unconditional switch to NovoRapid - in-trial - full analysis set

The Mixed procedure
 Number of Observations

Parameter Code=C64849B Parameter=HbA1c (%)

O b s	I m p u t a t i o n s	S T U D Y I D	L a b e l	N	N O b s R e a d	N O b s U s e d	S u m F r e q s R e a d	S u m F r e q s U s e d
1	1	NN1218-4131	Number of Observations Read	1025	1025	1025	1025	1025
2	1	NN1218-4131	Number of Observations Used	1025	1025	1025	1025	1025
3	1	NN1218-4131	Number of Observations Not Used	0	1025	1025	1025	1025

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - unconditional
switch to NovoRapid - in-trial - full analysis set

The Mixed procedure
Covariance Parameter Estimates

Parameter Code=C64849B Parameter=HbA1c (%)

Obs	_Imputation_	STUDYID	CovParm	Estimate
1	1	NN1218-4131	Residual	0.3676

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - unconditional
switch to NovoRapid - in-trial - full analysis set

The Mixed procedure
Fit Statistics

Parameter Code=C64849B Parameter=HbA1c (%)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	-2 Res Log Likelihood	1912.4
2	1	NN1218-4131	AIC (Smaller is Better)	1914.4
3	1	NN1218-4131	AICC (Smaller is Better)	1914.4
4	1	NN1218-4131	BIC (Smaller is Better)	1919.3

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - unconditional switch to NovoRapid - in-trial - full analysis set

The Mixed procedure
 Solution for Fixed Effects

Parameter Code=C64849B Parameter=HbA1c (%)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1
1	1	NN1218-4131	TRTPN	2	
2	1	NN1218-4131	TRTPN	3	
3	1	NN1218-4131	TRTPN	4	
4	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)
5	1	NN1218-4131	REGION1	—	EUROPE
6	1	NN1218-4131	REGION1	—	JAPAN
7	1	NN1218-4131	REGION1	—	NORTH AMERICA
8	1	NN1218-4131	BOLAD1	—	
9	1	NN1218-4131	BOLAD1	—	
10	1	NN1218-4131	BASE	—	

Obs	BOLAD1	Estimate
1		2.0749
2		2.1870
3		2.0979
4		-0.1372
5		0.09154
6		-0.1147
7		0
8	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.00596
9	CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY	0
10		-0.2930

Obs	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	0.2112	1017	9.82	<.0001	0.05	1.6605	2.4894
2	0.2101	1017	10.41	<.0001	0.05	1.7747	2.5993
3	0.2102	1017	9.98	<.0001	0.05	1.6853	2.5104
4	0.06918	1017	-1.98	0.0477	0.05	-0.2729	-0.00141
5	0.04880	1017	1.88	0.0610	0.05	-0.00422	0.1873
6	0.05460	1017	-2.10	0.0359	0.05	-0.2219	-0.00758
7
8	0.04249	1017	-0.14	0.8885	0.05	-0.08934	0.07743
9
10	0.02739	1017	-10.70	<.0001	0.05	-0.3467	-0.2393

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - unconditional
 switch to NovoRapid - in-trial - full analysis set

The Mixed procedure
 Least Squares Means

Obs	_Imputation_	PARAMCD	PARAM	STUDYID	Effect	TRTPN	Margins	
1	1	C64849B	HbA1c (%)	NN1218-4131	TRTPN	2	WORK.IMPUTE	
2	1	C64849B	HbA1c (%)	NN1218-4131	TRTPN	3	WORK.IMPUTE	
3	1	C64849B	HbA1c (%)	NN1218-4131	TRTPN	4	WORK.IMPUTE	
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	-0.1185	0.03284	1017	-3.61	0.0003	0.05	-0.1829	-0.05402
2	-0.00641	0.03287	1017	-0.20	0.8454	0.05	-0.07091	0.05809
3	-0.09555	0.03282	1017	-2.91	0.0037	0.05	-0.1600	-0.03115

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - unconditional switch to NovoRapid - in-trial - full analysis set

The Mixed procedure
 Least Squares Means Estimate

Parameter Code=C64849B Parameter=HbA1c (%)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
1	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
2	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	WORK.IMPUTE	-0.02291	0.04646	1017	-0.49	0.6221	0.05	-0.1141	0.06827
2	WORK.IMPUTE	0.08914	0.04646	1017	1.92	0.0553	0.05	-0.00204	0.1803

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - unconditional switch to NovoRapid - in-trial - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=C64849B Parameter=HbA1c (%)

The MIANALYZE Procedure

Model Information

Data Set WORK.MI_MEANS
 Number of Imputations 100

Variance Information

Parameter	Between	Within	Total	DF
Estimate	0.000013422	0.001081	0.001094	645303

Variance Information

Parameter	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
Estimate	0.012541	0.012389	0.999876

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits	DF
Estimate	-0.120198	0.033083	-0.18504 -0.05536	645303

Parameter Estimates

Parameter	Minimum	Maximum	Theta0	t for H0: Parameter=Theta0	Pr > t
Estimate	-0.129961	-0.110724	0	-3.63	0.0003

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - unconditional switch to NovoRapid - in-trial - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=C64849B Parameter=HbA1c (%)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	100

Variance Information

Parameter	-----Variance-----			DF
	Between	Within	Total	
Estimate	0.000021469	0.001083	0.001105	256958

Variance Information

Parameter	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
Estimate	0.020021	0.019636	0.999804

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF
Estimate	-0.005319	0.033237	-0.07046	0.059825	256958

Parameter Estimates

Parameter	Minimum	Maximum	Theta0	t for H0: Parameter=Theta0	Pr > t
Estimate	-0.017816	0.006926	0	-0.16	0.8729

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - unconditional switch to NovoRapid - in-trial - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=C64849B Parameter=HbA1c (%)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	100

Variance Information

Parameter	-----Variance-----			
	Between	Within	Total	DF
Estimate	0.000011709	0.001080	0.001092	843338

Variance Information

Parameter	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
Estimate	0.010953	0.010837	0.999892

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF
Estimate	-0.097093	0.033038	-0.16185	-0.03234	843338

Parameter Estimates

Parameter	Minimum	Maximum	Theta0	t for H0: Parameter=Theta0	Pr > t
Estimate	-0.104884	-0.088529	0	-2.94	0.0033

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - unconditional switch to NovoRapid - in-trial - full analysis set

Parameter Code=C64849B Label=Faster aspart (meal) - NovoRapid (meal) Parameter=HbA1c (%)

The MIANALYZE Procedure

Model Information

Data Set WORK.MI_ESTIMATE
 Number of Imputations 100

Variance Information

Parameter	Between	Within	Total	DF
Estimate	0.000020228	0.002164	0.002184	1.13E6

Variance Information

Parameter	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
Estimate	0.009441	0.009354	0.999906

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits	DF
Estimate	-0.023105	0.046738	-0.11471 0.068500	1.13E6

Parameter Estimates

Parameter	Minimum	Maximum	Theta0	t for H0: Parameter=Theta0	Pr > t
Estimate	-0.032632	-0.011362	0	-0.49	0.6211

HbA1c 26 weeks after randomisation - statistical sensitivity analysis - unconditional switch to NovoRapid - in-trial - full analysis set

Parameter Code=C64849B Label=Faster aspart (post) - NovoRapid (meal) Parameter=HbA1c (%)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	100

Variance Information

Parameter	-----Variance-----			DF
	Between	Within	Total	
Estimate	0.000032440	0.002164	0.002197	445027

Variance Information

Parameter	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
Estimate	0.015141	0.014919	0.999851

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits	DF
Estimate	0.091773	0.046869	-0.00009 0.183636	445027

Parameter Estimates

Parameter	Minimum	Maximum	Theta0	t for H0: Parameter=Theta0	Pr > t
Estimate	0.080245	0.105518	0	1.96	0.0502

6: HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=C64849B Planned Treatment for Period 30 (N)=2

Obs	PARAM	Description	Value
1	HbA1c (%)	Data Set	WORK.ENDPOINT_PARAM
2	HbA1c (%)	Method	Monotone-data_MCMC
3	HbA1c (%)	Multiple Imputation Chain	Multiple Chains
4	HbA1c (%)	Initial Estimates for MCMC	EM Posterior Mode
5	HbA1c (%)	Start	Starting Value
6	HbA1c (%)	Prior	Jeffreys
7	HbA1c (%)	Number of Imputations	100
8	HbA1c (%)	Number of Burn-in Iterations	200
9	HbA1c (%)	Seed for random number generator	76122

Parameter Code=C64849B Planned Treatment for Period 30 (N)=3

Obs	PARAM	Description	Value
10	HbA1c (%)	Data Set	WORK.ENDPOINT_PARAM
11	HbA1c (%)	Method	Monotone-data_MCMC
12	HbA1c (%)	Multiple Imputation Chain	Multiple Chains
13	HbA1c (%)	Initial Estimates for MCMC	EM Posterior Mode
14	HbA1c (%)	Start	Starting Value
15	HbA1c (%)	Prior	Jeffreys
16	HbA1c (%)	Number of Imputations	100
17	HbA1c (%)	Number of Burn-in Iterations	200
18	HbA1c (%)	Seed for random number generator	695346756

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The MI Procedure with MCMC
Model Information

Parameter Code=C64849B Planned Treatment for Period 30 (N)=4

Obs	PARAM	Description	Value
19	HbA1c (%)	Data Set	WORK.ENDPOINT_PARAM
20	HbA1c (%)	Method	Monotone-data_MCMC
21	HbA1c (%)	Multiple Imputation Chain	Multiple Chains
22	HbA1c (%)	Initial Estimates for MCMC	EM Posterior Mode
23	HbA1c (%)	Start	Starting Value
24	HbA1c (%)	Prior	Jeffreys
25	HbA1c (%)	Number of Imputations	100
26	HbA1c (%)	Number of Burn-in Iterations	200
27	HbA1c (%)	Seed for random number generator	614808148

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The MI Procedure with MCMC
Missing data pattern

Parameter Code=C64849B Planned Treatment for Period 30 (N)=2

Obs	PARAM	Group	BASE_ Miss	visit1400_ Miss	visit1800_ Miss	visit2200_ Miss	visit2600_ Miss	visit3000_ Miss	visit3400_ Miss	visit3600_ Miss	Freq	Percent
1	HbA1c (%)	1	X	X	X	X	X	X	X	X	328	95.91
2	HbA1c (%)	2	X	X	X	X	X	X	X	O	2	0.58
3	HbA1c (%)	3	X	X	X	X	X	X	.	X	3	0.88
4	HbA1c (%)	4	X	X	X	X	X	O	O	O	1	0.29
5	HbA1c (%)	5	X	X	X	O	O	O	O	O	2	0.58
6	HbA1c (%)	6	X	X	.	X	X	X	X	X	2	0.58
7	HbA1c (%)	7	X	X	.	.	X	X	X	X	1	0.29
8	HbA1c (%)	8	X	X	O	O	O	O	O	O	2	0.58
9	HbA1c (%)	9	X	.	X	X	X	.	.	X	1	0.29

Obs	BASE	visit1400	visit1800	visit2200	visit2600	visit3000	visit3400	visit3600
1	7.446951	-0.105183	-0.132012	-0.170427	-0.112500	-0.127744	-0.096951	-0.123476
2	7.850000	-0.200000	-0.250000	-0.350000	-0.200000	-0.300000	-0.400000	.
3	7.666667	-0.133333	-0.133333	-0.300000	-0.333333	-0.500000	.	0.266667
4	7.300000	-1.000000	-1.700000	-1.800000	-2.500000	.	.	.
5	7.800000	-0.150000	-0.400000
6	8.000000	-0.250000	.	0.100000	0.050000	-0.350000	0	0.150000
7	7.800000	0	.	.	0	-0.200000	-0.700000	-0.700000
8	7.750000	0.200000
9	6.300000	.	0.100000	0	-0.100000	.	.	-0.100000

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The MI Procedure with MCMC
Missing data pattern

Parameter Code=C64849B Planned Treatment for Period 30 (N)=3

Obs	PARAM	Group	BASE_ Miss	visit1400_ Miss	visit1800_ Miss	visit2200_ Miss	visit2600_ Miss	visit3000_ Miss	visit3400_ Miss	visit3600_ Miss	Freq	Percent
10	HbA1c (%)	1	X	X	X	X	X	X	X	X	323	94.72
11	HbA1c (%)	2	X	X	X	X	X	X	.	X	3	0.88
12	HbA1c (%)	3	X	X	X	X	X	X	O	O	2	0.59
13	HbA1c (%)	4	X	X	X	X	X	.	X	X	2	0.59
14	HbA1c (%)	5	X	X	X	X	X	O	O	O	1	0.29
15	HbA1c (%)	6	X	X	X	X	.	X	X	X	1	0.29
16	HbA1c (%)	7	X	X	X	X	.	.	.	X	1	0.29
17	HbA1c (%)	8	X	X	X	X	O	O	O	O	3	0.88
18	HbA1c (%)	9	X	X	X	O	O	O	O	O	1	0.29
19	HbA1c (%)	10	X	X	.	X	X	X	X	X	1	0.29
20	HbA1c (%)	11	X	X	O	O	O	O	O	O	1	0.29

Obs	BASE	visit1400	visit1800	visit2200	visit2600	visit3000	visit3400	visit3600
10	7.414861	-0.052012	-0.020433	-0.044272	0.021362	0.021053	0.029721	-0.013003
11	6.700000	-0.100000	-0.166667	-0.300000	0.033333	0.366667	.	0.100000
12	6.700000	0.100000	0.100000	0	0.050000	0	.	.
13	7.350000	0.100000	-0.250000	-0.200000	0	.	0.800000	0.650000
14	8.000000	-0.600000	-0.600000	-0.800000	-0.700000	.	.	.
15	7.100000	0.100000	0.600000	1.000000	.	1.500000	1.600000	1.200000
16	8.100000	-0.400000	0.500000	0.700000	.	.	.	1.300000
17	7.500000	-0.100000	0.066667	0.233333
18	7.400000	0.600000	0.900000
19	7.400000	0.100000	.	0.100000	0.300000	0	0.100000	0.300000
20	6.600000	0.200000

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The MI Procedure with MCMC
Missing data pattern

Parameter Code=C64849B Planned Treatment for Period 30 (N)=3

(continued)

Obs	PARAM	Group	BASE_ Miss	visit1400_ Miss	visit1800_ Miss	visit2200_ Miss	visit2600_ Miss	visit3000_ Miss	visit3400_ Miss	visit3600_ Miss	Freq	Percent
21	HbA1c (%)	12	X	.	X	X	X	X	X	X	1	0.29
22	HbA1c (%)	13	X	O	O	O	O	O	O	O	1	0.29

Obs	BASE	visit1400	visit1800	visit2200	visit2600	visit3000	visit3400	visit3600
21	7.800000	.	-0.200000	-0.600000	-0.700000	-0.300000	-0.300000	-0.200000
22	6.900000

Parameter Code=C64849B Planned Treatment for Period 30 (N)=4

Obs	PARAM	Group	BASE_ Miss	visit1400_ Miss	visit1800_ Miss	visit2200_ Miss	visit2600_ Miss	visit3000_ Miss	visit3400_ Miss	visit3600_ Miss	Freq	Percent
23	HbA1c (%)	1	X	X	X	X	X	X	X	X	326	95.32
24	HbA1c (%)	2	X	X	X	X	X	X	X	O	1	0.29
25	HbA1c (%)	3	X	X	X	X	X	X	.	X	2	0.58

Obs	BASE	visit1400	visit1800	visit2200	visit2600	visit3000	visit3400	visit3600
23	7.407362	-0.065644	-0.050307	-0.065951	-0.029755	-0.073313	-0.064417	-0.103374
24	6.900000	0.100000	-0.100000	-0.400000	-0.200000	-0.100000	-0.100000	.
25	8.000000	-0.100000	0.350000	0.300000	0.350000	0.450000	.	0

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The MI Procedure with MCMC
Missing data pattern

Parameter Code=C64849B Planned Treatment for Period 30 (N)=4

(continued)

Obs	PARAM	Group	BASE_ Miss	visit1400_ Miss	visit1800_ Miss	visit2200_ Miss	visit2600_ Miss	visit3000_ Miss	visit3400_ Miss	visit3600_ Miss	Freq	Percent
26	HbA1c (%)	4	X	X	X	X	X	O	O	O	1	0.29
27	HbA1c (%)	5	X	X	X	X	.	X	X	X	1	0.29
28	HbA1c (%)	6	X	X	X	X	.	.	X	X	1	0.29
29	HbA1c (%)	7	X	X	X	X	O	O	O	O	4	1.17
30	HbA1c (%)	8	X	X	X	.	X	X	X	X	1	0.29
31	HbA1c (%)	9	X	X	.	X	X	X	X	X	1	0.29
32	HbA1c (%)	10	X	X	O	O	O	O	O	O	2	0.58
33	HbA1c (%)	11	X	.	X	X	X	X	X	O	1	0.29
34	HbA1c (%)	12	X	O	O	O	O	O	O	O	1	0.29

Obs	BASE	visit1400	visit1800	visit2200	visit2600	visit3000	visit3400	visit3600
26	8.700000	0.500000	0.300000	-0.100000	-0.700000	.	.	.
27	7.900000	0	-0.600000	0	.	-0.100000	0	0
28	7.300000	-1.000000	0.400000	0.200000	.	.	1.400000	1.400000
29	7.500000	0.175000	0.450000	0.375000
30	7.100000	-0.300000	-0.200000	.	0.700000	0.500000	0.100000	-0.200000
31	7.200000	-0.700000	.	-0.700000	-0.700000	-0.800000	-0.800000	-0.800000
32	7.350000	0.250000
33	6.900000	.	1.100000	1.400000	1.500000	1.300000	1.100000	.
34	7.800000

nn1218/nn1218-4131/ctr_20180214_er
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HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=C64849B Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM	Description	Value
1	1	HbA1c (%)	Data Set	WORK.MONOTONE
2	1	HbA1c (%)	Method	Monotone
3	1	HbA1c (%)	Number of Imputations	1
4	1	HbA1c (%)	Seed for random number generator	75222

Parameter Code=C64849B Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM	Description	Value
5	1	HbA1c (%)	Data Set	WORK.MONOTONE
6	1	HbA1c (%)	Method	Monotone
7	1	HbA1c (%)	Number of Imputations	1
8	1	HbA1c (%)	Seed for random number generator	337477447

Parameter Code=C64849B Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM	Description	Value
9	1	HbA1c (%)	Data Set	WORK.MONOTONE
10	1	HbA1c (%)	Method	Monotone
11	1	HbA1c (%)	Number of Imputations	1
12	1	HbA1c (%)	Seed for random number generator	156967520

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Missing Data Pattern

Parameter Code=C64849B Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM	Group	REGION1_ Miss	BOLAD1_ Miss	BASE_ Miss	visit1400_ Miss	visit1800_ Miss	visit2200_ Miss
1	1	HbA1c (%)	1	X	X	X	X	X	X
2	1	HbA1c (%)	2	X	X	X	X	X	X
3	1	HbA1c (%)	3	X	X	X	X	X	X
4	1	HbA1c (%)	4	X	X	X	X	X	.
5	1	HbA1c (%)	5	X	X	X	X	.	.

Obs	visit2600_ Miss	visit3000_ Miss	visit3400_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit1400
1	X	X	X	X	335	97.95	7.449851	-0.106110
2	X	X	X	.	2	0.58	7.850000	-0.200000
3	X	.	.	.	1	0.29	7.300000	-1.000000
4	2	0.58	7.800000	-0.150000
5	2	0.58	7.750000	0.200000

Obs	visit1800	visit2200	visit2600	visit3000	visit3400	visit3600
1	-0.129690	-0.167979	-0.113134	-0.132278	-0.097530	-0.120000
2	-0.250000	-0.350000	-0.200000	-0.300000	-0.400000	.
3	-1.700000	-1.800000	-2.500000	.	.	.
4	-0.400000
5

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Missing Data Pattern

Parameter Code=C64849B Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM	Group	REGION1_ Miss	BOLAD1_ Miss	BASE_ Miss	visit1400_ Miss	visit1800_ Miss	visit2200_ Miss
6	1	HbA1c (%)	1	X	X	X	X	X	X
7	1	HbA1c (%)	2	X	X	X	X	X	X
8	1	HbA1c (%)	3	X	X	X	X	X	X
9	1	HbA1c (%)	4	X	X	X	X	X	X
10	1	HbA1c (%)	5	X	X	X	X	X	.
11	1	HbA1c (%)	6	X	X	X	X	.	.

Obs	visit2600_ Miss	visit3000_ Miss	visit3400_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit1400
6	X	X	X	X	332	97.36	7.410241	-0.052947
7	X	X	.	.	2	0.59	6.700000	0.100000
8	X	.	.	.	1	0.29	8.000000	-0.600000
9	3	0.88	7.500000	-0.100000
10	1	0.29	7.400000	0.600000
11	1	0.29	6.600000	0.200000

Obs	visit1800	visit2200	visit2600	visit3000	visit3400	visit3600
6	-0.020226	-0.043373	0.025500	0.031728	0.047941	0
7	0.100000	0	0.050000	0	.	.
8	-0.600000	-0.800000	-0.700000	.	.	.
9	0.066667	0.233333
10	0.900000
11

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Missing Data Pattern

Parameter Code=C64849B Planned Treatment for Period 30 (N)=3

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Obs	_Imputation_	PARAM	Group	REGION1_	BOLAD1_	BASE_	visit1400_	visit1800_	visit2200_
				Miss	Miss	Miss	Miss	Miss	Miss
12	1	HbA1c (%)	7	X	X	X	.	.	.
Obs	visit2600_	visit3000_	visit3400_	visit3600_		Freq	Percent	BASE	visit1400
	Miss	Miss	Miss	Miss					
12		1	0.29	6.900000	.
Obs	visit1800	visit2200	visit2600	visit3000		visit3400	visit3600		
12

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Missing Data Pattern

Parameter Code=C64849B Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM	Group	REGION1_ Miss	BOLAD1_ Miss	BASE_ Miss	visit1400_ Miss	visit1800_ Miss	visit2200_ Miss
13	1	HbA1c (%)	1	X	X	X	X	X	X
14	1	HbA1c (%)	2	X	X	X	X	X	X
15	1	HbA1c (%)	3	X	X	X	X	X	X
16	1	HbA1c (%)	4	X	X	X	X	X	X
17	1	HbA1c (%)	5	X	X	X	X	.	.
18	1	HbA1c (%)	6	X	X	X	.	.	.

Obs	visit2600_ Miss	visit3000_ Miss	visit3400_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit1400
13	X	X	X	X	332	97.08	7.410542	-0.071084
14	X	X	X	.	2	0.58	6.900000	0.269610
15	X	.	.	.	1	0.29	8.700000	0.500000
16	4	1.17	7.500000	0.175000
17	2	0.58	7.350000	0.250000
18	1	0.29	7.800000	.

Obs	visit1800	visit2200	visit2600	visit3000	visit3400	visit3600
13	-0.051518	-0.064718	-0.023761	-0.065462	-0.059971	-0.100301
14	0.500000	0.500000	0.650000	0.600000	0.500000	.
15	0.300000	-0.100000	-0.700000	.	.	.
16	0.450000	0.375000
17
18

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Parameter Code=C64849B Planned Treatment for Period 30 (N)=2 Imputed Variable=visit1800

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
1	1	HbA1c (%)	Intercept			0.00458	-0.034206
2	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)		-0.00555	0.008993
3	1	HbA1c (%)	REGION1	EUROPE		-0.01231	-0.000497
4	1	HbA1c (%)	REGION1	JAPAN		-0.02947	-0.060358
5	1	HbA1c (%)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.03074	-0.042529
6	1	HbA1c (%)	BASE			-0.09678	-0.093569
7	1	HbA1c (%)	visit1400			0.79373	0.740488

Parameter Code=C64849B Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
8	1	HbA1c (%)	Intercept			0.00485	-0.009418
9	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)		0.02923	-0.014198
10	1	HbA1c (%)	REGION1	EUROPE		0.03244	-0.019376
11	1	HbA1c (%)	REGION1	JAPAN		-0.03275	0.015025
12	1	HbA1c (%)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.03297	-0.028165
13	1	HbA1c (%)	BASE			-0.08598	-0.089632
14	1	HbA1c (%)	visit1400			0.07203	0.050142
15	1	HbA1c (%)	visit1800			0.76818	0.785290

Parameter Code=C64849B Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
16	1	HbA1c (%)	Intercept			-0.03763	-0.079719
17	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)		-0.16206	-0.278121

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Parameter Code=C64849B Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2600

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Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
18	1	HbA1c (%)	REGION1	EUROPE		0.10790	0.168490
19	1	HbA1c (%)	REGION1	JAPAN		-0.01175	0.022669
20	1	HbA1c (%)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.00137	-0.015216
21	1	HbA1c (%)	BASE			-0.08449	-0.115213
22	1	HbA1c (%)	visit1400			-0.01358	-0.039788
23	1	HbA1c (%)	visit1800			0.01550	0.071518
24	1	HbA1c (%)	visit2200			0.83307	0.781121

Parameter Code=C64849B Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3000

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
25	1	HbA1c (%)	Intercept			-0.00431	-0.010789
26	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)		0.07281	0.125306
27	1	HbA1c (%)	REGION1	EUROPE		-0.01292	-0.033096
28	1	HbA1c (%)	REGION1	JAPAN		-0.05966	-0.106854
29	1	HbA1c (%)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.01821	0.046803
30	1	HbA1c (%)	BASE			-0.04811	-0.049508
31	1	HbA1c (%)	visit1400			-0.01272	-0.093957
32	1	HbA1c (%)	visit1800			-0.02709	-0.038632
33	1	HbA1c (%)	visit2200			0.12102	0.269529
34	1	HbA1c (%)	visit2600			0.80712	0.796203

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Parameter Code=C64849B Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3400

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
35	1	HbA1c (%)	Intercept			-0.01417	0.008741
36	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)		-0.01935	-0.099644
37	1	HbA1c (%)	REGION1	EUROPE		0.05802	0.085281
38	1	HbA1c (%)	REGION1	JAPAN		0.00284	0.031473
39	1	HbA1c (%)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.03704	0.051474
40	1	HbA1c (%)	BASE			-0.02714	-0.073975
41	1	HbA1c (%)	visit1400			0.03830	0.007454
42	1	HbA1c (%)	visit1800			0.06362	0.090124
43	1	HbA1c (%)	visit2200			0.09889	0.058268
44	1	HbA1c (%)	visit2600			0.04126	0.043024
45	1	HbA1c (%)	visit3000			0.69448	0.717152

Parameter Code=C64849B Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
46	1	HbA1c (%)	Intercept			-0.01247	-0.002955
47	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)		0.00863	0.005613
48	1	HbA1c (%)	REGION1	EUROPE		0.07777	0.106892
49	1	HbA1c (%)	REGION1	JAPAN		-0.02667	-0.067137
50	1	HbA1c (%)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.03358	0.068392
51	1	HbA1c (%)	BASE			-0.01113	0.025344
52	1	HbA1c (%)	visit1400			-0.05473	-0.086885
53	1	HbA1c (%)	visit1800			0.05941	0.137458
54	1	HbA1c (%)	visit2200			-0.02798	-0.092771
55	1	HbA1c (%)	visit2600			-0.01901	-0.028391
56	1	HbA1c (%)	visit3000			0.18164	0.263939
57	1	HbA1c (%)	visit3400			0.78523	0.749835

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Parameter Code=C64849B Planned Treatment for Period 30 (N)=3 Imputed Variable=visit1400

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
58	1	HbA1c (%)	Intercept			0.03791	-0.070895
59	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)		0.15632	-0.155801
60	1	HbA1c (%)	REGION1	EUROPE		-0.03398	0.106118
61	1	HbA1c (%)	REGION1	JAPAN		0.01572	0.113433
62	1	HbA1c (%)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.07937	0.004464
63	1	HbA1c (%)	BASE			-0.18542	-0.253561

Parameter Code=C64849B Planned Treatment for Period 30 (N)=3 Imputed Variable=visit1800

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
64	1	HbA1c (%)	Intercept			-0.01982	0.061990
65	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)		-0.10522	-0.012954
66	1	HbA1c (%)	REGION1	EUROPE		0.06232	0.031367
67	1	HbA1c (%)	REGION1	JAPAN		0.00601	-0.014176
68	1	HbA1c (%)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.00936	-0.043834
69	1	HbA1c (%)	BASE			-0.08360	-0.112575
70	1	HbA1c (%)	visit1400			0.68571	0.678218

Parameter Code=C64849B Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
71	1	HbA1c (%)	Intercept			0.01321	-0.017197
72	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)		-0.00739	-0.017251
73	1	HbA1c (%)	REGION1	EUROPE		-0.05043	-0.040149
74	1	HbA1c (%)	REGION1	JAPAN		0.02175	-0.042769

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Parameter Code=C64849B Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2200

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Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
75	1	HbA1c (%)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.05051	-0.048349
76	1	HbA1c (%)	BASE			-0.08137	-0.064833
77	1	HbA1c (%)	visit1400			-0.12463	-0.138472
78	1	HbA1c (%)	visit1800			0.88542	0.912039

Parameter Code=C64849B Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
79	1	HbA1c (%)	Intercept			-0.01764	-0.026785
80	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)		-0.11097	-0.098195
81	1	HbA1c (%)	REGION1	EUROPE		0.03611	0.093311
82	1	HbA1c (%)	REGION1	JAPAN		-0.06988	-0.061818
83	1	HbA1c (%)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.00115	0.021992
84	1	HbA1c (%)	BASE			-0.04868	-0.053211
85	1	HbA1c (%)	visit1400			-0.04046	-0.007242
86	1	HbA1c (%)	visit1800			0.02808	-0.135931
87	1	HbA1c (%)	visit2200			0.80637	0.868630

Parameter Code=C64849B Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3000

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
88	1	HbA1c (%)	Intercept			-0.02496	-0.031772
89	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)		-0.09195	-0.151449

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Parameter Code=C64849B Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3000

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Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
90	1	HbA1c (%)	REGION1	EUROPE		0.08343	0.156967
91	1	HbA1c (%)	REGION1	JAPAN		-0.06204	-0.058510
92	1	HbA1c (%)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.00741	0.036091
93	1	HbA1c (%)	BASE			-0.03514	-0.034362
94	1	HbA1c (%)	visit1400			0.06328	0.151633
95	1	HbA1c (%)	visit1800			0.01791	-0.061588
96	1	HbA1c (%)	visit2200			0.07104	0.122386
97	1	HbA1c (%)	visit2600			0.74399	0.726434

Parameter Code=C64849B Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3400

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
98	1	HbA1c (%)	Intercept			-0.00637	-0.008117
99	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)		-0.00714	-0.079224
100	1	HbA1c (%)	REGION1	EUROPE		0.11350	0.104774
101	1	HbA1c (%)	REGION1	JAPAN		-0.05489	-0.036970
102	1	HbA1c (%)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.01168	-0.011773
103	1	HbA1c (%)	BASE			-0.05494	-0.053560
104	1	HbA1c (%)	visit1400			-0.00937	0.011352
105	1	HbA1c (%)	visit1800			0.19306	0.117149
106	1	HbA1c (%)	visit2200			-0.13494	-0.038424
107	1	HbA1c (%)	visit2600			-0.08169	-0.022712
108	1	HbA1c (%)	visit3000			0.87773	0.814221

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Parameter Code=C64849B Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
109	1	HbA1c (%)	Intercept			-0.00837	-0.016740
110	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)		-0.01168	-0.090840
111	1	HbA1c (%)	REGION1	EUROPE		-0.00143	0.024223
112	1	HbA1c (%)	REGION1	JAPAN		-0.03079	-0.000939
113	1	HbA1c (%)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.05167	0.046071
114	1	HbA1c (%)	BASE			-0.04338	0.009824
115	1	HbA1c (%)	visit1400			0.03191	0.028280
116	1	HbA1c (%)	visit1800			-0.02994	-0.025427
117	1	HbA1c (%)	visit2200			0.07320	-0.034351
118	1	HbA1c (%)	visit2600			0.00392	0.124801
119	1	HbA1c (%)	visit3000			0.00935	-0.039542
120	1	HbA1c (%)	visit3400			0.85683	0.874281

Parameter Code=C64849B Planned Treatment for Period 30 (N)=4 Imputed Variable=visit1400

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
121	1	HbA1c (%)	Intercept			0.01527	0.042220
122	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)		0.09956	0.247596
123	1	HbA1c (%)	REGION1	EUROPE		-0.03703	-0.132301
124	1	HbA1c (%)	REGION1	JAPAN		-0.08604	-0.254641
125	1	HbA1c (%)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.02052	-0.060333
126	1	HbA1c (%)	BASE			-0.10288	-0.191064

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Parameter Code=C64849B Planned Treatment for Period 30 (N)=4 Imputed Variable=visit1800

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
127	1	HbA1c (%)	Intercept			0.01108	-0.045082
128	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)		0.10979	0.084412
129	1	HbA1c (%)	REGION1	EUROPE		0.02170	0.063169
130	1	HbA1c (%)	REGION1	JAPAN		-0.14569	-0.058272
131	1	HbA1c (%)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.00596	-0.068333
132	1	HbA1c (%)	BASE			-0.22470	-0.235856
133	1	HbA1c (%)	visit1400			0.58595	0.643681

Parameter Code=C64849B Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
134	1	HbA1c (%)	Intercept			0.00714	-0.012363
135	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)		0.04584	-0.058414
136	1	HbA1c (%)	REGION1	EUROPE		-0.00901	0.105652
137	1	HbA1c (%)	REGION1	JAPAN		-0.05356	0.070357
138	1	HbA1c (%)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.01303	-0.030599
139	1	HbA1c (%)	BASE			-0.08981	-0.050099
140	1	HbA1c (%)	visit1400			0.10098	0.050828
141	1	HbA1c (%)	visit1800			0.72683	0.787567

Parameter Code=C64849B Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
142	1	HbA1c (%)	Intercept			-0.01022	-0.053681
143	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)		-0.13746	-0.136285

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Parameter Code=C64849B Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2600

(continued)

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
144	1	HbA1c (%)	REGION1	EUROPE		0.03083	0.086069
145	1	HbA1c (%)	REGION1	JAPAN		0.06004	-0.012113
146	1	HbA1c (%)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.0008315	0.053767
147	1	HbA1c (%)	BASE			-0.08602	-0.079119
148	1	HbA1c (%)	visit1400			-0.10446	-0.113668
149	1	HbA1c (%)	visit1800			0.11827	0.176916
150	1	HbA1c (%)	visit2200			0.71072	0.667799

Parameter Code=C64849B Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3000

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
151	1	HbA1c (%)	Intercept			-0.00569	-0.017449
152	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)		-0.03333	0.009302
153	1	HbA1c (%)	REGION1	EUROPE		0.07173	0.106419
154	1	HbA1c (%)	REGION1	JAPAN		-0.02161	-0.047707
155	1	HbA1c (%)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.04235	-0.054467
156	1	HbA1c (%)	BASE			-0.07205	-0.026377
157	1	HbA1c (%)	visit1400			-0.03243	-0.110959
158	1	HbA1c (%)	visit1800			-0.04917	0.065565
159	1	HbA1c (%)	visit2200			-0.07102	-0.080950
160	1	HbA1c (%)	visit2600			0.93682	0.934045

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Parameter Code=C64849B Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3400

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
161	1	HbA1c (%)	Intercept			-0.02004	-0.016339
162	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)		-0.16140	-0.133367
163	1	HbA1c (%)	REGION1	EUROPE		0.12196	0.119275
164	1	HbA1c (%)	REGION1	JAPAN		0.02407	0.030482
165	1	HbA1c (%)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.02076	-0.026963
166	1	HbA1c (%)	BASE			-0.07675	-0.096469
167	1	HbA1c (%)	visit1400			-0.04648	-0.048015
168	1	HbA1c (%)	visit1800			0.11450	0.112303
169	1	HbA1c (%)	visit2200			0.06541	0.117295
170	1	HbA1c (%)	visit2600			-0.05235	-0.096382
171	1	HbA1c (%)	visit3000			0.79737	0.776628

Parameter Code=C64849B Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
172	1	HbA1c (%)	Intercept			0.00120	0.055725
173	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)		-0.05634	-0.012351
174	1	HbA1c (%)	REGION1	EUROPE		0.06980	0.047805
175	1	HbA1c (%)	REGION1	JAPAN		-0.00677	-0.005661
176	1	HbA1c (%)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.03406	-0.074661
177	1	HbA1c (%)	BASE			-0.02772	-0.060424
178	1	HbA1c (%)	visit1400			-0.02471	-0.010350
179	1	HbA1c (%)	visit1800			0.01762	-0.008396
180	1	HbA1c (%)	visit2200			0.10684	0.084999
181	1	HbA1c (%)	visit2600			-0.03469	-0.009915
182	1	HbA1c (%)	visit3000			-0.19977	-0.236912
183	1	HbA1c (%)	visit3400			1.01732	1.022724

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Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=2

Obs	PARAM	Description	Value
1	HbA1c (mmol/mol)	Data Set	WORK.ENDPOINT_PARAM
2	HbA1c (mmol/mol)	Method	Monotone-data_MCMC
3	HbA1c (mmol/mol)	Multiple Imputation Chain	Multiple Chains
4	HbA1c (mmol/mol)	Initial Estimates for MCMC	EM Posterior Mode
5	HbA1c (mmol/mol)	Start	Starting Value
6	HbA1c (mmol/mol)	Prior	Jeffreys
7	HbA1c (mmol/mol)	Number of Imputations	100
8	HbA1c (mmol/mol)	Number of Burn-in Iterations	200
9	HbA1c (mmol/mol)	Seed for random number generator	76122

Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=3

Obs	PARAM	Description	Value
10	HbA1c (mmol/mol)	Data Set	WORK.ENDPOINT_PARAM
11	HbA1c (mmol/mol)	Method	Monotone-data_MCMC
12	HbA1c (mmol/mol)	Multiple Imputation Chain	Multiple Chains
13	HbA1c (mmol/mol)	Initial Estimates for MCMC	EM Posterior Mode
14	HbA1c (mmol/mol)	Start	Starting Value
15	HbA1c (mmol/mol)	Prior	Jeffreys
16	HbA1c (mmol/mol)	Number of Imputations	100
17	HbA1c (mmol/mol)	Number of Burn-in Iterations	200
18	HbA1c (mmol/mol)	Seed for random number generator	695346756

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Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=4

Obs	PARAM	Description	Value
19	HbA1c (mmol/mol)	Data Set	WORK.ENDPOINT_PARAM
20	HbA1c (mmol/mol)	Method	Monotone-data_MCMC
21	HbA1c (mmol/mol)	Multiple Imputation Chain	Multiple Chains
22	HbA1c (mmol/mol)	Initial Estimates for MCMC	EM Posterior Mode
23	HbA1c (mmol/mol)	Start	Starting Value
24	HbA1c (mmol/mol)	Prior	Jeffreys
25	HbA1c (mmol/mol)	Number of Imputations	100
26	HbA1c (mmol/mol)	Number of Burn-in Iterations	200
27	HbA1c (mmol/mol)	Seed for random number generator	614808148

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Missing data pattern

Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=2

Obs	PARAM	Group	BASE_ Miss	visit1400_ Miss	visit1800_ Miss	visit2200_ Miss	visit2600_ Miss	visit3000_ Miss	visit3400_ Miss	visit3600_ Miss	Freq
1	HbA1c (mmol/mol)	1	X	X	X	X	X	X	X	X	328
2	HbA1c (mmol/mol)	2	X	X	X	X	X	X	X	O	2
3	HbA1c (mmol/mol)	3	X	X	X	X	X	X	.	X	3
4	HbA1c (mmol/mol)	4	X	X	X	X	X	O	O	O	1
5	HbA1c (mmol/mol)	5	X	X	X	O	O	O	O	O	2
6	HbA1c (mmol/mol)	6	X	X	.	X	X	X	X	X	2
7	HbA1c (mmol/mol)	7	X	X	.	.	X	X	X	X	1
8	HbA1c (mmol/mol)	8	X	X	O	O	O	O	O	O	2
9	HbA1c (mmol/mol)	9	X	.	X	X	X	.	.	X	1

Obs	Percent	BASE	visit1400	visit1800	visit2200	visit2600	visit3000	visit3400	visit3600
1	95.91	57.895177	-1.149649	-1.442893	-1.862765	-1.229625	-1.396241	-1.059677	-1.349588
2	0.58	62.300500	-2.186000	-2.732500	-3.825500	-2.186000	-3.279000	-4.372000	.
3	0.88	60.296667	-1.457333	-1.457333	-3.279000	-3.643333	-5.465000	.	2.914667
4	0.29	56.289000	-10.930000	-18.581000	-19.674000	-27.325000	.	.	.
5	0.58	61.754000	-1.639500	-4.372000
6	0.58	63.940000	-2.732500	.	1.093000	0.546500	-3.825500	0	1.639500
7	0.29	61.754000	0	.	.	0	-2.186000	-7.651000	-7.651000
8	0.58	61.207500	2.186000
9	0.29	45.359000	.	1.093000	0	-1.093000	.	.	-1.093000

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Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=3

Obs	PARAM	Group	BASE_ Miss	visit1400_ Miss	visit1800_ Miss	visit2200_ Miss	visit2600_ Miss	visit3000_ Miss	visit3400_ Miss	visit3600_ Miss	Freq
10	HbA1c (mmol/mol)	1	X	X	X	X	X	X	X	X	323
11	HbA1c (mmol/mol)	2	X	X	X	X	X	X	.	X	3
12	HbA1c (mmol/mol)	3	X	X	X	X	X	X	O	O	2
13	HbA1c (mmol/mol)	4	X	X	X	X	X	.	X	X	2
14	HbA1c (mmol/mol)	5	X	X	X	X	X	O	O	O	1
15	HbA1c (mmol/mol)	6	X	X	X	X	.	X	X	X	1
16	HbA1c (mmol/mol)	7	X	X	X	X	.	.	.	X	1
17	HbA1c (mmol/mol)	8	X	X	X	X	O	O	O	O	3
18	HbA1c (mmol/mol)	9	X	X	X	O	O	O	O	O	1
19	HbA1c (mmol/mol)	10	X	X	.	X	X	X	X	X	1
20	HbA1c (mmol/mol)	11	X	X	O	O	O	O	O	O	1

Obs	Percent	BASE	visit1400	visit1800	visit2200	visit2600	visit3000	visit3400	visit3600
10	94.72	57.544427	-0.568495	-0.223337	-0.483898	0.233489	0.230105	0.324854	-0.142124
11	0.88	49.731000	-1.093000	-1.821667	-3.279000	0.364333	4.007667	.	1.093000
12	0.59	49.731000	1.093000	1.093000	0	0.546500	0	.	.
13	0.59	56.835500	1.093000	-2.732500	-2.186000	0	.	8.744000	7.104500
14	0.29	63.940000	-6.558000	-6.558000	-8.744000	-7.651000	.	.	.
15	0.29	54.103000	1.093000	6.558000	10.930000	.	16.395000	17.488000	13.116000
16	0.29	65.033000	-4.372000	5.465000	7.651000	.	.	.	14.209000
17	0.88	58.475000	-1.093000	0.728667	2.550333
18	0.29	57.382000	6.558000	9.837000
19	0.29	57.382000	1.093000	.	1.093000	3.279000	0	1.093000	3.279000
20	0.29	48.638000	2.186000

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Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=3

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Obs	PARAM	Group	BASE_ Miss	visit1400_ Miss	visit1800_ Miss	visit2200_ Miss	visit2600_ Miss	visit3000_ Miss	visit3400_ Miss	visit3600_ Miss	Freq
21	HbA1c (mmol/mol)	12	X	.	X	X	X	X	X	X	1
22	HbA1c (mmol/mol)	13	X	O	O	O	O	O	O	O	1

Obs	Percent	BASE	visit1400	visit1800	visit2200	visit2600	visit3000	visit3400	visit3600
21	0.29	61.754000	.	-2.186000	-6.558000	-7.651000	-3.279000	-3.279000	-2.186000
22	0.29	51.917000

Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=4

Obs	PARAM	Group	BASE_ Miss	visit1400_ Miss	visit1800_ Miss	visit2200_ Miss	visit2600_ Miss	visit3000_ Miss	visit3400_ Miss	visit3600_ Miss	Freq
23	HbA1c (mmol/mol)	1	X	X	X	X	X	X	X	X	326
24	HbA1c (mmol/mol)	2	X	X	X	X	X	X	X	O	1
25	HbA1c (mmol/mol)	3	X	X	X	X	X	X	.	X	2

Obs	Percent	BASE	visit1400	visit1800	visit2200	visit2600	visit3000	visit3400	visit3600
23	95.32	57.462466	-0.717491	-0.549853	-0.720844	-0.325218	-0.801310	-0.704080	-1.129880
24	0.29	51.917000	1.093000	-1.093000	-4.372000	-2.186000	-1.093000	-1.093000	.
25	0.58	63.940000	-1.093000	3.825500	3.279000	3.825500	4.918500	.	0

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Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=4

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Obs	PARAM	Group	BASE_ Miss	visit1400_ Miss	visit1800_ Miss	visit2200_ Miss	visit2600_ Miss	visit3000_ Miss	visit3400_ Miss	visit3600_ Miss	Freq
26	HbA1c (mmol/mol)	4	X	X	X	X	X	O	O	O	1
27	HbA1c (mmol/mol)	5	X	X	X	X	.	X	X	X	1
28	HbA1c (mmol/mol)	6	X	X	X	X	.	.	X	X	1
29	HbA1c (mmol/mol)	7	X	X	X	X	O	O	O	O	4
30	HbA1c (mmol/mol)	8	X	X	X	.	X	X	X	X	1
31	HbA1c (mmol/mol)	9	X	X	.	X	X	X	X	X	1
32	HbA1c (mmol/mol)	10	X	X	O	O	O	O	O	O	2
33	HbA1c (mmol/mol)	11	X	.	X	X	X	X	X	O	1
34	HbA1c (mmol/mol)	12	X	O	O	O	O	O	O	O	1

Obs	Percent	BASE	visit1400	visit1800	visit2200	visit2600	visit3000	visit3400	visit3600
26	0.29	71.591000	5.465000	3.279000	-1.093000	-7.651000	.	.	.
27	0.29	62.847000	0	-6.558000	0	.	-1.093000	0	0
28	0.29	56.289000	-10.930000	4.372000	2.186000	.	.	15.302000	15.302000
29	1.17	58.475000	1.912750	4.918500	4.098750
30	0.29	54.103000	-3.279000	-2.186000	.	7.651000	5.465000	1.093000	-2.186000
31	0.29	55.196000	-7.651000	.	-7.651000	-7.651000	-8.744000	-8.744000	-8.744000
32	0.58	56.835500	2.732500
33	0.29	51.917000	.	12.023000	15.302000	16.395000	14.209000	12.023000	.
34	0.29	61.754000

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Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM	Description	Value
1	1	HbA1c (mmol/mol)	Data Set	WORK.MONOTONE
2	1	HbA1c (mmol/mol)	Method	Monotone
3	1	HbA1c (mmol/mol)	Number of Imputations	1
4	1	HbA1c (mmol/mol)	Seed for random number generator	75222

Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM	Description	Value
5	1	HbA1c (mmol/mol)	Data Set	WORK.MONOTONE
6	1	HbA1c (mmol/mol)	Method	Monotone
7	1	HbA1c (mmol/mol)	Number of Imputations	1
8	1	HbA1c (mmol/mol)	Seed for random number generator	337477447

Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM	Description	Value
9	1	HbA1c (mmol/mol)	Data Set	WORK.MONOTONE
10	1	HbA1c (mmol/mol)	Method	Monotone
11	1	HbA1c (mmol/mol)	Number of Imputations	1
12	1	HbA1c (mmol/mol)	Seed for random number generator	156967520

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Missing Data Pattern

Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM	Group	REGION1_ Miss	BOLAD1_ Miss	BASE_ Miss	visit1400_ Miss	visit1800_ Miss	visit2200_ Miss
1	1	HbA1c (mmol/mol)	1	X	X	X	X	X	X
2	1	HbA1c (mmol/mol)	2	X	X	X	X	X	X
3	1	HbA1c (mmol/mol)	3	X	X	X	X	X	X
4	1	HbA1c (mmol/mol)	4	X	X	X	X	X	.
5	1	HbA1c (mmol/mol)	5	X	X	X	X	.	.

Obs	visit2600_ Miss	visit3000_ Miss	visit3400_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit1400
1	X	X	X	X	335	97.95	57.926869	-1.159782
2	X	X	X	.	2	0.58	62.300500	-2.186000
3	X	.	.	.	1	0.29	56.289000	-10.930000
4	2	0.58	61.754000	-1.639500
5	2	0.58	61.207500	2.186000

Obs	visit1800	visit2200	visit2600	visit3000	visit3400	visit3600
1	-1.417515	-1.836010	-1.236558	-1.445802	-1.065998	-1.311600
2	-2.732500	-3.825500	-2.186000	-3.279000	-4.372000	.
3	-18.581000	-19.674000	-27.325000	.	.	.
4	-4.372000
5

Fast-acting insulin aspart
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HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM	Group	REGION1_	BOLAD1_	BASE_	visit1400_	visit1800_	visit2200_
				Miss	Miss	Miss	Miss	Miss	Miss
6	1	HbA1c (mmol/mol)	1	X	X	X	X	X	X
7	1	HbA1c (mmol/mol)	2	X	X	X	X	X	X
8	1	HbA1c (mmol/mol)	3	X	X	X	X	X	X
9	1	HbA1c (mmol/mol)	4	X	X	X	X	X	X
10	1	HbA1c (mmol/mol)	5	X	X	X	X	X	.
11	1	HbA1c (mmol/mol)	6	X	X	X	X	.	.

Obs	visit2600_	visit3000_	visit3400_	visit3600_	Freq	Percent	BASE	visit1400
	Miss	Miss	Miss	Miss				
6	X	X	X	X	332	97.36	57.493934	-0.578706
7	X	X	.	.	2	0.59	49.731000	1.093000
8	X	.	.	.	1	0.29	63.940000	-6.558000
9	3	0.88	58.475000	-1.093000
10	1	0.29	57.382000	6.558000
11	1	0.29	48.638000	2.186000

Obs	visit1800	visit2200	visit2600	visit3000	visit3400	visit3600
6	-0.221065	-0.474072	0.278712	0.346785	0.523994	0
7	1.093000	0	0.546500	0	.	.
8	-6.558000	-8.744000	-7.651000	.	.	.
9	0.728667	2.550333
10	9.837000
11

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Fast-acting insulin aspart
NN1218-4131

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The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=3

(continued)

Obs	_Imputation_	PARAM	Group	REGION1_	BOLAD1_	BASE_	visit1400_	visit1800_	visit2200_
				Miss	Miss	Miss	Miss	Miss	Miss
12	1	HbA1c (mmol/mol)	7	X	X	X	.	.	.
Obs	visit2600_	visit3000_	visit3400_	visit3600_	Freq	Percent	BASE	visit1400	
	Miss	Miss	Miss	Miss					
12	1	0.29	51.917000	.	.
Obs	visit1800	visit2200	visit2600	visit3000	visit3400	visit3600			
12

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Fast-acting insulin aspart
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HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM	Group	REGION1_ Miss	BOLAD1_ Miss	BASE_ Miss	visit1400_ Miss	visit1800_ Miss	visit2200_ Miss
13	1	HbA1c (mmol/mol)	1	X	X	X	X	X	X
14	1	HbA1c (mmol/mol)	2	X	X	X	X	X	X
15	1	HbA1c (mmol/mol)	3	X	X	X	X	X	X
16	1	HbA1c (mmol/mol)	4	X	X	X	X	X	X
17	1	HbA1c (mmol/mol)	5	X	X	X	X	.	.
18	1	HbA1c (mmol/mol)	6	X	X	X	.	.	.

Obs	visit2600_ Miss	visit3000_ Miss	visit3400_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit1400
13	X	X	X	X	332	97.08	57.497226	-0.776952
14	X	X	X	.	2	0.58	51.917000	2.946842
15	X	.	.	.	1	0.29	71.591000	5.465000
16	4	1.17	58.475000	1.912750
17	2	0.58	56.835500	2.732500
18	1	0.29	61.754000	.

Obs	visit1800	visit2200	visit2600	visit3000	visit3400	visit3600
13	-0.563091	-0.707365	-0.259704	-0.715503	-0.655479	-1.096292
14	5.465000	5.465000	7.104500	6.558000	5.465000	.
15	3.279000	-1.093000	-7.651000	.	.	.
16	4.918500	4.098750
17
18

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HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=2 Imputed Variable=visit1800

O b s	i n s	P u t a t i o n	P A R A M E T E R	E f f e c t	R E G I O N 1	B O L A D 1	O b s e r v e d	I n t e r c e p t
1	1	HbA1c	(mmol/mol)	Intercept			0.00458	-0.034206
2	1	HbA1c	(mmol/mol)	REGION1	ASIA (EXCLUDING JAPAN)		-0.00555	0.008993
3	1	HbA1c	(mmol/mol)	REGION1	EUROPE		-0.01231	-0.000497
4	1	HbA1c	(mmol/mol)	REGION1	JAPAN		-0.02947	-0.060358
5	1	HbA1c	(mmol/mol)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.03074	-0.042529
6	1	HbA1c	(mmol/mol)	BASE			-0.09678	-0.093569
7	1	HbA1c	(mmol/mol)	visit1400			0.79373	0.740488

HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2200

O b s	i	n	P A R A M E T E R	E f f e c t	R E G I O N 1	B O L A D 1	O b s e r v e d	I
8	1	HbA1c	(mmol/mol)	Intercept			0.00485	-0.009418
9	1	HbA1c	(mmol/mol)	REGION1	ASIA (EXCLUDING JAPAN)		0.02923	-0.014198
10	1	HbA1c	(mmol/mol)	REGION1	EUROPE		0.03244	-0.019376
11	1	HbA1c	(mmol/mol)	REGION1	JAPAN		-0.03275	0.015025
12	1	HbA1c	(mmol/mol)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.03297	-0.028165
13	1	HbA1c	(mmol/mol)	BASE			-0.08598	-0.089632
14	1	HbA1c	(mmol/mol)	visit1400			0.07203	0.050142
15	1	HbA1c	(mmol/mol)	visit1800			0.76818	0.785290

HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2600

O b s	i n s	P a r a m e t e r	E f f e c t	R e g i o n	B o l u s	O b s e r v e d	I n t e r c e p t
16	1	HbA1c (mmol/mol)	Intercept			-0.03763	-0.079719
17	1	HbA1c (mmol/mol)	REGION1	ASIA (EXCLUDING JAPAN)		-0.16206	-0.278121
18	1	HbA1c (mmol/mol)	REGION1	EUROPE		0.10790	0.168490
19	1	HbA1c (mmol/mol)	REGION1	JAPAN		-0.01175	0.022669
20	1	HbA1c (mmol/mol)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.00137	-0.015216
21	1	HbA1c (mmol/mol)	BASE			-0.08449	-0.115213
22	1	HbA1c (mmol/mol)	visit1400			-0.01358	-0.039788
23	1	HbA1c (mmol/mol)	visit1800			0.01550	0.071518
24	1	HbA1c (mmol/mol)	visit2200			0.83307	0.781121

HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3000

O b s	i n s	P a r a m e t e r	E f f e c t	R e g i o n	B o l u s	O b s e r v e d	I m p u t e d
25	1	HbA1c (mmol/mol)	Intercept			-0.00431	-0.010789
26	1	HbA1c (mmol/mol)	REGION1	ASIA (EXCLUDING JAPAN)		0.07281	0.125306
27	1	HbA1c (mmol/mol)	REGION1	EUROPE		-0.01292	-0.033096
28	1	HbA1c (mmol/mol)	REGION1	JAPAN		-0.05966	-0.106854
29	1	HbA1c (mmol/mol)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.01821	0.046803
30	1	HbA1c (mmol/mol)	BASE			-0.04811	-0.049508
31	1	HbA1c (mmol/mol)	visit1400			-0.01272	-0.093957
32	1	HbA1c (mmol/mol)	visit1800			-0.02709	-0.038632
33	1	HbA1c (mmol/mol)	visit2200			0.12102	0.269529
34	1	HbA1c (mmol/mol)	visit2600			0.80712	0.796203

HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3400

O b s	i n s	P a r a m e t e r	E f f e c t	R e g i o n	B o l u s	O b s e r v e d	I n t e r c e p t
35	1	HbA1c (mmol/mol)	Intercept			-0.01417	0.008741
36	1	HbA1c (mmol/mol)	REGION1	ASIA (EXCLUDING JAPAN)		-0.01935	-0.099644
37	1	HbA1c (mmol/mol)	REGION1	EUROPE		0.05802	0.085281
38	1	HbA1c (mmol/mol)	REGION1	JAPAN		0.00284	0.031473
39	1	HbA1c (mmol/mol)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.03704	0.051474
40	1	HbA1c (mmol/mol)	BASE			-0.02714	-0.073975
41	1	HbA1c (mmol/mol)	visit1400			0.03830	0.007454
42	1	HbA1c (mmol/mol)	visit1800			0.06362	0.090124
43	1	HbA1c (mmol/mol)	visit2200			0.09889	0.058268
44	1	HbA1c (mmol/mol)	visit2600			0.04126	0.043024
45	1	HbA1c (mmol/mol)	visit3000			0.69448	0.717152

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	Observed	Predicted	Residual	Observed	Predicted	Residual
	Obs	Pred	Res	Obs	Pred	Res
58	1	HbA1c (mmol/mol)	Intercept			
59	1	HbA1c (mmol/mol)	REGION1 ASIA (EXCLUDING JAPAN)			
60	1	HbA1c (mmol/mol)	REGION1 EUROPE			
61	1	HbA1c (mmol/mol)	REGION1 JAPAN			
62	1	HbA1c (mmol/mol)	BOLAD1 BOLUS INSULIN ALGORITHM (SLIDING SCALE)			
63	1	HbA1c (mmol/mol)	BASE			

HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2200

O b s	i n s	P a r a m e t e r	E f f e c t	R e g i o n	B o l u s	O b s	I
71	1	HbA1c (mmol/mol)	Intercept			0.01321	-0.017197
72	1	HbA1c (mmol/mol)	REGION1	ASIA (EXCLUDING JAPAN)		-0.00739	-0.017251
73	1	HbA1c (mmol/mol)	REGION1	EUROPE		-0.05043	-0.040149
74	1	HbA1c (mmol/mol)	REGION1	JAPAN		0.02175	-0.042769
75	1	HbA1c (mmol/mol)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.05051	-0.048349
76	1	HbA1c (mmol/mol)	BASE			-0.08137	-0.064833
77	1	HbA1c (mmol/mol)	visit1400			-0.12463	-0.138472
78	1	HbA1c (mmol/mol)	visit1800			0.88542	0.912039

HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2600

O b s —	P A R A M E T E R	E F F E C T	R E G I O N	B O L A D 1	O b s V a l	T
79	1	HbA1c (mmol/mol)	Intercept		-0.01764	-0.026785
80	1	HbA1c (mmol/mol)	REGION1 ASIA (EXCLUDING JAPAN)		-0.11097	-0.098195
81	1	HbA1c (mmol/mol)	REGION1 EUROPE		0.03611	0.093311
82	1	HbA1c (mmol/mol)	REGION1 JAPAN		-0.06988	-0.061818
83	1	HbA1c (mmol/mol)	BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.00115	0.021992
84	1	HbA1c (mmol/mol)	BASE		-0.04868	-0.053211
85	1	HbA1c (mmol/mol)	visit1400		-0.04046	-0.007242
86	1	HbA1c (mmol/mol)	visit1800		0.02808	-0.135931
87	1	HbA1c (mmol/mol)	visit2200		0.80637	0.868630

HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3000

Obs	N	HbA1c	(mmol/mol)	Intercept	REGION1	ASIA (EXCLUDING JAPAN)	EUROPE	JAPAN	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	BASE	visit1400	visit1800	visit2200	visit2600	R	E	G	I	O	A	D	1	O	b	s	V	a	l	I	
88	1	HbA1c	(mmol/mol)	Intercept																										
89	1	HbA1c	(mmol/mol)	REGION1	ASIA (EXCLUDING JAPAN)																									
90	1	HbA1c	(mmol/mol)	REGION1	EUROPE																									
91	1	HbA1c	(mmol/mol)	REGION1	JAPAN																									
92	1	HbA1c	(mmol/mol)	BOLAD1																										
93	1	HbA1c	(mmol/mol)	BASE																										
94	1	HbA1c	(mmol/mol)	visit1400																										
95	1	HbA1c	(mmol/mol)	visit1800																										
96	1	HbA1c	(mmol/mol)	visit2200																										
97	1	HbA1c	(mmol/mol)	visit2600																										

HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression Regression Information

Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3400

	O	b	s		P	A	R	E	G	I	N	B	O	L	D	O	b	s	V	a	l	T
					M			f	e	c	t											
98	1	HbA1c	(mmol/mol)	Intercept												-0.00637						-0.008117
99	1	HbA1c	(mmol/mol)	REGION1	ASIA (EXCLUDING JAPAN)											-0.00714						-0.079224
100	1	HbA1c	(mmol/mol)	REGION1	EUROPE											0.11350						0.104774
101	1	HbA1c	(mmol/mol)	REGION1	JAPAN											-0.05489						-0.036970
102	1	HbA1c	(mmol/mol)	BOLAD1												-0.01168						-0.011773
103	1	HbA1c	(mmol/mol)	BASE												-0.05494						-0.053560
104	1	HbA1c	(mmol/mol)	visit1400												-0.00937						0.011352
105	1	HbA1c	(mmol/mol)	visit1800												0.19306						0.117149
106	1	HbA1c	(mmol/mol)	visit2200												-0.13494						-0.038424
107	1	HbA1c	(mmol/mol)	visit2600												-0.08169						-0.022712
108	1	HbA1c	(mmol/mol)	visit3000												0.87773						0.814221

HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

O b s	i n s	P a r a m e t e r	E f f e c t	R e g i o n	B o l u s	O b s e r v e d	I n t e r c e p t
109	1	HbA1c (mmol/mol)	Intercept			-0.00837	-0.016740
110	1	HbA1c (mmol/mol)	REGION1	ASIA (EXCLUDING JAPAN)		-0.01168	-0.090840
111	1	HbA1c (mmol/mol)	REGION1	EUROPE		-0.00143	0.024223
112	1	HbA1c (mmol/mol)	REGION1	JAPAN		-0.03079	-0.000939
113	1	HbA1c (mmol/mol)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.05167	0.046071
114	1	HbA1c (mmol/mol)	BASE			-0.04338	0.009824
115	1	HbA1c (mmol/mol)	visit1400			0.03191	0.028280
116	1	HbA1c (mmol/mol)	visit1800			-0.02994	-0.025427
117	1	HbA1c (mmol/mol)	visit2200			0.07320	-0.034351
118	1	HbA1c (mmol/mol)	visit2600			0.00392	0.124801
119	1	HbA1c (mmol/mol)	visit3000			0.00935	-0.039542
120	1	HbA1c (mmol/mol)	visit3400			0.85683	0.874281

HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression Regression Information

Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=4 Imputed Variable=visit1400

	O	b	s	P	E	R	B	O	I
	A	R	A	f	E	G	O	b	
	M	M	M	c	N		L	s	
				t	1		D	a	
							1	l	T
121	1	HbA1c	(mmol/mol)	Intercept				0.01527	0.042220
122	1	HbA1c	(mmol/mol)	REGION1 ASIA (EXCLUDING JAPAN)				0.09956	0.247596
123	1	HbA1c	(mmol/mol)	REGION1 EUROPE				-0.03703	-0.132301
124	1	HbA1c	(mmol/mol)	REGION1 JAPAN				-0.08604	-0.254641
125	1	HbA1c	(mmol/mol)	BOLAD1 BOLUS INSULIN ALGORITHM (SLIDING SCALE)				-0.02052	-0.060333
126	1	HbA1c	(mmol/mol)	BASE				-0.10288	-0.191064

HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=4 Imputed Variable=visit1800

Imputed		Observed		Region		Treatment		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		Parameter		Estimate		Standard Error	
O	b	s	—	P	A	R	E	B	O	O	b	s	—	l	—
127	1	HbA1c	(mmol/mol)	Intercept										0.01108	-0.045082
128	1	HbA1c	(mmol/mol)	REGION1	ASIA (EXCLUDING JAPAN)									0.10979	0.084412
129	1	HbA1c	(mmol/mol)	REGION1	EUROPE									0.02170	0.063169
130	1	HbA1c	(mmol/mol)	REGION1	JAPAN									-0.14569	-0.058272
131	1	HbA1c	(mmol/mol)	BOLAD1										-0.00596	-0.068333
132	1	HbA1c	(mmol/mol)	BASE										-0.22470	-0.235856
133	1	HbA1c	(mmol/mol)	visit1400										0.58595	0.643681

HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression Regression Information

Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2200

	O b s	P A R M	E f f e c t	R E G I O N 1	B O L U S D 1	O b s V a l	I
134	1	HbA1c (mmol/mol)	Intercept			0.00714	-0.012363
135	1	HbA1c (mmol/mol)	REGION1 ASIA (EXCLUDING JAPAN)			0.04584	-0.058414
136	1	HbA1c (mmol/mol)	REGION1 EUROPE			-0.00901	0.105652
137	1	HbA1c (mmol/mol)	REGION1 JAPAN			-0.05356	0.070357
138	1	HbA1c (mmol/mol)	BOLAD1 BOLUS INSULIN ALGORITHM (SLIDING SCALE)			-0.01303	-0.030599
139	1	HbA1c (mmol/mol)	BASE			-0.08981	-0.050099
140	1	HbA1c (mmol/mol)	visit1400			0.10098	0.050828
141	1	HbA1c (mmol/mol)	visit1800			0.72683	0.787567

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HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3000

O b s	i n s	P a r a m e t e r	E f f e c t	R e g i o n	B o l u s	O b s e r v e d	I n t e r c e p t
151	1	HbA1c (mmol/mol)	Intercept			-0.00569	-0.017449
152	1	HbA1c (mmol/mol)	REGION1	ASIA (EXCLUDING JAPAN)		-0.03333	0.009302
153	1	HbA1c (mmol/mol)	REGION1	EUROPE		0.07173	0.106419
154	1	HbA1c (mmol/mol)	REGION1	JAPAN		-0.02161	-0.047707
155	1	HbA1c (mmol/mol)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.04235	-0.054467
156	1	HbA1c (mmol/mol)	BASE			-0.07205	-0.026377
157	1	HbA1c (mmol/mol)	visit1400			-0.03243	-0.110959
158	1	HbA1c (mmol/mol)	visit1800			-0.04917	0.065565
159	1	HbA1c (mmol/mol)	visit2200			-0.07102	-0.080950
160	1	HbA1c (mmol/mol)	visit2600			0.93682	0.934045

HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression Regression Information

Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3400

	Obs	Patient	Effort	REGIONS	BOLD	Observed	T
161	1	HbA1c (mmol/mol)	Intercept			-0.02004	-0.016339
162	1	HbA1c (mmol/mol)	REGION1 ASIA (EXCLUDING JAPAN)			-0.16140	-0.133367
163	1	HbA1c (mmol/mol)	REGION1 EUROPE			0.12196	0.119275
164	1	HbA1c (mmol/mol)	REGION1 JAPAN			0.02407	0.030482
165	1	HbA1c (mmol/mol)	BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.02076	-0.026963
166	1	HbA1c (mmol/mol)	BASE			-0.07675	-0.096469
167	1	HbA1c (mmol/mol)	visit1400			-0.04648	-0.048015
168	1	HbA1c (mmol/mol)	visit1800			0.11450	0.112303
169	1	HbA1c (mmol/mol)	visit2200			0.06541	0.117295
170	1	HbA1c (mmol/mol)	visit2600			-0.05235	-0.096382
171	1	HbA1c (mmol/mol)	visit3000			0.79737	0.776628

HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

O b s —		P A R A M E T E R	E F F E C T	R E G I O N	B O L A D 1	O b s V a l	\bar{I}
172	1	HbA1c (mmol/mol)	Intercept			0.00120	0.055725
173	1	HbA1c (mmol/mol)	REGION1	ASIA (EXCLUDING JAPAN)		-0.05634	-0.012351
174	1	HbA1c (mmol/mol)	REGION1	EUROPE		0.06980	0.047805
175	1	HbA1c (mmol/mol)	REGION1	JAPAN		-0.00677	-0.005661
176	1	HbA1c (mmol/mol)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.03406	-0.074661
177	1	HbA1c (mmol/mol)	BASE			-0.02772	-0.060424
178	1	HbA1c (mmol/mol)	visit1400			-0.02471	-0.010350
179	1	HbA1c (mmol/mol)	visit1800			0.01762	-0.008396
180	1	HbA1c (mmol/mol)	visit2200			0.10684	0.084999
181	1	HbA1c (mmol/mol)	visit2600			-0.03469	-0.009915
182	1	HbA1c (mmol/mol)	visit3000			-0.19977	-0.236912
183	1	HbA1c (mmol/mol)	visit3400			1.01732	1.022724

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HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Model Information

Parameter Code=C64849B Parameter=HbA1c (%)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Data Set	WORK.IMPUTE
2	1	NN1218-4131	Dependent Variable	eotVisit
3	1	NN1218-4131	Covariance Structure	Diagonal
4	1	NN1218-4131	Estimation Method	REML
5	1	NN1218-4131	Residual Variance Method	Profile
6	1	NN1218-4131	Fixed Effects SE Method	Model-Based
7	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=HBA1CONV Parameter=HbA1c (mmol/mol)

Obs	_Imputation_	STUDYID	Descr	Value
8	1	NN1218-4131	Data Set	WORK.IMPUTE
9	1	NN1218-4131	Dependent Variable	eotVisit
10	1	NN1218-4131	Covariance Structure	Diagonal
11	1	NN1218-4131	Estimation Method	REML
12	1	NN1218-4131	Residual Variance Method	Profile
13	1	NN1218-4131	Fixed Effects SE Method	Model-Based
14	1	NN1218-4131	Degrees of Freedom Method	Residual

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HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Class Level Information

Parameter Code=C64849B Parameter=HbA1c (%)

Input				Output			
Source				Statistic			
Model				Variable			
Number				Level			
1	1	NN1218-4131	TRTPN	3	2	3	4
2	1	NN1218-4131	REGION1	4	ASIA (EXCLUDING JAPAN)	EUROPE	JAPAN NORTH AMERICA
3	1	NN1218-4131	BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	CARBOHYDRATE COUNTING (FLEXIBLE)	BOLUS INSULI
							85

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HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Dimensions

Parameter Code=C64849B Parameter=HbA1c (%)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Covariance Parameters	1
2	1	NN1218-4131	Columns in X	10
3	1	NN1218-4131	Columns in Z	0
4	1	NN1218-4131	Subjects	1
5	1	NN1218-4131	Max Obs per Subject	1025

Parameter Code=HBA1CONV Parameter=HbA1c (mmol/mol)

Obs	_Imputation_	STUDYID	Descr	Value
6	1	NN1218-4131	Covariance Parameters	1
7	1	NN1218-4131	Columns in X	10
8	1	NN1218-4131	Columns in Z	0
9	1	NN1218-4131	Subjects	1
10	1	NN1218-4131	Max Obs per Subject	1025

HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Number of Observations

Parameter Code=C64849B Parameter=HbA1c (%)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
1	1	NN1218-4131	Number of Observations Read	1025	1025	1025	1025	1025
2	1	NN1218-4131	Number of Observations Used	1025	1025	1025	1025	1025
3	1	NN1218-4131	Number of Observations Not Used	0	1025	1025	1025	1025

Parameter Code=HBA1CONV Parameter=HbA1c (mmol/mol)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
4	1	NN1218-4131	Number of Observations Read	1025	1025	1025	1025	1025
5	1	NN1218-4131	Number of Observations Used	1025	1025	1025	1025	1025
6	1	NN1218-4131	Number of Observations Not Used	0	1025	1025	1025	1025

HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Covariance Parameter Estimates

Parameter Code=C64849B Parameter=HbA1c (%)

Obs	_Imputation_	STUDYID	CovParm	Estimate
1	1	NN1218-4131	Residual	0.3630

Parameter Code=HBA1CONV Parameter=HbA1c (mmol/mol)

Obs	_Imputation_	STUDYID	CovParm	Estimate
101	1	NN1218-4131	Residual	43.3693

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The Mixed procedure
Fit Statistics

Parameter Code=C64849B Parameter=HbA1c (%)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	-2 Res Log Likelihood	1899.6
2	1	NN1218-4131	AIC (Smaller is Better)	1901.6
3	1	NN1218-4131	AICC (Smaller is Better)	1901.7
4	1	NN1218-4131	BIC (Smaller is Better)	1906.6

Parameter Code=HBA1CONV Parameter=HbA1c (mmol/mol)

Obs	_Imputation_	STUDYID	Descr	Value
5	1	NN1218-4131	-2 Res Log Likelihood	6768.8
6	1	NN1218-4131	AIC (Smaller is Better)	6770.8
7	1	NN1218-4131	AICC (Smaller is Better)	6770.8
8	1	NN1218-4131	BIC (Smaller is Better)	6775.7

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HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Solution for Fixed Effects

Parameter Code=C64849B Parameter=HbA1c (%)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
1	1	NN1218-4131	TRTPN	2				
2	1	NN1218-4131	TRTPN	3				
3	1	NN1218-4131	TRTPN	4				
4	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
5	1	NN1218-4131	REGION1	—	EUROPE			
6	1	NN1218-4131	REGION1	—	JAPAN			
7	1	NN1218-4131	REGION1	—	NORTH AMERICA			
8	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
9	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
10	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	2.1189	0.2099	1017	10.10	<.0001	0.05	1.7070	2.5307
2	2.2428	0.2088	1017	10.74	<.0001	0.05	1.8331	2.6526
3	2.1422	0.2089	1017	10.25	<.0001	0.05	1.7323	2.5522
4	-0.1285	0.06875	1017	-1.87	0.0618	0.05	-0.2635	0.006372
5	0.1006	0.04850	1017	2.07	0.0382	0.05	0.005464	0.1958
6	-0.09768	0.05426	1017	-1.80	0.0721	0.05	-0.2042	0.008797
7	0
8	-0.02718	0.04223	1017	-0.64	0.5200	0.05	-0.1100	0.05569
9	0
10	-0.2985	0.02722	1017	-10.97	<.0001	0.05	-0.3519	-0.2451

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The Mixed procedure
Solution for Fixed Effects

Parameter Code=HBA1CONV Parameter=HbA1c (mmol/mol)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
11	1	NN1218-4131	TRTPN	2				
12	1	NN1218-4131	TRTPN	3				
13	1	NN1218-4131	TRTPN	4				
14	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
15	1	NN1218-4131	REGION1	—	EUROPE			
16	1	NN1218-4131	REGION1	—	JAPAN			
17	1	NN1218-4131	REGION1	—	NORTH AMERICA			
18	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
19	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
20	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
11	16.1452	1.6754	1017	9.64	<.0001	0.05	12.8576	19.4328
12	17.5001	1.6642	1017	10.52	<.0001	0.05	14.2345	20.7658
13	16.4005	1.6660	1017	9.84	<.0001	0.05	13.1314	19.6696
14	-1.4050	0.7515	1017	-1.87	0.0618	0.05	-2.8795	0.06964
15	1.0999	0.5301	1017	2.07	0.0382	0.05	0.05973	2.1401
16	-1.0676	0.5931	1017	-1.80	0.0721	0.05	-2.2314	0.09615
17	0
18	-0.2970	0.4616	1017	-0.64	0.5200	0.05	-1.2028	0.6087
19	0
20	-0.2985	0.02722	1017	-10.97	<.0001	0.05	-0.3519	-0.2451

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HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Least Squares Means

Obs	_Imputation_	PARAMCD	PARAM	STUDYID	Effect	TRTPN	Margins
1	1	C64849B	HbA1c (%)	NN1218-4131	TRTPN	2	WORK.IMPUTE
2	1	C64849B	HbA1c (%)	NN1218-4131	TRTPN	3	WORK.IMPUTE
3	1	C64849B	HbA1c (%)	NN1218-4131	TRTPN	4	WORK.IMPUTE
4	1	HBA1CONV	HbA1c (mmol/mol)	NN1218-4131	TRTPN	2	WORK.IMPUTE
5	1	HBA1CONV	HbA1c (mmol/mol)	NN1218-4131	TRTPN	3	WORK.IMPUTE
6	1	HBA1CONV	HbA1c (mmol/mol)	NN1218-4131	TRTPN	4	WORK.IMPUTE

Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	-0.1193	0.03263	1017	-3.65	0.0003	0.05	-0.1833	-0.05522
2	0.004714	0.03267	1017	0.14	0.8853	0.05	-0.05939	0.06881
3	-0.09590	0.03262	1017	-2.94	0.0034	0.05	-0.1599	-0.03190
4	-1.3034	0.3567	1017	-3.65	0.0003	0.05	-2.0034	-0.6035
5	0.05153	0.3570	1017	0.14	0.8853	0.05	-0.6491	0.7521
6	-1.0481	0.3565	1017	-2.94	0.0034	0.05	-1.7477	-0.3486

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HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Least Squares Means Estimate

Parameter Code=C64849B Parameter=HbA1c (%)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
1	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
2	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	WORK.IMPUTE	-0.02336	0.04617	1017	-0.51	0.6131	0.05	-0.1140	0.06725
2	WORK.IMPUTE	0.1006	0.04617	1017	2.18	0.0296	0.05	0.01000	0.1912

Parameter Code=HBA1CONV Parameter=HbA1c (mmol/mol)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
3	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
4	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
3	WORK.IMPUTE	-0.2553	0.5047	1017	-0.51	0.6131	0.05	-1.2456	0.7351
4	WORK.IMPUTE	1.0997	0.5047	1017	2.18	0.0296	0.05	0.1093	2.0900

HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=C64849B Parameter=HbA1c (%) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	100

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000011792	0.001074	0.001086	823304	0.011087	0.010968	0.999890

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.124273	0.032955	-0.18886	-0.05968	823304	-0.133379	-0.115381

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-3.77	0.0002

HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=HBA1CONV Parameter=HbA1c (mmol/mol) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	100

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.001409	0.128323	0.129746	823304	0.011087	0.010968	0.999890

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-1.358299	0.360202	-2.06428	-0.65231	823304	-1.457830	-1.261113

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-3.77	0.0002

HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=C64849B Parameter=HbA1c (%) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	100

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000017174	0.001076	0.001094	393493	0.016117	0.015867	0.999841

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.003464	0.033069	-0.06828	0.061351	393493	-0.013947	0.007216

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-0.10	0.9166

HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=HBA1CONV Parameter=HbA1c (mmol/mol) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	100

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.002052	0.128572	0.130644	393493	0.016117	0.015867	0.999841

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.037863	0.361447	-0.74629	0.670563	393493	-0.152442	0.078876

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-0.10	0.9166

HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=C64849B Parameter=HbA1c (%) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	100

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000019715	0.001073	0.001093	298182	0.018559	0.018228	0.999818

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.094558	0.033058	-0.15935	-0.02977	298182	-0.106403	-0.085346

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-2.86	0.0042

HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=HBA1CONV Parameter=HbA1c (mmol/mol) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	100

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.002355	0.128174	0.130553	298182	0.018559	0.018228	0.999818

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-1.033520	0.361322	-1.74170	-0.32534	298182	-1.162989	-0.932829

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-2.86	0.0042

HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=C64849B Label=Faster aspart (meal) - NovoRapid (meal) Parameter=HbA1c (%) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	100

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000030198	0.002150	0.002181	506198	0.014183	0.013989	0.999860

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.029714	0.046700	-0.12125	0.061817	506198	-0.043502	-0.017542

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-0.64	0.5246

HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=C64849B Label=Faster aspart (post) - NovoRapid (meal) Parameter=HbA1c (%) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	100

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000034677	0.002150	0.002185	385440	0.016288	0.016032	0.999840

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.091094	0.046748	-0.00053	0.182719	385440	0.076661	0.104755

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	1.95	0.0513

HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=HBA1CONV Label=Faster aspart (meal) - NovoRapid (meal) Parameter=HbA1c (mmol/mol) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	100

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.003608	0.256900	0.260543	506198	0.014183	0.013989	0.999860

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.324779	0.510435	-1.32522	0.675656	506198	-0.475482	-0.191732

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-0.64	0.5246

HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=HBA1CONV Label=Faster aspart (post) - NovoRapid (meal) Parameter=HbA1c (mmol/mol) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	100

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.004143	0.256893	0.261077	385440	0.016288	0.016032	0.999840

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits	DF	Minimum	Maximum
Estimate	0.995657	0.510957	-0.00580 1.997118	385440	0.837909	1.144970

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	1.95	0.0513

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HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Model Information

Parameter Code=C64849B Parameter=HbA1c (%)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Data Set	WORK.IMPUTE_ABS
2	1	NN1218-4131	Dependent Variable	eotVisitAbs
3	1	NN1218-4131	Covariance Structure	Diagonal
4	1	NN1218-4131	Estimation Method	REML
5	1	NN1218-4131	Residual Variance Method	Profile
6	1	NN1218-4131	Fixed Effects SE Method	Model-Based
7	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=HBA1CONV Parameter=HbA1c (mmol/mol)

Obs	_Imputation_	STUDYID	Descr	Value
8	1	NN1218-4131	Data Set	WORK.IMPUTE_ABS
9	1	NN1218-4131	Dependent Variable	eotVisitAbs
10	1	NN1218-4131	Covariance Structure	Diagonal
11	1	NN1218-4131	Estimation Method	REML
12	1	NN1218-4131	Residual Variance Method	Profile
13	1	NN1218-4131	Fixed Effects SE Method	Model-Based
14	1	NN1218-4131	Degrees of Freedom Method	Residual

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HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Class Level Information

Parameter Code=C64849B Parameter=HbA1c (%)

Input				Output			
Subject				Variable			
Observations				Levels			
Study				Treatment			
1	1	NN1218-4131	TRTPN	3	2	3	4
2	1	NN1218-4131	REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA		
3	1	NN1218-4131	BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULI		

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HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Dimensions

Parameter Code=C64849B Parameter=HbA1c (%)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Covariance Parameters	1
2	1	NN1218-4131	Columns in X	10
3	1	NN1218-4131	Columns in Z	0
4	1	NN1218-4131	Subjects	1
5	1	NN1218-4131	Max Obs per Subject	1025

Parameter Code=HBA1CONV Parameter=HbA1c (mmol/mol)

Obs	_Imputation_	STUDYID	Descr	Value
6	1	NN1218-4131	Covariance Parameters	1
7	1	NN1218-4131	Columns in X	10
8	1	NN1218-4131	Columns in Z	0
9	1	NN1218-4131	Subjects	1
10	1	NN1218-4131	Max Obs per Subject	1025

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HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Number of Observations

Parameter Code=C64849B Parameter=HbA1c (%)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
1	1	NN1218-4131	Number of Observations Read	1025	1025	1025	1025	1025
2	1	NN1218-4131	Number of Observations Used	1025	1025	1025	1025	1025
3	1	NN1218-4131	Number of Observations Not Used	0	1025	1025	1025	1025

Parameter Code=HBA1CONV Parameter=HbA1c (mmol/mol)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
4	1	NN1218-4131	Number of Observations Read	1025	1025	1025	1025	1025
5	1	NN1218-4131	Number of Observations Used	1025	1025	1025	1025	1025
6	1	NN1218-4131	Number of Observations Not Used	0	1025	1025	1025	1025

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The Mixed procedure
Covariance Parameter Estimates

Parameter Code=C64849B Parameter=HbA1c (%)

Obs	_Imputation_	STUDYID	CovParm	Estimate
1	1	NN1218-4131	Residual	0.3630

Parameter Code=HBA1CONV Parameter=HbA1c (mmol/mol)

Obs	_Imputation_	STUDYID	CovParm	Estimate
101	1	NN1218-4131	Residual	43.3693

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The Mixed procedure
Fit Statistics

Parameter Code=C64849B Parameter=HbA1c (%)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	-2 Res Log Likelihood	1899.6
2	1	NN1218-4131	AIC (Smaller is Better)	1901.6
3	1	NN1218-4131	AICC (Smaller is Better)	1901.7
4	1	NN1218-4131	BIC (Smaller is Better)	1906.6

Parameter Code=HBA1CONV Parameter=HbA1c (mmol/mol)

Obs	_Imputation_	STUDYID	Descr	Value
5	1	NN1218-4131	-2 Res Log Likelihood	6768.8
6	1	NN1218-4131	AIC (Smaller is Better)	6770.8
7	1	NN1218-4131	AICC (Smaller is Better)	6770.8
8	1	NN1218-4131	BIC (Smaller is Better)	6775.7

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HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Solution for Fixed Effects

Parameter Code=C64849B Parameter=HbA1c (%)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
1	1	NN1218-4131	TRTPN	2				
2	1	NN1218-4131	TRTPN	3				
3	1	NN1218-4131	TRTPN	4				
4	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
5	1	NN1218-4131	REGION1	—	EUROPE			
6	1	NN1218-4131	REGION1	—	JAPAN			
7	1	NN1218-4131	REGION1	—	NORTH AMERICA			
8	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
9	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
10	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	2.1189	0.2099	1017	10.10	<.0001	0.05	1.7070	2.5307
2	2.2428	0.2088	1017	10.74	<.0001	0.05	1.8331	2.6526
3	2.1422	0.2089	1017	10.25	<.0001	0.05	1.7323	2.5522
4	-0.1285	0.06875	1017	-1.87	0.0618	0.05	-0.2635	0.006372
5	0.1006	0.04850	1017	2.07	0.0382	0.05	0.005464	0.1958
6	-0.09768	0.05426	1017	-1.80	0.0721	0.05	-0.2042	0.008797
7	0
8	-0.02718	0.04223	1017	-0.64	0.5200	0.05	-0.1100	0.05569
9	0
10	0.7015	0.02722	1017	25.77	<.0001	0.05	0.6481	0.7549

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HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Solution for Fixed Effects

Parameter Code=HBA1CONV Parameter=HbA1c (mmol/mol)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
11	1	NN1218-4131	TRTPN	2				
12	1	NN1218-4131	TRTPN	3				
13	1	NN1218-4131	TRTPN	4				
14	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
15	1	NN1218-4131	REGION1	—	EUROPE			
16	1	NN1218-4131	REGION1	—	JAPAN			
17	1	NN1218-4131	REGION1	—	NORTH AMERICA			
18	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
19	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
20	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
11	16.1452	1.6754	1017	9.64	<.0001	0.05	12.8576	19.4328
12	17.5001	1.6642	1017	10.52	<.0001	0.05	14.2345	20.7658
13	16.4005	1.6660	1017	9.84	<.0001	0.05	13.1314	19.6696
14	-1.4050	0.7515	1017	-1.87	0.0618	0.05	-2.8795	0.06964
15	1.0999	0.5301	1017	2.07	0.0382	0.05	0.05973	2.1401
16	-1.0676	0.5931	1017	-1.80	0.0721	0.05	-2.2314	0.09615
17	0
18	-0.2970	0.4616	1017	-0.64	0.5200	0.05	-1.2028	0.6087
19	0
20	0.7015	0.02722	1017	25.77	<.0001	0.05	0.6481	0.7549

nn1218/nn1218-4131/ctr_20180214_er
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HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Least Squares Means

Obs	_Imputation_	PARAMCD	PARAM	STUDYID	Effect	TRTPN	Margins
1	1	C64849B	HbA1c (%)	NN1218-4131	TRTPN	2	WORK.IMPUTE
101	1	HBA1CONV	HbA1c (mmol/mol)	NN1218-4131	TRTPN	2	WORK.IMPUTE
201	1	C64849B	HbA1c (%)	NN1218-4131	TRTPN	3	WORK.IMPUTE
301	1	HBA1CONV	HbA1c (mmol/mol)	NN1218-4131	TRTPN	3	WORK.IMPUTE
401	1	C64849B	HbA1c (%)	NN1218-4131	TRTPN	4	WORK.IMPUTE
501	1	HBA1CONV	HbA1c (mmol/mol)	NN1218-4131	TRTPN	4	WORK.IMPUTE

Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	-0.1193	0.03263	1017	-3.65	0.0003	0.05	-0.1833	-0.05522
101	-1.3034	0.3567	1017	-3.65	0.0003	0.05	-2.0034	-0.6035
201	0.004714	0.03267	1017	0.14	0.8853	0.05	-0.05939	0.06881
301	0.05153	0.3570	1017	0.14	0.8853	0.05	-0.6491	0.7521
401	-0.09590	0.03262	1017	-2.94	0.0034	0.05	-0.1599	-0.03190
501	-1.0481	0.3565	1017	-2.94	0.0034	0.05	-1.7477	-0.3486

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HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Least Squares Means Estimate

Parameter Code=C64849B Parameter=HbA1c (%)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
1	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
101	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	WORK.IMPUTE	-0.02336	0.04617	1017	-0.51	0.6131	0.05	-0.1140	0.06725
101	WORK.IMPUTE	0.1006	0.04617	1017	2.18	0.0296	0.05	0.01000	0.1912

Parameter Code=HBA1CONV Parameter=HbA1c (mmol/mol)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
201	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
301	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
201	WORK.IMPUTE	-0.2553	0.5047	1017	-0.51	0.6131	0.05	-1.2456	0.7351
301	WORK.IMPUTE	1.0997	0.5047	1017	2.18	0.0296	0.05	0.1093	2.0900

nn1218/nn1218-4131/ctr_20180214_er
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HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=C64849B Parameter=HbA1c (%) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	100

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000011792	0.001074	0.001086	823304	0.011087	0.010968	0.999890

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	7.300215	0.032955	7.235624	7.364807	823304	7.291109	7.309107

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	221.52	<.0001

HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=HBA1CONV Parameter=HbA1c (mmol/mol) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	100

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.001409	0.128323	0.129746	823304	0.011087	0.010968	0.999890

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	56.291352	0.360202	55.58537	56.99734	823304	56.191822	56.388539

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	156.28	<.0001

HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=C64849B Parameter=HbA1c (%) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	100

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000017174	0.001076	0.001094	393493	0.016117	0.015867	0.999841

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	7.421024	0.033069	7.356209	7.485838	393493	7.410541	7.431704

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	224.41	<.0001

HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=HBA1CONV Parameter=HbA1c (mmol/mol) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	100

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.002052	0.128572	0.130644	393493	0.016117	0.015867	0.999841

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	57.611789	0.361447	56.90336	58.32021	393493	57.497209	57.728527

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	159.39	<.0001

HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=C64849B Parameter=HbA1c (%) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	100

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000019715	0.001073	0.001093	298182	0.018559	0.018228	0.999818

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	7.329930	0.033058	7.265137	7.394722	298182	7.318084	7.339142

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	221.73	<.0001

HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=HBA1CONV Parameter=HbA1c (mmol/mol) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	100

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.002355	0.128174	0.130553	298182	0.018559	0.018228	0.999818

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	56.616132	0.361322	55.90795	57.32431	298182	56.486662	56.716822

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	156.69	<.0001

7: HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - per protocol analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=C64849B Planned Treatment for Period 30 (N)=2

Obs	PARAM	Description	Value
1	HbA1c (%)	Data Set	WORK.ENDPOINT_PARAM
2	HbA1c (%)	Method	Monotone-data_MCMC
3	HbA1c (%)	Multiple Imputation Chain	Multiple Chains
4	HbA1c (%)	Initial Estimates for MCMC	EM Posterior Mode
5	HbA1c (%)	Start	Starting Value
6	HbA1c (%)	Prior	Jeffreys
7	HbA1c (%)	Number of Imputations	100
8	HbA1c (%)	Number of Burn-in Iterations	200
9	HbA1c (%)	Seed for random number generator	8975

Parameter Code=C64849B Planned Treatment for Period 30 (N)=3

Obs	PARAM	Description	Value
10	HbA1c (%)	Data Set	WORK.ENDPOINT_PARAM
11	HbA1c (%)	Method	Monotone-data_MCMC
12	HbA1c (%)	Multiple Imputation Chain	Multiple Chains
13	HbA1c (%)	Initial Estimates for MCMC	EM Posterior Mode
14	HbA1c (%)	Start	Starting Value
15	HbA1c (%)	Prior	Jeffreys
16	HbA1c (%)	Number of Imputations	100
17	HbA1c (%)	Number of Burn-in Iterations	200
18	HbA1c (%)	Seed for random number generator	608321526

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Parameter Code=C64849B Planned Treatment for Period 30 (N)=4

Obs	PARAM	Description	Value
19	HbA1c (%)	Data Set	WORK.ENDPOINT_PARAM
20	HbA1c (%)	Method	Monotone-data_MCMC
21	HbA1c (%)	Multiple Imputation Chain	Multiple Chains
22	HbA1c (%)	Initial Estimates for MCMC	EM Posterior Mode
23	HbA1c (%)	Start	Starting Value
24	HbA1c (%)	Prior	Jeffreys
25	HbA1c (%)	Number of Imputations	100
26	HbA1c (%)	Number of Burn-in Iterations	200
27	HbA1c (%)	Seed for random number generator	1680600489

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Missing data pattern

Parameter Code=C64849B Planned Treatment for Period 30 (N)=2

Obs	PARAM	Group	BASE_ Miss	visit1400_ Miss	visit1800_ Miss	visit2200_ Miss	visit2600_ Miss	visit3000_ Miss	visit3400_ Miss	visit3600_ Miss	Freq	Percent
1	HbA1c (%)	1	X	X	X	X	X	X	X	X	328	95.91
2	HbA1c (%)	2	X	X	X	X	X	X	X	O	2	0.58
3	HbA1c (%)	3	X	X	X	X	X	X	.	X	3	0.88
4	HbA1c (%)	4	X	X	X	X	X	O	O	O	1	0.29
5	HbA1c (%)	5	X	X	X	O	O	O	O	O	2	0.58
6	HbA1c (%)	6	X	X	.	X	X	X	X	X	2	0.58
7	HbA1c (%)	7	X	X	.	.	X	X	X	X	1	0.29
8	HbA1c (%)	8	X	X	O	O	O	O	O	O	2	0.58
9	HbA1c (%)	9	X	.	X	X	X	.	.	X	1	0.29

Obs	BASE	visit1400	visit1800	visit2200	visit2600	visit3000	visit3400	visit3600
1	7.446951	-0.105183	-0.132012	-0.170427	-0.112500	-0.127744	-0.096951	-0.123476
2	7.850000	-0.200000	-0.250000	-0.350000	-0.200000	-0.300000	-0.400000	.
3	7.666667	-0.133333	-0.133333	-0.300000	-0.333333	-0.500000	.	0.266667
4	7.300000	-1.000000	-1.700000	-1.800000	-2.500000	.	.	.
5	7.800000	-0.150000	-0.400000
6	8.000000	-0.250000	.	0.100000	0.050000	-0.350000	0	0.150000
7	7.800000	0	.	.	0	-0.200000	-0.700000	-0.700000
8	7.750000	0.200000
9	6.300000	.	0.100000	0	-0.100000	.	.	-0.100000

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Missing data pattern

Parameter Code=C64849B Planned Treatment for Period 30 (N)=3

Obs	PARAM	Group	BASE_ Miss	visit1400_ Miss	visit1800_ Miss	visit2200_ Miss	visit2600_ Miss	visit3000_ Miss	visit3400_ Miss	visit3600_ Miss	Freq	Percent
10	HbA1c (%)	1	X	X	X	X	X	X	X	X	323	94.72
11	HbA1c (%)	2	X	X	X	X	X	X	.	X	3	0.88
12	HbA1c (%)	3	X	X	X	X	X	X	O	O	2	0.59
13	HbA1c (%)	4	X	X	X	X	X	.	X	X	2	0.59
14	HbA1c (%)	5	X	X	X	X	X	O	O	O	1	0.29
15	HbA1c (%)	6	X	X	X	X	.	X	X	X	1	0.29
16	HbA1c (%)	7	X	X	X	X	.	.	.	X	1	0.29
17	HbA1c (%)	8	X	X	X	X	O	O	O	O	3	0.88
18	HbA1c (%)	9	X	X	X	O	O	O	O	O	1	0.29
19	HbA1c (%)	10	X	X	.	X	X	X	X	X	1	0.29
20	HbA1c (%)	11	X	X	O	O	O	O	O	O	1	0.29

Obs	BASE	visit1400	visit1800	visit2200	visit2600	visit3000	visit3400	visit3600
10	7.414861	-0.052012	-0.020433	-0.044272	0.021362	0.021053	0.029721	-0.013003
11	6.700000	-0.100000	-0.166667	-0.300000	0.033333	0.366667	.	0.100000
12	6.700000	0.100000	0.100000	0	0.050000	0	.	.
13	7.350000	0.100000	-0.250000	-0.200000	0	.	0.800000	0.650000
14	8.000000	-0.600000	-0.600000	-0.800000	-0.700000	.	.	.
15	7.100000	0.100000	0.600000	1.000000	.	1.500000	1.600000	1.200000
16	8.100000	-0.400000	0.500000	0.700000	.	.	.	1.300000
17	7.500000	-0.100000	0.066667	0.233333
18	7.400000	0.600000	0.900000
19	7.400000	0.100000	.	0.100000	0.300000	0	0.100000	0.300000
20	6.600000	0.200000

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The MI Procedure with MCMC
Missing data pattern

Parameter Code=C64849B Planned Treatment for Period 30 (N)=3

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Obs	PARAM	Group	BASE_ Miss	visit1400_ Miss	visit1800_ Miss	visit2200_ Miss	visit2600_ Miss	visit3000_ Miss	visit3400_ Miss	visit3600_ Miss	Freq	Percent
21	HbA1c (%)	12	X	.	X	X	X	X	X	X	1	0.29
22	HbA1c (%)	13	X	O	O	O	O	O	O	O	1	0.29

Obs	BASE	visit1400	visit1800	visit2200	visit2600	visit3000	visit3400	visit3600
21	7.800000	.	-0.200000	-0.600000	-0.700000	-0.300000	-0.300000	-0.200000
22	6.900000

Parameter Code=C64849B Planned Treatment for Period 30 (N)=4

Obs	PARAM	Group	BASE_ Miss	visit1400_ Miss	visit1800_ Miss	visit2200_ Miss	visit2600_ Miss	visit3000_ Miss	visit3400_ Miss	visit3600_ Miss	Freq	Percent
23	HbA1c (%)	1	X	X	X	X	X	X	X	X	326	95.32
24	HbA1c (%)	2	X	X	X	X	X	X	X	O	1	0.29
25	HbA1c (%)	3	X	X	X	X	X	X	.	X	2	0.58

Obs	BASE	visit1400	visit1800	visit2200	visit2600	visit3000	visit3400	visit3600
23	7.407362	-0.065644	-0.050307	-0.065951	-0.029755	-0.073313	-0.064417	-0.103374
24	6.900000	0.100000	-0.100000	-0.400000	-0.200000	-0.100000	-0.100000	.
25	8.000000	-0.100000	0.350000	0.300000	0.350000	0.450000	.	0

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Missing data pattern

Parameter Code=C64849B Planned Treatment for Period 30 (N)=4

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Obs	PARAM	Group	BASE_ Miss	visit1400_ Miss	visit1800_ Miss	visit2200_ Miss	visit2600_ Miss	visit3000_ Miss	visit3400_ Miss	visit3600_ Miss	Freq	Percent
26	HbA1c (%)	4	X	X	X	X	X	O	O	O	1	0.29
27	HbA1c (%)	5	X	X	X	X	.	X	X	X	1	0.29
28	HbA1c (%)	6	X	X	X	X	.	.	X	X	1	0.29
29	HbA1c (%)	7	X	X	X	X	O	O	O	O	4	1.17
30	HbA1c (%)	8	X	X	X	.	X	X	X	X	1	0.29
31	HbA1c (%)	9	X	X	.	X	X	X	X	X	1	0.29
32	HbA1c (%)	10	X	X	O	O	O	O	O	O	2	0.58
33	HbA1c (%)	11	X	.	X	X	X	X	X	O	1	0.29
34	HbA1c (%)	12	X	O	O	O	O	O	O	O	1	0.29

Obs	BASE	visit1400	visit1800	visit2200	visit2600	visit3000	visit3400	visit3600
26	8.700000	0.500000	0.300000	-0.100000	-0.700000	.	.	.
27	7.900000	0	-0.600000	0	.	-0.100000	0	0
28	7.300000	-1.000000	0.400000	0.200000	.	.	1.400000	1.400000
29	7.500000	0.175000	0.450000	0.375000
30	7.100000	-0.300000	-0.200000	.	0.700000	0.500000	0.100000	-0.200000
31	7.200000	-0.700000	.	-0.700000	-0.700000	-0.800000	-0.800000	-0.800000
32	7.350000	0.250000
33	6.900000	.	1.100000	1.400000	1.500000	1.300000	1.100000	.
34	7.800000

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Model Information

Parameter Code=C64849B Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM	Description	Value
1	1	HbA1c (%)	Data Set	WORK.MONOTONE
2	1	HbA1c (%)	Method	Monotone
3	1	HbA1c (%)	Number of Imputations	1
4	1	HbA1c (%)	Seed for random number generator	12062

Parameter Code=C64849B Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM	Description	Value
5	1	HbA1c (%)	Data Set	WORK.MONOTONE
6	1	HbA1c (%)	Method	Monotone
7	1	HbA1c (%)	Number of Imputations	1
8	1	HbA1c (%)	Seed for random number generator	1744192987

Parameter Code=C64849B Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM	Description	Value
9	1	HbA1c (%)	Data Set	WORK.MONOTONE
10	1	HbA1c (%)	Method	Monotone
11	1	HbA1c (%)	Number of Imputations	1
12	1	HbA1c (%)	Seed for random number generator	542742855

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Missing Data Pattern

Parameter Code=C64849B Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM	Group	REGION1_ Miss	BOLAD1_ Miss	BASE_ Miss	visit1400_ Miss	visit1800_ Miss	visit2200_ Miss
1	1	HbA1c (%)	1	X	X	X	X	X	X
2	1	HbA1c (%)	2	X	X	X	X	X	X
3	1	HbA1c (%)	3	X	X	X	X	X	X
4	1	HbA1c (%)	4	X	X	X	X	X	.
5	1	HbA1c (%)	5	X	X	X	X	.	.

Obs	visit2600_ Miss	visit3000_ Miss	visit3400_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit1400
1	X	X	X	X	335	97.95	7.449851	-0.105534
2	X	X	X	.	2	0.58	7.850000	-0.200000
3	X	.	.	.	1	0.29	7.300000	-1.000000
4	2	0.58	7.800000	-0.150000
5	2	0.58	7.750000	0.200000

Obs	visit1800	visit2200	visit2600	visit3000	visit3400	visit3600
1	-0.129333	-0.170067	-0.113134	-0.132723	-0.097296	-0.120000
2	-0.250000	-0.350000	-0.200000	-0.300000	-0.400000	.
3	-1.700000	-1.800000	-2.500000	.	.	.
4	-0.400000
5

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Missing Data Pattern

Parameter Code=C64849B Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM	Group	REGION1_ Miss	BOLAD1_ Miss	BASE_ Miss	visit1400_ Miss	visit1800_ Miss	visit2200_ Miss
6	1	HbA1c (%)	1	X	X	X	X	X	X
7	1	HbA1c (%)	2	X	X	X	X	X	X
8	1	HbA1c (%)	3	X	X	X	X	X	X
9	1	HbA1c (%)	4	X	X	X	X	X	X
10	1	HbA1c (%)	5	X	X	X	X	X	.
11	1	HbA1c (%)	6	X	X	X	X	.	.

Obs	visit2600_ Miss	visit3000_ Miss	visit3400_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit1400
6	X	X	X	X	332	97.36	7.410241	-0.051925
7	X	X	.	.	2	0.59	6.700000	0.100000
8	X	.	.	.	1	0.29	8.000000	-0.600000
9	3	0.88	7.500000	-0.100000
10	1	0.29	7.400000	0.600000
11	1	0.29	6.600000	0.200000

Obs	visit1800	visit2200	visit2600	visit3000	visit3400	visit3600
6	-0.019630	-0.043373	0.026209	0.030406	0.045020	0
7	0.100000	0	0.050000	0	.	.
8	-0.600000	-0.800000	-0.700000	.	.	.
9	0.066667	0.233333
10	0.900000
11

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Parameter Code=C64849B Planned Treatment for Period 30 (N)=3

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Obs	_Imputation_	PARAM	Group	REGION1_	BOLAD1_	BASE_	visit1400_	visit1800_	visit2200_
				Miss	Miss	Miss	Miss	Miss	Miss
12	1	HbA1c (%)	7	X	X	X	.	.	.
Obs	visit2600_	visit3000_	visit3400_	visit3600_		Freq	Percent	BASE	visit1400
	Miss	Miss	Miss	Miss					
12		1	0.29	6.900000	.
Obs	visit1800	visit2200	visit2600	visit3000		visit3400	visit3600		
12		

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Missing Data Pattern

Parameter Code=C64849B Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM	Group	REGION1_ Miss	BOLAD1_ Miss	BASE_ Miss	visit1400_ Miss	visit1800_ Miss	visit2200_ Miss
13	1	HbA1c (%)	1	X	X	X	X	X	X
14	1	HbA1c (%)	2	X	X	X	X	X	X
15	1	HbA1c (%)	3	X	X	X	X	X	X
16	1	HbA1c (%)	4	X	X	X	X	X	X
17	1	HbA1c (%)	5	X	X	X	X	.	.
18	1	HbA1c (%)	6	X	X	X	.	.	.

Obs	visit2600_ Miss	visit3000_ Miss	visit3400_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit1400
13	X	X	X	X	332	97.08	7.410542	-0.071084
14	X	X	X	.	2	0.58	6.900000	0.468903
15	X	.	.	.	1	0.29	8.700000	0.500000
16	4	1.17	7.500000	0.175000
17	2	0.58	7.350000	0.250000
18	1	0.29	7.800000	.

Obs	visit1800	visit2200	visit2600	visit3000	visit3400	visit3600
13	-0.050291	-0.064895	-0.026857	-0.068152	-0.060043	-0.100301
14	0.500000	0.500000	0.650000	0.600000	0.500000	.
15	0.300000	-0.100000	-0.700000	.	.	.
16	0.450000	0.375000
17
18

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Regression Information

Parameter Code=C64849B Planned Treatment for Period 30 (N)=2 Imputed Variable=visit1800

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
1	1	HbA1c (%)	Intercept			0.00639	0.030295
2	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)		-0.00397	-0.080742
3	1	HbA1c (%)	REGION1	EUROPE		-0.01838	-0.008851
4	1	HbA1c (%)	REGION1	JAPAN		-0.02133	0.066650
5	1	HbA1c (%)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.03348	-0.006927
6	1	HbA1c (%)	BASE			-0.09369	-0.114860
7	1	HbA1c (%)	visit1400			0.79293	0.790290

Parameter Code=C64849B Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
8	1	HbA1c (%)	Intercept			0.00358	-0.049185
9	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)		0.02904	-0.016547
10	1	HbA1c (%)	REGION1	EUROPE		0.03115	0.093679
11	1	HbA1c (%)	REGION1	JAPAN		-0.03608	-0.145467
12	1	HbA1c (%)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.02776	-0.019356
13	1	HbA1c (%)	BASE			-0.08869	-0.048912
14	1	HbA1c (%)	visit1400			0.07228	0.118740
15	1	HbA1c (%)	visit1800			0.76800	0.715296

Parameter Code=C64849B Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
16	1	HbA1c (%)	Intercept			-0.03726	-0.051076
17	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)		-0.16165	-0.230016

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Parameter Code=C64849B Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2600

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Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
18	1	HbA1c (%)	REGION1	EUROPE		0.11329	0.128863
19	1	HbA1c (%)	REGION1	JAPAN		-0.01346	0.023797
20	1	HbA1c (%)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.00216	-0.017601
21	1	HbA1c (%)	BASE			-0.08287	-0.163134
22	1	HbA1c (%)	visit1400			-0.01416	-0.012006
23	1	HbA1c (%)	visit1800			0.01579	0.025271
24	1	HbA1c (%)	visit2200			0.83374	0.789972

Parameter Code=C64849B Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3000

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
25	1	HbA1c (%)	Intercept			-0.00383	-0.002846
26	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)		0.07355	0.106175
27	1	HbA1c (%)	REGION1	EUROPE		-0.01207	-0.060214
28	1	HbA1c (%)	REGION1	JAPAN		-0.05891	-0.046961
29	1	HbA1c (%)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.01686	-0.003239
30	1	HbA1c (%)	BASE			-0.04663	-0.028801
31	1	HbA1c (%)	visit1400			-0.01127	0.022466
32	1	HbA1c (%)	visit1800			-0.03336	-0.035810
33	1	HbA1c (%)	visit2200			0.12767	0.128763
34	1	HbA1c (%)	visit2600			0.80549	0.826496

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Parameter Code=C64849B Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3400

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
35	1	HbA1c (%)	Intercept			-0.01524	0.007331
36	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)		-0.02216	-0.100682
37	1	HbA1c (%)	REGION1	EUROPE		0.06348	0.094848
38	1	HbA1c (%)	REGION1	JAPAN		0.00166	0.036583
39	1	HbA1c (%)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.03787	0.059346
40	1	HbA1c (%)	BASE			-0.02768	-0.009303
41	1	HbA1c (%)	visit1400			0.02900	-0.041852
42	1	HbA1c (%)	visit1800			0.07132	0.079834
43	1	HbA1c (%)	visit2200			0.11248	0.175282
44	1	HbA1c (%)	visit2600			0.03175	-0.085275
45	1	HbA1c (%)	visit3000			0.69093	0.759019

Parameter Code=C64849B Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
46	1	HbA1c (%)	Intercept			-0.01257	-0.053579
47	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)		0.00827	0.015092
48	1	HbA1c (%)	REGION1	EUROPE		0.07571	0.088187
49	1	HbA1c (%)	REGION1	JAPAN		-0.02707	-0.077316
50	1	HbA1c (%)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.03386	0.053494
51	1	HbA1c (%)	BASE			-0.01153	-0.022121
52	1	HbA1c (%)	visit1400			-0.05724	-0.016244
53	1	HbA1c (%)	visit1800			0.06590	0.105655
54	1	HbA1c (%)	visit2200			-0.02967	-0.148627
55	1	HbA1c (%)	visit2600			-0.02253	-0.001334
56	1	HbA1c (%)	visit3000			0.18199	0.153611
57	1	HbA1c (%)	visit3400			0.78741	0.819855

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Parameter Code=C64849B Planned Treatment for Period 30 (N)=3 Imputed Variable=visit1400

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
58	1	HbA1c (%)	Intercept			0.03816	0.079494
59	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)		0.15715	0.403576
60	1	HbA1c (%)	REGION1	EUROPE		-0.02843	-0.087338
61	1	HbA1c (%)	REGION1	JAPAN		0.01433	-0.188348
62	1	HbA1c (%)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.08341	-0.109016
63	1	HbA1c (%)	BASE			-0.18384	-0.240280

Parameter Code=C64849B Planned Treatment for Period 30 (N)=3 Imputed Variable=visit1800

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
64	1	HbA1c (%)	Intercept			-0.01854	-0.024560
65	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)		-0.09749	0.000323
66	1	HbA1c (%)	REGION1	EUROPE		0.05573	0.100477
67	1	HbA1c (%)	REGION1	JAPAN		0.00413	-0.133024
68	1	HbA1c (%)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.01219	0.048950
69	1	HbA1c (%)	BASE			-0.08475	-0.122926
70	1	HbA1c (%)	visit1400			0.68629	0.681417

Parameter Code=C64849B Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
71	1	HbA1c (%)	Intercept			0.01209	-0.029222
72	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)		-0.01396	-0.069781
73	1	HbA1c (%)	REGION1	EUROPE		-0.04753	0.009328
74	1	HbA1c (%)	REGION1	JAPAN		0.02411	0.005100

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Parameter Code=C64849B Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2200

(continued)

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
75	1	HbA1c (%)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.05128	-0.056618
76	1	HbA1c (%)	BASE			-0.08115	-0.070487
77	1	HbA1c (%)	visit1400			-0.12968	-0.126604
78	1	HbA1c (%)	visit1800			0.88913	0.910423

Parameter Code=C64849B Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
79	1	HbA1c (%)	Intercept			-0.01841	0.008543
80	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)		-0.11287	0.011671
81	1	HbA1c (%)	REGION1	EUROPE		0.03948	-0.056695
82	1	HbA1c (%)	REGION1	JAPAN		-0.07110	-0.049005
83	1	HbA1c (%)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.00108	-0.015617
84	1	HbA1c (%)	BASE			-0.04928	-0.065390
85	1	HbA1c (%)	visit1400			-0.04442	-0.074602
86	1	HbA1c (%)	visit1800			0.03194	0.054341
87	1	HbA1c (%)	visit2200			0.80586	0.792381

Parameter Code=C64849B Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3000

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
88	1	HbA1c (%)	Intercept			-0.02231	0.028501
89	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)		-0.08391	-0.136221

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Parameter Code=C64849B Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3000

(continued)

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
90	1	HbA1c (%)	REGION1	EUROPE		0.07484	0.127567
91	1	HbA1c (%)	REGION1	JAPAN		-0.05798	-0.097467
92	1	HbA1c (%)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.0006146	0.011848
93	1	HbA1c (%)	BASE			-0.03591	-0.039717
94	1	HbA1c (%)	visit1400			0.06041	0.104609
95	1	HbA1c (%)	visit1800			0.02379	-0.023836
96	1	HbA1c (%)	visit2200			0.05723	0.077347
97	1	HbA1c (%)	visit2600			0.75261	0.787367

Parameter Code=C64849B Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3400

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
98	1	HbA1c (%)	Intercept			-0.00924	0.004529
99	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)		-0.01353	0.039823
100	1	HbA1c (%)	REGION1	EUROPE		0.12195	0.130323
101	1	HbA1c (%)	REGION1	JAPAN		-0.06695	-0.063766
102	1	HbA1c (%)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.00425	-0.075874
103	1	HbA1c (%)	BASE			-0.04464	0.005276
104	1	HbA1c (%)	visit1400			-0.01011	0.016828
105	1	HbA1c (%)	visit1800			0.19217	0.266133
106	1	HbA1c (%)	visit2200			-0.11909	-0.302867
107	1	HbA1c (%)	visit2600			-0.07608	-0.097972
108	1	HbA1c (%)	visit3000			0.86365	1.019770

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Parameter Code=C64849B Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
109	1	HbA1c (%)	Intercept			-0.00765	-0.035246
110	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)		-0.01202	-0.009100
111	1	HbA1c (%)	REGION1	EUROPE		-0.00388	0.010618
112	1	HbA1c (%)	REGION1	JAPAN		-0.02210	-0.077851
113	1	HbA1c (%)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.04956	0.041597
114	1	HbA1c (%)	BASE			-0.05107	-0.050083
115	1	HbA1c (%)	visit1400			0.03663	0.049510
116	1	HbA1c (%)	visit1800			-0.03385	-0.026602
117	1	HbA1c (%)	visit2200			0.06658	0.004559
118	1	HbA1c (%)	visit2600			-0.01151	0.014266
119	1	HbA1c (%)	visit3000			0.03272	-0.000143
120	1	HbA1c (%)	visit3400			0.85292	0.892199

Parameter Code=C64849B Planned Treatment for Period 30 (N)=4 Imputed Variable=visit1400

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
121	1	HbA1c (%)	Intercept			0.01582	-0.044342
122	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)		0.09893	0.215706
123	1	HbA1c (%)	REGION1	EUROPE		-0.04085	-0.123022
124	1	HbA1c (%)	REGION1	JAPAN		-0.08888	-0.116016
125	1	HbA1c (%)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.02327	-0.129873
126	1	HbA1c (%)	BASE			-0.10504	-0.073701

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Parameter Code=C64849B Planned Treatment for Period 30 (N)=4 Imputed Variable=visit1800

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
127	1	HbA1c (%)	Intercept			0.00943	-0.017580
128	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)		0.10713	0.089265
129	1	HbA1c (%)	REGION1	EUROPE		0.02976	0.077973
130	1	HbA1c (%)	REGION1	JAPAN		-0.14690	-0.185552
131	1	HbA1c (%)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.00181	0.042617
132	1	HbA1c (%)	BASE			-0.22452	-0.233303
133	1	HbA1c (%)	visit1400			0.58687	0.629091

Parameter Code=C64849B Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
134	1	HbA1c (%)	Intercept			0.00819	0.017120
135	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)		0.04853	0.107203
136	1	HbA1c (%)	REGION1	EUROPE		-0.01235	-0.027983
137	1	HbA1c (%)	REGION1	JAPAN		-0.05082	-0.042794
138	1	HbA1c (%)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.01505	-0.055192
139	1	HbA1c (%)	BASE			-0.08880	-0.115988
140	1	HbA1c (%)	visit1400			0.10643	0.117817
141	1	HbA1c (%)	visit1800			0.72408	0.673635

Parameter Code=C64849B Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
142	1	HbA1c (%)	Intercept			-0.00768	0.025035
143	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)		-0.13140	-0.132637

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Parameter Code=C64849B Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2600

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Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
144	1	HbA1c (%)	REGION1	EUROPE		0.02017	-0.029917
145	1	HbA1c (%)	REGION1	JAPAN		0.06258	0.074856
146	1	HbA1c (%)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.00412	-0.074169
147	1	HbA1c (%)	BASE			-0.09055	-0.092287
148	1	HbA1c (%)	visit1400			-0.07777	-0.038366
149	1	HbA1c (%)	visit1800			0.09814	0.001140
150	1	HbA1c (%)	visit2200			0.71313	0.776751

Parameter Code=C64849B Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3000

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
151	1	HbA1c (%)	Intercept			-0.00605	0.010445
152	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)		-0.03462	0.005549
153	1	HbA1c (%)	REGION1	EUROPE		0.07363	0.038813
154	1	HbA1c (%)	REGION1	JAPAN		-0.02228	-0.016491
155	1	HbA1c (%)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.04195	-0.089409
156	1	HbA1c (%)	BASE			-0.07276	-0.059509
157	1	HbA1c (%)	visit1400			-0.03674	-0.023941
158	1	HbA1c (%)	visit1800			-0.04918	-0.059163
159	1	HbA1c (%)	visit2200			-0.06338	0.019549
160	1	HbA1c (%)	visit2600			0.93081	0.853648

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Parameter Code=C64849B Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3400

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
161	1	HbA1c (%)	Intercept			-0.02177	-0.005021
162	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)		-0.16683	-0.191042
163	1	HbA1c (%)	REGION1	EUROPE		0.12683	0.155599
164	1	HbA1c (%)	REGION1	JAPAN		0.02343	0.031103
165	1	HbA1c (%)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.01675	-0.032151
166	1	HbA1c (%)	BASE			-0.07402	-0.034914
167	1	HbA1c (%)	visit1400			-0.05841	-0.058097
168	1	HbA1c (%)	visit1800			0.12237	0.123572
169	1	HbA1c (%)	visit2200			0.07108	0.123461
170	1	HbA1c (%)	visit2600			-0.06216	-0.134717
171	1	HbA1c (%)	visit3000			0.80080	0.821645

Parameter Code=C64849B Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
172	1	HbA1c (%)	Intercept			0.00204	0.018580
173	1	HbA1c (%)	REGION1	ASIA (EXCLUDING JAPAN)		-0.05393	-0.033459
174	1	HbA1c (%)	REGION1	EUROPE		0.06712	0.042920
175	1	HbA1c (%)	REGION1	JAPAN		-0.00631	0.019897
176	1	HbA1c (%)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.03625	-0.063387
177	1	HbA1c (%)	BASE			-0.02899	-0.056317
178	1	HbA1c (%)	visit1400			-0.02160	-0.010628
179	1	HbA1c (%)	visit1800			0.01385	0.054644
180	1	HbA1c (%)	visit2200			0.10982	0.103707
181	1	HbA1c (%)	visit2600			-0.03828	-0.126796
182	1	HbA1c (%)	visit3000			-0.20201	-0.171484
183	1	HbA1c (%)	visit3400			1.02047	1.045187

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The MI Procedure with MCMC
Model Information

Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=2

Obs	PARAM	Description	Value
1	HbA1c (mmol/mol)	Data Set	WORK.ENDPOINT_PARAM
2	HbA1c (mmol/mol)	Method	Monotone-data_MCMC
3	HbA1c (mmol/mol)	Multiple Imputation Chain	Multiple Chains
4	HbA1c (mmol/mol)	Initial Estimates for MCMC	EM Posterior Mode
5	HbA1c (mmol/mol)	Start	Starting Value
6	HbA1c (mmol/mol)	Prior	Jeffreys
7	HbA1c (mmol/mol)	Number of Imputations	100
8	HbA1c (mmol/mol)	Number of Burn-in Iterations	200
9	HbA1c (mmol/mol)	Seed for random number generator	8975

Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=3

Obs	PARAM	Description	Value
10	HbA1c (mmol/mol)	Data Set	WORK.ENDPOINT_PARAM
11	HbA1c (mmol/mol)	Method	Monotone-data_MCMC
12	HbA1c (mmol/mol)	Multiple Imputation Chain	Multiple Chains
13	HbA1c (mmol/mol)	Initial Estimates for MCMC	EM Posterior Mode
14	HbA1c (mmol/mol)	Start	Starting Value
15	HbA1c (mmol/mol)	Prior	Jeffreys
16	HbA1c (mmol/mol)	Number of Imputations	100
17	HbA1c (mmol/mol)	Number of Burn-in Iterations	200
18	HbA1c (mmol/mol)	Seed for random number generator	608321526

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The MI Procedure with MCMC
Model Information

Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=4

Obs	PARAM	Description	Value
19	HbA1c (mmol/mol)	Data Set	WORK.ENDPOINT_PARAM
20	HbA1c (mmol/mol)	Method	Monotone-data_MCMC
21	HbA1c (mmol/mol)	Multiple Imputation Chain	Multiple Chains
22	HbA1c (mmol/mol)	Initial Estimates for MCMC	EM Posterior Mode
23	HbA1c (mmol/mol)	Start	Starting Value
24	HbA1c (mmol/mol)	Prior	Jeffreys
25	HbA1c (mmol/mol)	Number of Imputations	100
26	HbA1c (mmol/mol)	Number of Burn-in Iterations	200
27	HbA1c (mmol/mol)	Seed for random number generator	1680600489

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The MI Procedure with MCMC
Missing data pattern

Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=2

Obs	PARAM	Group	BASE_ Miss	visit1400_ Miss	visit1800_ Miss	visit2200_ Miss	visit2600_ Miss	visit3000_ Miss	visit3400_ Miss	visit3600_ Miss	Freq
1	HbA1c (mmol/mol)	1	X	X	X	X	X	X	X	X	328
2	HbA1c (mmol/mol)	2	X	X	X	X	X	X	X	O	2
3	HbA1c (mmol/mol)	3	X	X	X	X	X	X	.	X	3
4	HbA1c (mmol/mol)	4	X	X	X	X	X	O	O	O	1
5	HbA1c (mmol/mol)	5	X	X	X	O	O	O	O	O	2
6	HbA1c (mmol/mol)	6	X	X	.	X	X	X	X	X	2
7	HbA1c (mmol/mol)	7	X	X	.	.	X	X	X	X	1
8	HbA1c (mmol/mol)	8	X	X	O	O	O	O	O	O	2
9	HbA1c (mmol/mol)	9	X	.	X	X	X	.	.	X	1

Obs	Percent	BASE	visit1400	visit1800	visit2200	visit2600	visit3000	visit3400	visit3600
1	95.91	57.895177	-1.149649	-1.442893	-1.862765	-1.229625	-1.396241	-1.059677	-1.349588
2	0.58	62.300500	-2.186000	-2.732500	-3.825500	-2.186000	-3.279000	-4.372000	.
3	0.88	60.296667	-1.457333	-1.457333	-3.279000	-3.643333	-5.465000	.	2.914667
4	0.29	56.289000	-10.930000	-18.581000	-19.674000	-27.325000	.	.	.
5	0.58	61.754000	-1.639500	-4.372000
6	0.58	63.940000	-2.732500	.	1.093000	0.546500	-3.825500	0	1.639500
7	0.29	61.754000	0	.	.	0	-2.186000	-7.651000	-7.651000
8	0.58	61.207500	2.186000
9	0.29	45.359000	.	1.093000	0	-1.093000	.	.	-1.093000

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HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - per protocol analysis set

The MI Procedure with MCMC
Missing data pattern

Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=3

Obs	PARAM	Group	BASE_ Miss	visit1400_ Miss	visit1800_ Miss	visit2200_ Miss	visit2600_ Miss	visit3000_ Miss	visit3400_ Miss	visit3600_ Miss	Freq
10	HbA1c (mmol/mol)	1	X	X	X	X	X	X	X	X	323
11	HbA1c (mmol/mol)	2	X	X	X	X	X	X	.	X	3
12	HbA1c (mmol/mol)	3	X	X	X	X	X	X	O	O	2
13	HbA1c (mmol/mol)	4	X	X	X	X	X	.	X	X	2
14	HbA1c (mmol/mol)	5	X	X	X	X	X	O	O	O	1
15	HbA1c (mmol/mol)	6	X	X	X	X	.	X	X	X	1
16	HbA1c (mmol/mol)	7	X	X	X	X	.	.	.	X	1
17	HbA1c (mmol/mol)	8	X	X	X	X	O	O	O	O	3
18	HbA1c (mmol/mol)	9	X	X	X	O	O	O	O	O	1
19	HbA1c (mmol/mol)	10	X	X	.	X	X	X	X	X	1
20	HbA1c (mmol/mol)	11	X	X	O	O	O	O	O	O	1

Obs	Percent	BASE	visit1400	visit1800	visit2200	visit2600	visit3000	visit3400	visit3600
10	94.72	57.544427	-0.568495	-0.223337	-0.483898	0.233489	0.230105	0.324854	-0.142124
11	0.88	49.731000	-1.093000	-1.821667	-3.279000	0.364333	4.007667	.	1.093000
12	0.59	49.731000	1.093000	1.093000	0	0.546500	0	.	.
13	0.59	56.835500	1.093000	-2.732500	-2.186000	0	.	8.744000	7.104500
14	0.29	63.940000	-6.558000	-6.558000	-8.744000	-7.651000	.	.	.
15	0.29	54.103000	1.093000	6.558000	10.930000	.	16.395000	17.488000	13.116000
16	0.29	65.033000	-4.372000	5.465000	7.651000	.	.	.	14.209000
17	0.88	58.475000	-1.093000	0.728667	2.550333
18	0.29	57.382000	6.558000	9.837000
19	0.29	57.382000	1.093000	.	1.093000	3.279000	0	1.093000	3.279000
20	0.29	48.638000	2.186000

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The MI Procedure with MCMC
Missing data pattern

Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=3

(continued)

Obs	PARAM	Group	BASE_ Miss	visit1400_ Miss	visit1800_ Miss	visit2200_ Miss	visit2600_ Miss	visit3000_ Miss	visit3400_ Miss	visit3600_ Miss	Freq
21	HbA1c (mmol/mol)	12	X	.	X	X	X	X	X	X	1
22	HbA1c (mmol/mol)	13	X	O	O	O	O	O	O	O	1

Obs	Percent	BASE	visit1400	visit1800	visit2200	visit2600	visit3000	visit3400	visit3600
21	0.29	61.754000	.	-2.186000	-6.558000	-7.651000	-3.279000	-3.279000	-2.186000
22	0.29	51.917000

Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=4

Obs	PARAM	Group	BASE_ Miss	visit1400_ Miss	visit1800_ Miss	visit2200_ Miss	visit2600_ Miss	visit3000_ Miss	visit3400_ Miss	visit3600_ Miss	Freq
23	HbA1c (mmol/mol)	1	X	X	X	X	X	X	X	X	326
24	HbA1c (mmol/mol)	2	X	X	X	X	X	X	X	O	1
25	HbA1c (mmol/mol)	3	X	X	X	X	X	X	.	X	2

Obs	Percent	BASE	visit1400	visit1800	visit2200	visit2600	visit3000	visit3400	visit3600
23	95.32	57.462466	-0.717491	-0.549853	-0.720844	-0.325218	-0.801310	-0.704080	-1.129880
24	0.29	51.917000	1.093000	-1.093000	-4.372000	-2.186000	-1.093000	-1.093000	.
25	0.58	63.940000	-1.093000	3.825500	3.279000	3.825500	4.918500	.	0

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The MI Procedure with MCMC
Missing data pattern

Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=4

(continued)

Obs	PARAM	Group	BASE_ Miss	visit1400_ Miss	visit1800_ Miss	visit2200_ Miss	visit2600_ Miss	visit3000_ Miss	visit3400_ Miss	visit3600_ Miss	Freq
26	HbA1c (mmol/mol)	4	X	X	X	X	X	O	O	O	1
27	HbA1c (mmol/mol)	5	X	X	X	X	.	X	X	X	1
28	HbA1c (mmol/mol)	6	X	X	X	X	.	.	X	X	1
29	HbA1c (mmol/mol)	7	X	X	X	X	O	O	O	O	4
30	HbA1c (mmol/mol)	8	X	X	X	.	X	X	X	X	1
31	HbA1c (mmol/mol)	9	X	X	.	X	X	X	X	X	1
32	HbA1c (mmol/mol)	10	X	X	O	O	O	O	O	O	2
33	HbA1c (mmol/mol)	11	X	.	X	X	X	X	X	O	1
34	HbA1c (mmol/mol)	12	X	O	O	O	O	O	O	O	1

Obs	Percent	BASE	visit1400	visit1800	visit2200	visit2600	visit3000	visit3400	visit3600
26	0.29	71.591000	5.465000	3.279000	-1.093000	-7.651000	.	.	.
27	0.29	62.847000	0	-6.558000	0	.	-1.093000	0	0
28	0.29	56.289000	-10.930000	4.372000	2.186000	.	.	15.302000	15.302000
29	1.17	58.475000	1.912750	4.918500	4.098750
30	0.29	54.103000	-3.279000	-2.186000	.	7.651000	5.465000	1.093000	-2.186000
31	0.29	55.196000	-7.651000	.	-7.651000	-7.651000	-8.744000	-8.744000	-8.744000
32	0.58	56.835500	2.732500
33	0.29	51.917000	.	12.023000	15.302000	16.395000	14.209000	12.023000	.
34	0.29	61.754000

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The MI Procedure with Monotone Regression
Model Information

Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM	Description	Value
1	1	HbA1c (mmol/mol)	Data Set	WORK.MONOTONE
2	1	HbA1c (mmol/mol)	Method	Monotone
3	1	HbA1c (mmol/mol)	Number of Imputations	1
4	1	HbA1c (mmol/mol)	Seed for random number generator	12062

Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM	Description	Value
5	1	HbA1c (mmol/mol)	Data Set	WORK.MONOTONE
6	1	HbA1c (mmol/mol)	Method	Monotone
7	1	HbA1c (mmol/mol)	Number of Imputations	1
8	1	HbA1c (mmol/mol)	Seed for random number generator	1744192987

Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM	Description	Value
9	1	HbA1c (mmol/mol)	Data Set	WORK.MONOTONE
10	1	HbA1c (mmol/mol)	Method	Monotone
11	1	HbA1c (mmol/mol)	Number of Imputations	1
12	1	HbA1c (mmol/mol)	Seed for random number generator	542742855

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The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM	Group	REGION1_	BOLAD1_	BASE_	visit1400_	visit1800_	visit2200_
				Miss	Miss	Miss	Miss	Miss	Miss
1	1	HbA1c (mmol/mol)	1	X	X	X	X	X	X
2	1	HbA1c (mmol/mol)	2	X	X	X	X	X	X
3	1	HbA1c (mmol/mol)	3	X	X	X	X	X	X
4	1	HbA1c (mmol/mol)	4	X	X	X	X	X	.
5	1	HbA1c (mmol/mol)	5	X	X	X	X	.	.

Obs	visit2600_	visit3000_	visit3400_	visit3600_	Freq	Percent	BASE	visit1400
	Miss	Miss	Miss	Miss				
1	X	X	X	X	335	97.95	57.926869	-1.153483
2	X	X	X	.	2	0.58	62.300500	-2.186000
3	X	.	.	.	1	0.29	56.289000	-10.930000
4	2	0.58	61.754000	-1.639500
5	2	0.58	61.207500	2.186000

Obs	visit1800	visit2200	visit2600	visit3000	visit3400	visit3600
1	-1.413607	-1.858833	-1.236558	-1.450666	-1.063448	-1.311600
2	-2.732500	-3.825500	-2.186000	-3.279000	-4.372000	.
3	-18.581000	-19.674000	-27.325000	.	.	.
4	-4.372000
5

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The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM	Group	REGION1_ Miss	BOLAD1_ Miss	BASE_ Miss	visit1400_ Miss	visit1800_ Miss	visit2200_ Miss
6	1	HbA1c (mmol/mol)	1	X	X	X	X	X	X
7	1	HbA1c (mmol/mol)	2	X	X	X	X	X	X
8	1	HbA1c (mmol/mol)	3	X	X	X	X	X	X
9	1	HbA1c (mmol/mol)	4	X	X	X	X	X	X
10	1	HbA1c (mmol/mol)	5	X	X	X	X	X	.
11	1	HbA1c (mmol/mol)	6	X	X	X	X	.	.

Obs	visit2600_ Miss	visit3000_ Miss	visit3400_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit1400
6	X	X	X	X	332	97.36	57.493934	-0.567543
7	X	X	.	.	2	0.59	49.731000	1.093000
8	X	.	.	.	1	0.29	63.940000	-6.558000
9	3	0.88	58.475000	-1.093000
10	1	0.29	57.382000	6.558000
11	1	0.29	48.638000	2.186000

Obs	visit1800	visit2200	visit2600	visit3000	visit3400	visit3600
6	-0.214557	-0.474072	0.286469	0.332339	0.492065	0
7	1.093000	0	0.546500	0	.	.
8	-6.558000	-8.744000	-7.651000	.	.	.
9	0.728667	2.550333
10	9.837000
11

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HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - per protocol analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=3

(continued)

Obs	_Imputation_	PARAM	Group	REGION1_	BOLAD1_	BASE_	visit1400_	visit1800_	visit2200_
				Miss	Miss	Miss	Miss	Miss	Miss
12	1	HbA1c (mmol/mol)	7	X	X	X	.	.	.
Obs	visit2600_	visit3000_	visit3400_	visit3600_	Freq	Percent	BASE	visit1400	
	Miss	Miss	Miss	Miss					
12	1	0.29	51.917000		.
Obs	visit1800	visit2200	visit2600	visit3000	visit3400	visit3600			
12		

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HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - per protocol analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM	Group	REGION1_ Miss	BOLAD1_ Miss	BASE_ Miss	visit1400_ Miss	visit1800_ Miss	visit2200_ Miss
13	1	HbA1c (mmol/mol)	1	X	X	X	X	X	X
14	1	HbA1c (mmol/mol)	2	X	X	X	X	X	X
15	1	HbA1c (mmol/mol)	3	X	X	X	X	X	X
16	1	HbA1c (mmol/mol)	4	X	X	X	X	X	X
17	1	HbA1c (mmol/mol)	5	X	X	X	X	.	.
18	1	HbA1c (mmol/mol)	6	X	X	X	.	.	.

Obs	visit2600_ Miss	visit3000_ Miss	visit3400_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit1400
13	X	X	X	X	332	97.08	57.497226	-0.776952
14	X	X	X	.	2	0.58	51.917000	5.125105
15	X	.	.	.	1	0.29	71.591000	5.465000
16	4	1.17	58.475000	1.912750
17	2	0.58	56.835500	2.732500
18	1	0.29	61.754000	.

Obs	visit1800	visit2200	visit2600	visit3000	visit3400	visit3600
13	-0.549680	-0.709305	-0.293548	-0.744902	-0.656268	-1.096292
14	5.465000	5.465000	7.104500	6.558000	5.465000	.
15	3.279000	-1.093000	-7.651000	.	.	.
16	4.918500	4.098750
17
18

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HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - per protocol analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=2 Imputed Variable=visit1800

O b s	i n s	P a r a m e t e r	E f f e c t	R e g i o n	B o l u s	O b s e r v e d	I n t e r c e p t
1	1	HbA1c (mmol/mol)	Intercept			0.00639	0.030295
2	1	HbA1c (mmol/mol)	REGION1	ASIA (EXCLUDING JAPAN)		-0.00397	-0.080742
3	1	HbA1c (mmol/mol)	REGION1	EUROPE		-0.01838	-0.008851
4	1	HbA1c (mmol/mol)	REGION1	JAPAN		-0.02133	0.066650
5	1	HbA1c (mmol/mol)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.03348	-0.006927
6	1	HbA1c (mmol/mol)	BASE			-0.09369	-0.114860
7	1	HbA1c (mmol/mol)	visit1400			0.79293	0.790290

HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - per protocol analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2600

Obs	N	P	E	R	B	O	T
1	2	3	4	5	6	7	8
16	1	HbA1c (mmol/mol)	Intercept			-0.03726	-0.051076
17	1	HbA1c (mmol/mol)	REGION1 ASIA (EXCLUDING JAPAN)			-0.16165	-0.230016
18	1	HbA1c (mmol/mol)	REGION1 EUROPE			0.11329	0.128863
19	1	HbA1c (mmol/mol)	REGION1 JAPAN			-0.01346	0.023797
20	1	HbA1c (mmol/mol)	BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.00216	-0.017601
21	1	HbA1c (mmol/mol)	BASE			-0.08287	-0.163134
22	1	HbA1c (mmol/mol)	visit1400			-0.01416	-0.012006
23	1	HbA1c (mmol/mol)	visit1800			0.01579	0.025271
24	1	HbA1c (mmol/mol)	visit2200			0.83374	0.789972

HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - per protocol analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3000

Obs	N	Variable	Type	Value	R	E	G	I	O	A	D	1	b	s	V	a	l	I
25	1	HbA1c (mmol/mol)	Intercept										-0.00383		-0.002846			
26	1	HbA1c (mmol/mol)	REGION1	ASIA (EXCLUDING JAPAN)									0.07355		0.106175			
27	1	HbA1c (mmol/mol)	REGION1	EUROPE									-0.01207		-0.060214			
28	1	HbA1c (mmol/mol)	REGION1	JAPAN									-0.05891		-0.046961			
29	1	HbA1c (mmol/mol)	BOLAD1										0.01686		-0.003239			
30	1	HbA1c (mmol/mol)	BASE										-0.04663		-0.028801			
31	1	HbA1c (mmol/mol)	visit1400										-0.01127		0.022466			
32	1	HbA1c (mmol/mol)	visit1800										-0.03336		-0.035810			
33	1	HbA1c (mmol/mol)	visit2200										0.12767		0.128763			
34	1	HbA1c (mmol/mol)	visit2600										0.80549		0.826496			

HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - per protocol analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3400

O b s —	P A R A M E T E R	E F F E C T	R E G I O N	B O L A D 1	O b s V a l	—
35	1	HbA1c (mmol/mol)	Intercept		-0.01524	0.007331
36	1	HbA1c (mmol/mol)	REGION1 ASIA (EXCLUDING JAPAN)		-0.02216	-0.100682
37	1	HbA1c (mmol/mol)	REGION1 EUROPE		0.06348	0.094848
38	1	HbA1c (mmol/mol)	REGION1 JAPAN		0.00166	0.036583
39	1	HbA1c (mmol/mol)	BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.03787	0.059346
40	1	HbA1c (mmol/mol)	BASE		-0.02768	-0.009303
41	1	HbA1c (mmol/mol)	visit1400		0.02900	-0.041852
42	1	HbA1c (mmol/mol)	visit1800		0.07132	0.079834
43	1	HbA1c (mmol/mol)	visit2200		0.11248	0.175282
44	1	HbA1c (mmol/mol)	visit2600		0.03175	-0.085275
45	1	HbA1c (mmol/mol)	visit3000		0.69093	0.759019

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The MI Procedure with Monotone Regression Regression Information

Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=3 Imputed Variable=visit1400

	Obs	Predicted	Residual	Standardized Residual	Cook's Distance	Leverage	Observed vs Predicted	
58	1	HbA1c (mmol/mol)	Intercept				0.03816	0.079494
59	1	HbA1c (mmol/mol)	REGION1 ASIA (EXCLUDING JAPAN)				0.15715	0.403576
60	1	HbA1c (mmol/mol)	REGION1 EUROPE				-0.02843	-0.087338
61	1	HbA1c (mmol/mol)	REGION1 JAPAN				0.01433	-0.188348
62	1	HbA1c (mmol/mol)	BOLAD1				-0.08341	-0.109016
63	1	HbA1c (mmol/mol)	BASE				-0.18384	-0.240280

HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - per protocol analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=3 Imputed Variable=visit1800

O b s	i n s	P a r a m e t e r	E f f e c t	R e g i o n	B o l u s	O b s e r v e d	T
64	1	HbA1c (mmol/mol)	Intercept			-0.01854	-0.024560
65	1	HbA1c (mmol/mol)	REGION1	ASIA (EXCLUDING JAPAN)		-0.09749	0.000323
66	1	HbA1c (mmol/mol)	REGION1	EUROPE		0.05573	0.100477
67	1	HbA1c (mmol/mol)	REGION1	JAPAN		0.00413	-0.133024
68	1	HbA1c (mmol/mol)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.01219	0.048950
69	1	HbA1c (mmol/mol)	BASE			-0.08475	-0.122926
70	1	HbA1c (mmol/mol)	visit1400			0.68629	0.681417

HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - per protocol analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2200

O b s	i	P a r a m e t e r	E f f e c t	R E G I O N	B O L A D 1	O b s e r v e d	T
71	1	HbA1c (mmol/mol)	Intercept			0.01209	-0.029222
72	1	HbA1c (mmol/mol)	REGION1	ASIA (EXCLUDING JAPAN)		-0.01396	-0.069781
73	1	HbA1c (mmol/mol)	REGION1	EUROPE		-0.04753	0.009328
74	1	HbA1c (mmol/mol)	REGION1	JAPAN		0.02411	0.005100
75	1	HbA1c (mmol/mol)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.05128	-0.056618
76	1	HbA1c (mmol/mol)	BASE			-0.08115	-0.070487
77	1	HbA1c (mmol/mol)	visit1400			-0.12968	-0.126604
78	1	HbA1c (mmol/mol)	visit1800			0.88913	0.910423

HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - per protocol analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2600

O b s —	P A R A M E T E R	E F F E C T	R E G I O N	B O L U S	O B S E R V E D	T
79	1	HbA1c (mmol/mol)	Intercept		-0.01841	0.008543
80	1	HbA1c (mmol/mol)	REGION1 ASIA (EXCLUDING JAPAN)		-0.11287	0.011671
81	1	HbA1c (mmol/mol)	REGION1 EUROPE		0.03948	-0.056695
82	1	HbA1c (mmol/mol)	REGION1 JAPAN		-0.07110	-0.049005
83	1	HbA1c (mmol/mol)	BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.00108	-0.015617
84	1	HbA1c (mmol/mol)	BASE		-0.04928	-0.065390
85	1	HbA1c (mmol/mol)	visit1400		-0.04442	-0.074602
86	1	HbA1c (mmol/mol)	visit1800		0.03194	0.054341
87	1	HbA1c (mmol/mol)	visit2200		0.80586	0.792381

HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - per protocol analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3000

Obs	N	P	E	R	B	O		\bar{I}
—		A	f	E	O	b		
		R	e	G	L	s		
		A	c	I	A	V		
		M	t	N	D	a		
				1	1	l		
88	1	HbA1c (mmol/mol)	Intercept				-0.02231	0.028501
89	1	HbA1c (mmol/mol)	REGION1 ASIA (EXCLUDING JAPAN)				-0.08391	-0.136221
90	1	HbA1c (mmol/mol)	REGION1 EUROPE				0.07484	0.127567
91	1	HbA1c (mmol/mol)	REGION1 JAPAN				-0.05798	-0.097467
92	1	HbA1c (mmol/mol)	BOLAD1				0.0006146	0.011848
93	1	HbA1c (mmol/mol)	BASE				-0.03591	-0.039717
94	1	HbA1c (mmol/mol)	visit1400				0.06041	0.104609
95	1	HbA1c (mmol/mol)	visit1800				0.02379	-0.023836
96	1	HbA1c (mmol/mol)	visit2200				0.05723	0.077347
97	1	HbA1c (mmol/mol)	visit2600				0.75261	0.787367

HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - per protocol analysis set

The MI Procedure with Monotone Regression Regression Information

Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3400

	Obs	Predictions	Efficient	REGIONS	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	Observed	T
98	1	HbA1c (mmol/mol)	Intercept			-0.00924	0.004529
99	1	HbA1c (mmol/mol)	REGION1 ASIA (EXCLUDING JAPAN)			-0.01353	0.039823
100	1	HbA1c (mmol/mol)	REGION1 EUROPE			0.12195	0.130323
101	1	HbA1c (mmol/mol)	REGION1 JAPAN			-0.06695	-0.063766
102	1	HbA1c (mmol/mol)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.00425	-0.075874
103	1	HbA1c (mmol/mol)	BASE			-0.04464	0.005276
104	1	HbA1c (mmol/mol)	visit1400			-0.01011	0.016828
105	1	HbA1c (mmol/mol)	visit1800			0.19217	0.266133
106	1	HbA1c (mmol/mol)	visit2200			-0.11909	-0.302867
107	1	HbA1c (mmol/mol)	visit2600			-0.07608	-0.097972
108	1	HbA1c (mmol/mol)	visit3000			0.86365	1.019770

HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - per protocol analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

Obs	N	S	—	P	A	M	E	f	c	t	R	E	G	I	O	N	1	B	O	L	A	D	1	O	b	s	V	a	l	\bar{I}
109	1		HbA1c	(mmol/mol)	Intercept																	-0.00765	-0.035246							
110	1		HbA1c	(mmol/mol)	REGION1	ASIA (EXCLUDING JAPAN)																	-0.01202	-0.009100						
111	1		HbA1c	(mmol/mol)	REGION1	EUROPE																	-0.00388	0.010618						
112	1		HbA1c	(mmol/mol)	REGION1	JAPAN																	-0.02210	-0.077851						
113	1		HbA1c	(mmol/mol)	BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)																	0.04956	0.041597						
114	1		HbA1c	(mmol/mol)	BASE																	-0.05107	-0.050083							
115	1		HbA1c	(mmol/mol)	visit1400																		0.03663	0.049510						
116	1		HbA1c	(mmol/mol)	visit1800																		-0.03385	-0.026602						
117	1		HbA1c	(mmol/mol)	visit2200																		0.06658	0.004559						
118	1		HbA1c	(mmol/mol)	visit2600																		-0.01151	0.014266						
119	1		HbA1c	(mmol/mol)	visit3000																		0.03272	-0.000143						
120	1		HbA1c	(mmol/mol)	visit3400																		0.85292	0.892199						

HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - per protocol analysis set

The MI Procedure with Monotone Regression Regression Information

Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=4 Imputed Variable=visit1400

	O	b	s	—	P A R A M	E f f e c t	R E G I O N 1	B O L U S D 1	O b s V a l	I
121	1	HbA1c	(mmol/mol)	Intercept					0.01582	-0.044342
122	1	HbA1c	(mmol/mol)	REGION1	ASIA (EXCLUDING JAPAN)				0.09893	0.215706
123	1	HbA1c	(mmol/mol)	REGION1	EUROPE				-0.04085	-0.123022
124	1	HbA1c	(mmol/mol)	REGION1	JAPAN				-0.08888	-0.116016
125	1	HbA1c	(mmol/mol)	BOLAD1				BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.02327	-0.129873
126	1	HbA1c	(mmol/mol)	BASE					-0.10504	-0.073701

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HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - per protocol analysis set

The MI Procedure with Monotone Regression Regression Information

Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2200

	O b s		P A R M	E f f e c t	R E G I O N 1	B O L U S D 1	O b s V a l	I
134	1	HbA1c	(mmol/mol)	Intercept			0.00819	0.017120
135	1	HbA1c	(mmol/mol)	REGION1	ASIA (EXCLUDING JAPAN)		0.04853	0.107203
136	1	HbA1c	(mmol/mol)	REGION1	EUROPE		-0.01235	-0.027983
137	1	HbA1c	(mmol/mol)	REGION1	JAPAN		-0.05082	-0.042794
138	1	HbA1c	(mmol/mol)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.01505	-0.055192
139	1	HbA1c	(mmol/mol)	BASE			-0.08880	-0.115988
140	1	HbA1c	(mmol/mol)	visit1400			0.10643	0.117817
141	1	HbA1c	(mmol/mol)	visit1800			0.72408	0.673635


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HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - per protocol analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3000

Obs	N	HbA1c	(mmol/mol)	Intercept	REGION1	EUROPE	JAPAN	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	BASE	visit1400	visit1800	visit2200	visit2600	-0.00605	0.010445
151	1	HbA1c	(mmol/mol)	Intercept										-0.00605	0.010445
152	1	HbA1c	(mmol/mol)	REGION1	ASIA (EXCLUDING JAPAN)									-0.03462	0.005549
153	1	HbA1c	(mmol/mol)	REGION1	EUROPE									0.07363	0.038813
154	1	HbA1c	(mmol/mol)	REGION1	JAPAN									-0.02228	-0.016491
155	1	HbA1c	(mmol/mol)	BOLAD1				BOLUS INSULIN ALGORITHM (SLIDING SCALE)						-0.04195	-0.089409
156	1	HbA1c	(mmol/mol)	BASE										-0.07276	-0.059509
157	1	HbA1c	(mmol/mol)	visit1400										-0.03674	-0.023941
158	1	HbA1c	(mmol/mol)	visit1800										-0.04918	-0.059163
159	1	HbA1c	(mmol/mol)	visit2200										-0.06338	0.019549
160	1	HbA1c	(mmol/mol)	visit2600										0.93081	0.853648

HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - per protocol analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3400

O b s —	P A R A M E T E R	E F F E C T	R E G I O N	B O L A D 1	O b s V a l	—
161	1	HbA1c (mmol/mol)	Intercept		-0.02177	-0.005021
162	1	HbA1c (mmol/mol)	REGION1 ASIA (EXCLUDING JAPAN)		-0.16683	-0.191042
163	1	HbA1c (mmol/mol)	REGION1 EUROPE		0.12683	0.155599
164	1	HbA1c (mmol/mol)	REGION1 JAPAN		0.02343	0.031103
165	1	HbA1c (mmol/mol)	BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.01675	-0.032151
166	1	HbA1c (mmol/mol)	BASE		-0.07402	-0.034914
167	1	HbA1c (mmol/mol)	visit1400		-0.05841	-0.058097
168	1	HbA1c (mmol/mol)	visit1800		0.12237	0.123572
169	1	HbA1c (mmol/mol)	visit2200		0.07108	0.123461
170	1	HbA1c (mmol/mol)	visit2600		-0.06216	-0.134717
171	1	HbA1c (mmol/mol)	visit3000		0.80080	0.821645

HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - per protocol analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=HBA1CONV Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

O b s —	P A R A M E T E R	E F F E C T	R E G I O N	B O L A D 1	O b s V a l	I
172	1	HbA1c (mmol/mol)	Intercept		0.00204	0.018580
173	1	HbA1c (mmol/mol)	REGION1 ASIA (EXCLUDING JAPAN)		-0.05393	-0.033459
174	1	HbA1c (mmol/mol)	REGION1 EUROPE		0.06712	0.042920
175	1	HbA1c (mmol/mol)	REGION1 JAPAN		-0.00631	0.019897
176	1	HbA1c (mmol/mol)	BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.03625	-0.063387
177	1	HbA1c (mmol/mol)	BASE		-0.02899	-0.056317
178	1	HbA1c (mmol/mol)	visit1400		-0.02160	-0.010628
179	1	HbA1c (mmol/mol)	visit1800		0.01385	0.054644
180	1	HbA1c (mmol/mol)	visit2200		0.10982	0.103707
181	1	HbA1c (mmol/mol)	visit2600		-0.03828	-0.126796
182	1	HbA1c (mmol/mol)	visit3000		-0.20201	-0.171484
183	1	HbA1c (mmol/mol)	visit3400		1.02047	1.045187

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The Mixed procedure
Model Information

Parameter Code=C64849B Parameter=HbA1c (%)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Data Set	WORK.IMPUTE
2	1	NN1218-4131	Dependent Variable	eotVisit
3	1	NN1218-4131	Covariance Structure	Diagonal
4	1	NN1218-4131	Estimation Method	REML
5	1	NN1218-4131	Residual Variance Method	Profile
6	1	NN1218-4131	Fixed Effects SE Method	Model-Based
7	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=HBA1CONV Parameter=HbA1c (mmol/mol)

Obs	_Imputation_	STUDYID	Descr	Value
8	1	NN1218-4131	Data Set	WORK.IMPUTE
9	1	NN1218-4131	Dependent Variable	eotVisit
10	1	NN1218-4131	Covariance Structure	Diagonal
11	1	NN1218-4131	Estimation Method	REML
12	1	NN1218-4131	Residual Variance Method	Profile
13	1	NN1218-4131	Fixed Effects SE Method	Model-Based
14	1	NN1218-4131	Degrees of Freedom Method	Residual

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The Mixed procedure
Class Level Information

Parameter Code=C64849B Parameter=HbA1c (%)

Input				Output			
Subject				Variable			
Observation				Level			
Study				Treatment			
1	1	NN1218-4131	TRTPN	3	2	3	4
2	1	NN1218-4131	REGION1	4	ASIA (EXCLUDING JAPAN)	EUROPE	JAPAN NORTH AMERICA
3	1	NN1218-4131	BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	CARBOHYDRATE COUNTING (FLEXIBLE)	BOLUS INSULI
							85

HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - per protocol analysis set

The Mixed procedure
Class Level Information

Parameter Code=HBA1CONV Parameter=HbA1c (mmol/mol)

Input				Output			
Subject				Variable			
Observation				Level			
Study				Treatment			
4	1	NN1218-4131	TRTPN	3	2	3	4
5	1	NN1218-4131	REGION1	4	ASIA (EXCLUDING JAPAN)	EUROPE	JAPAN NORTH AMERICA
6	1	NN1218-4131	BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	CARBOHYDRATE COUNTING (FLEXIBLE)	BOLUS INSULI
							85

HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - per protocol analysis set

The Mixed procedure
Dimensions

Parameter Code=C64849B Parameter=HbA1c (%)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Covariance Parameters	1
2	1	NN1218-4131	Columns in X	10
3	1	NN1218-4131	Columns in Z	0
4	1	NN1218-4131	Subjects	1
5	1	NN1218-4131	Max Obs per Subject	1025

Parameter Code=HBA1CONV Parameter=HbA1c (mmol/mol)

Obs	_Imputation_	STUDYID	Descr	Value
6	1	NN1218-4131	Covariance Parameters	1
7	1	NN1218-4131	Columns in X	10
8	1	NN1218-4131	Columns in Z	0
9	1	NN1218-4131	Subjects	1
10	1	NN1218-4131	Max Obs per Subject	1025

HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - per protocol analysis set

The Mixed procedure
Number of Observations

Parameter Code=C64849B Parameter=HbA1c (%)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
1	1	NN1218-4131	Number of Observations Read	1025	1025	1025	1025	1025
2	1	NN1218-4131	Number of Observations Used	1025	1025	1025	1025	1025
3	1	NN1218-4131	Number of Observations Not Used	0	1025	1025	1025	1025

Parameter Code=HBA1CONV Parameter=HbA1c (mmol/mol)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
4	1	NN1218-4131	Number of Observations Read	1025	1025	1025	1025	1025
5	1	NN1218-4131	Number of Observations Used	1025	1025	1025	1025	1025
6	1	NN1218-4131	Number of Observations Not Used	0	1025	1025	1025	1025

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The Mixed procedure
Covariance Parameter Estimates

Parameter Code=C64849B Parameter=HbA1c (%)

Obs	_Imputation_	STUDYID	CovParm	Estimate
1	1	NN1218-4131	Residual	0.3745

Parameter Code=HBA1CONV Parameter=HbA1c (mmol/mol)

Obs	_Imputation_	STUDYID	CovParm	Estimate
101	1	NN1218-4131	Residual	44.7420

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The Mixed procedure
Fit Statistics

Parameter Code=C64849B Parameter=HbA1c (%)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	-2 Res Log Likelihood	1931.3
2	1	NN1218-4131	AIC (Smaller is Better)	1933.3
3	1	NN1218-4131	AICC (Smaller is Better)	1933.3
4	1	NN1218-4131	BIC (Smaller is Better)	1938.3

Parameter Code=HBA1CONV Parameter=HbA1c (mmol/mol)

Obs	_Imputation_	STUDYID	Descr	Value
5	1	NN1218-4131	-2 Res Log Likelihood	6800.5
6	1	NN1218-4131	AIC (Smaller is Better)	6802.5
7	1	NN1218-4131	AICC (Smaller is Better)	6802.5
8	1	NN1218-4131	BIC (Smaller is Better)	6807.4

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HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - per protocol analysis set

The Mixed procedure
Solution for Fixed Effects

Parameter Code=C64849B Parameter=HbA1c (%)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
1	1	NN1218-4131	TRTPN	2				
2	1	NN1218-4131	TRTPN	3				
3	1	NN1218-4131	TRTPN	4				
4	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
5	1	NN1218-4131	REGION1	—	EUROPE			
6	1	NN1218-4131	REGION1	—	JAPAN			
7	1	NN1218-4131	REGION1	—	NORTH AMERICA			
8	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
9	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
10	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	2.1651	0.2132	1017	10.16	<.0001	0.05	1.7468	2.5835
2	2.2927	0.2121	1017	10.81	<.0001	0.05	1.8766	2.7089
3	2.1982	0.2122	1017	10.36	<.0001	0.05	1.7818	2.6146
4	-0.1436	0.06983	1017	-2.06	0.0400	0.05	-0.2807	-0.00660
5	0.09753	0.04926	1017	1.98	0.0480	0.05	0.000871	0.1942
6	-0.1042	0.05511	1017	-1.89	0.0590	0.05	-0.2123	0.003961
7	0
8	-0.02249	0.04289	1017	-0.52	0.6002	0.05	-0.1067	0.06168
9	0
10	-0.3060	0.02765	1017	-11.07	<.0001	0.05	-0.3602	-0.2517

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HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - per protocol analysis set

The Mixed procedure
Solution for Fixed Effects

Parameter Code=HBA1CONV Parameter=HbA1c (mmol/mol)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
11	1	NN1218-4131	TRTPN	2				
12	1	NN1218-4131	TRTPN	3				
13	1	NN1218-4131	TRTPN	4				
14	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
15	1	NN1218-4131	REGION1	—	EUROPE			
16	1	NN1218-4131	REGION1	—	JAPAN			
17	1	NN1218-4131	REGION1	—	NORTH AMERICA			
18	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
19	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
20	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
11	16.4749	1.7017	1017	9.68	<.0001	0.05	13.1357	19.8142
12	17.8697	1.6903	1017	10.57	<.0001	0.05	14.5527	21.1866
13	16.8359	1.6921	1017	9.95	<.0001	0.05	13.5154	20.1563
14	-1.5699	0.7633	1017	-2.06	0.0400	0.05	-3.0676	-0.07211
15	1.0660	0.5384	1017	1.98	0.0480	0.05	0.009523	2.1226
16	-1.1387	0.6024	1017	-1.89	0.0590	0.05	-2.3208	0.04330
17	0
18	-0.2458	0.4688	1017	-0.52	0.6002	0.05	-1.1658	0.6741
19	0
20	-0.3060	0.02765	1017	-11.07	<.0001	0.05	-0.3602	-0.2517

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HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - per protocol analysis set

The Mixed procedure
Least Squares Means

Obs	_Imputation_	PARAMCD	PARAM	STUDYID	Effect	TRTPN	Margins
1	1	C64849B	HbA1c (%)	NN1218-4131	TRTPN	2	WORK.IMPUTE
2	1	C64849B	HbA1c (%)	NN1218-4131	TRTPN	3	WORK.IMPUTE
3	1	C64849B	HbA1c (%)	NN1218-4131	TRTPN	4	WORK.IMPUTE
4	1	HBA1CONV	HbA1c (mmol/mol)	NN1218-4131	TRTPN	2	WORK.IMPUTE
5	1	HBA1CONV	HbA1c (mmol/mol)	NN1218-4131	TRTPN	3	WORK.IMPUTE
6	1	HBA1CONV	HbA1c (mmol/mol)	NN1218-4131	TRTPN	4	WORK.IMPUTE

Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	-0.1304	0.03315	1017	-3.93	<.0001	0.05	-0.1954	-0.06533
2	-0.00277	0.03318	1017	-0.08	0.9335	0.05	-0.06787	0.06234
3	-0.09735	0.03313	1017	-2.94	0.0034	0.05	-0.1624	-0.03234
4	-1.4250	0.3623	1017	-3.93	<.0001	0.05	-2.1359	-0.7141
5	-0.03025	0.3626	1017	-0.08	0.9335	0.05	-0.7419	0.6814
6	-1.0640	0.3621	1017	-2.94	0.0034	0.05	-1.7746	-0.3535

HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - per protocol analysis set

The Mixed procedure
Least Squares Means Estimate

Parameter Code=C64849B Parameter=HbA1c (%)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
1	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
2	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	WORK.IMPUTE	-0.03302	0.04690	1017	-0.70	0.4815	0.05	-0.1251	0.05901
2	WORK.IMPUTE	0.09458	0.04690	1017	2.02	0.0440	0.05	0.002553	0.1866

Parameter Code=HBA1CONV Parameter=HbA1c (mmol/mol)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
3	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
4	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
3	WORK.IMPUTE	-0.3609	0.5126	1017	-0.70	0.4815	0.05	-1.3668	0.6450
4	WORK.IMPUTE	1.0338	0.5126	1017	2.02	0.0440	0.05	0.02790	2.0397

HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - per protocol analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=C64849B Parameter=HbA1c (%) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	100

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000011326	0.001074	0.001086	891516	0.010650	0.010540	0.999895

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.124104	0.032947	-0.18868	-0.05953	891516	-0.132441	-0.116894

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-3.77	0.0002

HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - per protocol analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=HBA1CONV Parameter=HbA1c (mmol/mol) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	100

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.001353	0.128317	0.129683	891516	0.010650	0.010540	0.999895

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-1.356456	0.360115	-2.06227	-0.65064	891516	-1.447584	-1.277647

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-3.77	0.0002

HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - per protocol analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=C64849B Parameter=HbA1c (%) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	100

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000020841	0.001076	0.001097	269003	0.019559	0.019191	0.999808

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.003420	0.033124	-0.06834	0.061503	269003	-0.013362	0.008646

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-0.10	0.9178

HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - per protocol analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=HBA1CONV Parameter=HbA1c (mmol/mol) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	100

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.002490	0.128565	0.131080	269003	0.019559	0.019191	0.999808

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.037385	0.362050	-0.74699	0.672223	269003	-0.146043	0.094504

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-0.10	0.9178

HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - per protocol analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=C64849B Parameter=HbA1c (%) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	100

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000016513	0.001073	0.001090	422471	0.015546	0.015313	0.999847

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.094644	0.033008	-0.15934	-0.02995	422471	-0.106314	-0.084734

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-2.87	0.0041

HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - per protocol analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=HBA1CONV Parameter=HbA1c (mmol/mol) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	100

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.001973	0.128168	0.130160	422471	0.015546	0.015313	0.999847

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-1.034455	0.360778	-1.74157	-0.32734	422471	-1.162013	-0.926143

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-2.87	0.0041

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HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - per protocol analysis set

Parameter Code=C64849B Label=Faster aspart (meal) - NovoRapid (meal) Parameter=HbA1c (%) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	100

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000021477	0.002150	0.002172	992561	0.010088	0.009989	0.999900

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.029460	0.046605	-0.12080	0.061883	992561	-0.040571	-0.014225

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-0.63	0.5273

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HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - per protocol analysis set

Parameter Code=C64849B Label=Faster aspart (post) - NovoRapid (meal) Parameter=HbA1c (%) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	100

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000039513	0.002150	0.002190	298166	0.018560	0.018228	0.999818

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.091223	0.046799	-0.00050	0.182948	298166	0.077244	0.107016

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	1.95	0.0513

HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - per protocol analysis set

Parameter Code=HBA1CONV Label=Faster aspart (meal) - NovoRapid (meal) Parameter=HbA1c (mmol/mol) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	100

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.002566	0.256887	0.259478	992561	0.010088	0.009989	0.999900

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.322001	0.509390	-1.32039	0.676386	992561	-0.443442	-0.155482

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-0.63	0.5273

HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - per protocol analysis set

Parameter Code=HBA1CONV Label=Faster aspart (post) - NovoRapid (meal) Parameter=HbA1c (mmol/mol) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	100

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.004720	0.256880	0.261648	298166	0.018560	0.018228	0.999818

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits	DF	Minimum	Maximum
Estimate	0.997070	0.511515	-0.00548 1.999625	298166	0.844281	1.169687

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	1.95	0.0513

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HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - per protocol analysis set

The Mixed procedure
Model Information

Parameter Code=C64849B Parameter=HbA1c (%)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Data Set	WORK.IMPUTE_ABS
2	1	NN1218-4131	Dependent Variable	eotVisitAbs
3	1	NN1218-4131	Covariance Structure	Diagonal
4	1	NN1218-4131	Estimation Method	REML
5	1	NN1218-4131	Residual Variance Method	Profile
6	1	NN1218-4131	Fixed Effects SE Method	Model-Based
7	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=HBA1CONV Parameter=HbA1c (mmol/mol)

Obs	_Imputation_	STUDYID	Descr	Value
8	1	NN1218-4131	Data Set	WORK.IMPUTE_ABS
9	1	NN1218-4131	Dependent Variable	eotVisitAbs
10	1	NN1218-4131	Covariance Structure	Diagonal
11	1	NN1218-4131	Estimation Method	REML
12	1	NN1218-4131	Residual Variance Method	Profile
13	1	NN1218-4131	Fixed Effects SE Method	Model-Based
14	1	NN1218-4131	Degrees of Freedom Method	Residual

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HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - per protocol analysis set

The Mixed procedure
Class Level Information

Parameter Code=C64849B Parameter=HbA1c (%)

Input				Output			
Study				Variable			
ID				Level			
1				2			
3				4			
1	1	NN1218-4131	TRTPN	3	2	3	4
2	1	NN1218-4131	REGION1	4	ASIA (EXCLUDING JAPAN)	EUROPE	JAPAN NORTH AMERICA
3	1	NN1218-4131	BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	CARBOHYDRATE COUNTING (FLEXIBLE)	BOLUS INSULI
							85

HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - per protocol analysis set

The Mixed procedure
Class Level Information

Parameter Code=HBA1CONV Parameter=HbA1c (mmol/mol)

Input				Output			
Subject				Variable			
Observation				Level			
Study				Treatment			
4	1	NN1218-4131	TRTPN	3	2	3	4
5	1	NN1218-4131	REGION1	4	ASIA (EXCLUDING JAPAN)	EUROPE	JAPAN NORTH AMERICA
6	1	NN1218-4131	BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	CARBOHYDRATE COUNTING (FLEXIBLE)	BOLUS INSULI
							85

HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - per protocol analysis set

The Mixed procedure
Dimensions

Parameter Code=C64849B Parameter=HbA1c (%)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Covariance Parameters	1
2	1	NN1218-4131	Columns in X	10
3	1	NN1218-4131	Columns in Z	0
4	1	NN1218-4131	Subjects	1
5	1	NN1218-4131	Max Obs per Subject	1025

Parameter Code=HBA1CONV Parameter=HbA1c (mmol/mol)

Obs	_Imputation_	STUDYID	Descr	Value
6	1	NN1218-4131	Covariance Parameters	1
7	1	NN1218-4131	Columns in X	10
8	1	NN1218-4131	Columns in Z	0
9	1	NN1218-4131	Subjects	1
10	1	NN1218-4131	Max Obs per Subject	1025

HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - per protocol analysis set

The Mixed procedure
Number of Observations

Parameter Code=C64849B Parameter=HbA1c (%)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
1	1	NN1218-4131	Number of Observations Read	1025	1025	1025	1025	1025
2	1	NN1218-4131	Number of Observations Used	1025	1025	1025	1025	1025
3	1	NN1218-4131	Number of Observations Not Used	0	1025	1025	1025	1025

Parameter Code=HBA1CONV Parameter=HbA1c (mmol/mol)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
4	1	NN1218-4131	Number of Observations Read	1025	1025	1025	1025	1025
5	1	NN1218-4131	Number of Observations Used	1025	1025	1025	1025	1025
6	1	NN1218-4131	Number of Observations Not Used	0	1025	1025	1025	1025

HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - per protocol analysis set

The Mixed procedure
Covariance Parameter Estimates

Parameter Code=C64849B Parameter=HbA1c (%)

Obs	_Imputation_	STUDYID	CovParm	Estimate
1	1	NN1218-4131	Residual	0.3745

Parameter Code=HBA1CONV Parameter=HbA1c (mmol/mol)

Obs	_Imputation_	STUDYID	CovParm	Estimate
101	1	NN1218-4131	Residual	44.7420

HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - per protocol analysis set

The Mixed procedure
Fit Statistics

Parameter Code=C64849B Parameter=HbA1c (%)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	-2 Res Log Likelihood	1931.3
2	1	NN1218-4131	AIC (Smaller is Better)	1933.3
3	1	NN1218-4131	AICC (Smaller is Better)	1933.3
4	1	NN1218-4131	BIC (Smaller is Better)	1938.3

Parameter Code=HBA1CONV Parameter=HbA1c (mmol/mol)

Obs	_Imputation_	STUDYID	Descr	Value
5	1	NN1218-4131	-2 Res Log Likelihood	6800.5
6	1	NN1218-4131	AIC (Smaller is Better)	6802.5
7	1	NN1218-4131	AICC (Smaller is Better)	6802.5
8	1	NN1218-4131	BIC (Smaller is Better)	6807.4

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HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - per protocol analysis set

The Mixed procedure
Solution for Fixed Effects

Parameter Code=C64849B Parameter=HbA1c (%)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
1	1	NN1218-4131	TRTPN	2				
2	1	NN1218-4131	TRTPN	3				
3	1	NN1218-4131	TRTPN	4				
4	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
5	1	NN1218-4131	REGION1	—	EUROPE			
6	1	NN1218-4131	REGION1	—	JAPAN			
7	1	NN1218-4131	REGION1	—	NORTH AMERICA			
8	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
9	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
10	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	2.1651	0.2132	1017	10.16	<.0001	0.05	1.7468	2.5835
2	2.2927	0.2121	1017	10.81	<.0001	0.05	1.8766	2.7089
3	2.1982	0.2122	1017	10.36	<.0001	0.05	1.7818	2.6146
4	-0.1436	0.06983	1017	-2.06	0.0400	0.05	-0.2807	-0.00660
5	0.09753	0.04926	1017	1.98	0.0480	0.05	0.000871	0.1942
6	-0.1042	0.05511	1017	-1.89	0.0590	0.05	-0.2123	0.003961
7	0
8	-0.02249	0.04289	1017	-0.52	0.6002	0.05	-0.1067	0.06168
9	0
10	0.6940	0.02765	1017	25.10	<.0001	0.05	0.6398	0.7483

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HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - per protocol analysis set

The Mixed procedure
Solution for Fixed Effects

Parameter Code=HBA1CONV Parameter=HbA1c (mmol/mol)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
11	1	NN1218-4131	TRTPN	2				
12	1	NN1218-4131	TRTPN	3				
13	1	NN1218-4131	TRTPN	4				
14	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
15	1	NN1218-4131	REGION1	—	EUROPE			
16	1	NN1218-4131	REGION1	—	JAPAN			
17	1	NN1218-4131	REGION1	—	NORTH AMERICA			
18	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
19	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
20	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
11	16.4749	1.7017	1017	9.68	<.0001	0.05	13.1357	19.8142
12	17.8697	1.6903	1017	10.57	<.0001	0.05	14.5527	21.1866
13	16.8359	1.6921	1017	9.95	<.0001	0.05	13.5154	20.1563
14	-1.5699	0.7633	1017	-2.06	0.0400	0.05	-3.0676	-0.07211
15	1.0660	0.5384	1017	1.98	0.0480	0.05	0.009523	2.1226
16	-1.1387	0.6024	1017	-1.89	0.0590	0.05	-2.3208	0.04330
17	0
18	-0.2458	0.4688	1017	-0.52	0.6002	0.05	-1.1658	0.6741
19	0
20	0.6940	0.02765	1017	25.10	<.0001	0.05	0.6398	0.7483

nn1218/nn1218-4131/ctr_20180214_er
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HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - per protocol analysis set

The Mixed procedure
Least Squares Means

Obs	_Imputation_	PARAMCD	PARAM	STUDYID	Effect	TRTPN	Margins
1	1	C64849B	HbA1c (%)	NN1218-4131	TRTPN	2	WORK.IMPUTE
101	1	HBA1CONV	HbA1c (mmol/mol)	NN1218-4131	TRTPN	2	WORK.IMPUTE
201	1	C64849B	HbA1c (%)	NN1218-4131	TRTPN	3	WORK.IMPUTE
301	1	HBA1CONV	HbA1c (mmol/mol)	NN1218-4131	TRTPN	3	WORK.IMPUTE
401	1	C64849B	HbA1c (%)	NN1218-4131	TRTPN	4	WORK.IMPUTE
501	1	HBA1CONV	HbA1c (mmol/mol)	NN1218-4131	TRTPN	4	WORK.IMPUTE

Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	-0.1304	0.03315	1017	-3.93	<.0001	0.05	-0.1954	-0.06533
101	-1.4250	0.3623	1017	-3.93	<.0001	0.05	-2.1359	-0.7141
201	-0.00277	0.03318	1017	-0.08	0.9335	0.05	-0.06787	0.06234
301	-0.03025	0.3626	1017	-0.08	0.9335	0.05	-0.7419	0.6814
401	-0.09735	0.03313	1017	-2.94	0.0034	0.05	-0.1624	-0.03234
501	-1.0640	0.3621	1017	-2.94	0.0034	0.05	-1.7746	-0.3535

HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - per protocol analysis set

The Mixed procedure
Least Squares Means Estimate

Parameter Code=C64849B Parameter=HbA1c (%)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
1	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
101	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	WORK.IMPUTE	-0.03302	0.04690	1017	-0.70	0.4815	0.05	-0.1251	0.05901
101	WORK.IMPUTE	0.09458	0.04690	1017	2.02	0.0440	0.05	0.002553	0.1866

Parameter Code=HBA1CONV Parameter=HbA1c (mmol/mol)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
201	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
301	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
201	WORK.IMPUTE	-0.3609	0.5126	1017	-0.70	0.4815	0.05	-1.3668	0.6450
301	WORK.IMPUTE	1.0338	0.5126	1017	2.02	0.0440	0.05	0.02790	2.0397

HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - per protocol analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=C64849B Parameter=HbA1c (%) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	100

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000011326	0.001074	0.001086	891516	0.010650	0.010540	0.999895

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	7.300384	0.032947	7.235808	7.364960	891516	7.292046	7.307594

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	221.58	<.0001

HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - per protocol analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=HBA1CONV Parameter=HbA1c (mmol/mol) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	100

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.001353	0.128317	0.129683	891516	0.010650	0.010540	0.999895

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	56.293196	0.360115	55.58738	56.99901	891516	56.202068	56.372005

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	156.32	<.0001

HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - per protocol analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=C64849B Parameter=HbA1c (%) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	100

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000020841	0.001076	0.001097	269003	0.019559	0.019191	0.999808

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	7.421067	0.033124	7.356145	7.485990	269003	7.411126	7.433134

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	224.04	<.0001

HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - per protocol analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=HBA1CONV Parameter=HbA1c (mmol/mol) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	100

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.002490	0.128565	0.131080	269003	0.019559	0.019191	0.999808

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	57.612267	0.362050	56.90266	58.32187	269003	57.503609	57.744156

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	159.13	<.0001

HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - per protocol analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=C64849B Parameter=HbA1c (%) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	100

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000016513	0.001073	0.001090	422471	0.015546	0.015313	0.999847

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	7.329844	0.033008	7.265149	7.394539	422471	7.318174	7.339754

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	222.06	<.0001

HbA1c 26 weeks after randomisation - statistical analysis - on-treatment - per protocol analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=HBA1CONV Parameter=HbA1c (mmol/mol) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	100

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.001973	0.128168	0.130160	422471	0.015546	0.015313	0.999847

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	56.615197	0.360778	55.90808	57.32231	422471	56.487639	56.723508

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	156.93	<.0001

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8: Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=HBA70 Parameter=HbA1c <7.0% without severe hypo and with minimal weight gain Study Identifier=NN1218-4131

The GENMOD Procedure

Model Information

Data Set	WORK.ENDPOINT
Distribution	Binomial
Link Function	Logit
Dependent Variable	aval

Number of Observations Read	1025
Number of Observations Used	1025
Number of Events	183
Number of Trials	1025

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Response Profile

Ordered Value	aval	Total Frequency
1	0	183
2	1	842

PROC GENMOD is modeling the probability that aval='0'. One way to change this to model the probability that aval='1' is to

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=HBA70 Parameter=HbA1c <7.0% without severe hypo and with minimal weight gain Study Identifier=NN1218-4131

The GENMOD Procedure

specify the DESCENDING option in the PROC statement.

Parameter Information

Parameter	Effect	TRTPN	REGION1	BOLAD1
Prm1	Intercept			
Prm2	TRTPN	2		
Prm3	TRTPN	3		
Prm4	TRTPN	4		
Prm5	REGION1		ASIA (EXCLUDING JAPAN)	
Prm6	REGION1		EUROPE	
Prm7	REGION1		JAPAN	
Prm8	REGION1		NORTH AMERICA	
Prm9	BOLAD1			BOLUS INSULIN ALGORITHM (SLIDING SCALE)
Prm10	BOLAD1			CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY
Prm11	HBA1CBL			

Criteria For Assessing Goodness Of Fit

Criterion	DF	Value	Value/DF
Log Likelihood		-402.1974	
Full Log Likelihood		-402.1974	
AIC (smaller is better)		820.3948	
AICC (smaller is better)		820.5365	
BIC (smaller is better)		859.8544	

Algorithm converged.

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Parameter Code=HBA70 Parameter=HbA1c <7.0% without severe hypo and with minimal weight gain Study Identifier=NN1218-4131

The GENMOD Procedure

Analysis Of Maximum Likelihood Parameter Estimates

Parameter		DF	Estimate	Standard Error	Wald 95% Confidence Limits		Wald Chi-Square
Intercept		1	11.9030	1.2441	9.4646	14.3414	91.54
TRTPN	2	1	-0.1403	0.2202	-0.5720	0.2913	0.41
TRTPN	3	1	-0.0523	0.2149	-0.4735	0.3688	0.06
TRTPN	4	0	0.0000	0.0000	0.0000	0.0000	.
REGION1	ASIA (EXCLUDING JAPAN)	1	-0.4537	0.3588	-1.1569	0.2495	1.60
REGION1	EUROPE	1	-0.2426	0.2312	-0.6958	0.2106	1.10
REGION1	JAPAN	1	0.0871	0.2459	-0.3949	0.5691	0.13
REGION1	NORTH AMERICA	0	0.0000	0.0000	0.0000	0.0000	.
BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	1	-0.2004	0.1976	-0.5877	0.1869	1.03
BOLAD1	CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY	0	0.0000	0.0000	0.0000	0.0000	.
HBA1CBL	Scale	1	-1.8245	0.1719	-2.1613	-1.4877	112.70
		0	1.0000	0.0000	1.0000	1.0000	

Analysis Of Maximum Likelihood Parameter Estimates

Parameter		Pr > ChiSq
Intercept		<.0001
TRTPN	2	0.5240
TRTPN	3	0.8076
TRTPN	4	.
REGION1	ASIA (EXCLUDING JAPAN)	0.2060
REGION1	EUROPE	0.2941
REGION1	JAPAN	0.7232
REGION1	NORTH AMERICA	.
BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.3105
BOLAD1	CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY	.
HBA1CBL		<.0001

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=HBA70 Parameter=HbA1c <7.0% without severe hypo and with minimal weight gain Study Identifier=NN1218-4131

The GENMOD Procedure

Analysis Of Maximum Likelihood Parameter Estimates

Parameter Pr > ChiSq

Scale

NOTE: The scale parameter was held fixed.

Coefficients for TRTPN Least Squares Means Using WORK.ENDPOINT Margins

Parameter	Geographic Region Grouping Method 1
Intercept	
Planned Treatment (N) 2	
Planned Treatment (N) 3	
Planned Treatment (N) 4	
Geographic Region Grouping Method 1 ASIA (EXCLUDING JAPAN)	ASIA (EXCLUDING JAPAN)

Coefficients for TRTPN Least Squares Means Using WORK.ENDPOINT Margins

Bolus Adjustment Method at Timepoint 1	Planned Treatment (N)	Row		
		Row1	Row2	Row3
	2	1	1	1
	3	1	1	
	4			1
		0.1307	0.1307	0.1307

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=HBA70 Parameter=HbA1c <7.0% without severe hypo and with minimal weight gain Study Identifier=NN1218-4131

The GENMOD Procedure

Coefficients for TRTPN Least Squares Means Using WORK.ENDPOINT Margins

Parameter	Geographic Region Grouping Method 1
Geographic Region Grouping Method 1 EUROPE	EUROPE
Geographic Region Grouping Method 1 JAPAN	JAPAN
Geographic Region Grouping Method 1 NORTH AMERICA	NORTH AMERICA
Bolus Adjustment Method at Timepoint 1 BOLUS INSULIN ALGORITHM (SLIDING SCALE)	
Bolus Adjustment Method at Timepoint 1 CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY	
HbA1c at Baseline	

Coefficients for TRTPN Least Squares Means Using WORK.ENDPOINT Margins

	Planned Treatment (N)	Row1	Row2	Row3
Bolus Adjustment Method at Timepoint 1				
		0.3366	0.3366	0.3366
		0.239	0.239	0.239
		0.2937	0.2937	0.2937
BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.5824	0.5824	0.5824
CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0.4176	0.4176	0.4176
		7.4245	7.4245	7.4245

Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=HBA70 Parameter=HbA1c <7.0% without severe hypo and with minimal weight gain Study Identifier=NN1218-4131

The GENMOD Procedure

TRTPN Least Squares Means

Planned Treatment (N)	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
2	WORK.ENDPOINT	-2.0202	0.1736	-11.64	<.0001	0.05	-2.3604	-1.6800
3	WORK.ENDPOINT	-1.9322	0.1657	-11.66	<.0001	0.05	-2.2570	-1.6073
4	WORK.ENDPOINT	-1.8798	0.1660	-11.32	<.0001	0.05	-2.2052	-1.5545

Differences of TRTPN Least Squares Means

Planned Treatment (N)	Planned Treatment (N)	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
2	4	WORK.ENDPOINT	-0.1403	0.2202	-0.64	0.5240	0.05	-0.5720	0.2913
3	4	WORK.ENDPOINT	-0.05234	0.2149	-0.24	0.8076	0.05	-0.4735	0.3688

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) / NovoRapid (meal)	WORK.ENDPOINT	-0.1403	0.2202	-0.64	0.5240	0.05	-0.5720	0.2913

Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=HBA70 Parameter=HbA1c <7.0% without severe hypo and with minimal weight gain Study Identifier=NN1218-4131

The GENMOD Procedure

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
TRTPN	Faster aspart (post) / NovoRapid (meal)	WORK.ENDPOINT	-0.05234	0.2149	-0.24	0.8076	0.05	-0.4735	0.3688

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
1	1	0.4074833	-0.374379	0.2683126	0.2414407
2	0	0.4074833	-0.374379	0.2683126	0.2414407
3	1	0.2164243	-1.286627	0.2600044	0.1695848
4	1	0.187083	-1.469076	0.2617185	0.152083
5	1	0.187083	-1.469076	0.2617185	0.152083
6	1	0.1843661	-1.487042	0.2285833	0.1503752
7	1	0.2657724	-1.016179	0.2425458	0.1951374
8	1	0.1269248	-1.928427	0.2558144	0.1108149
9	1	0.0603003	-2.746223	0.3021542	0.0566642
10	1	0.3504855	-0.616906	0.2171098	0.2276454
11	0	0.4521644	-0.19193	0.2732063	0.2477118
12	1	0.5648742	0.2609679	0.2727297	0.2457913
13	0	0.3848931	-0.46883	0.248897	0.2367504
14	0	0.5326679	0.130858	0.2681454	0.2489328
15	1	0.0998516	-2.198875	0.279251	0.0898812
16	1	0.1552981	-1.693638	0.2572212	0.1311806

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Parameter Code=HBA70 Parameter=HbA1c <7.0% without severe hypo and with minimal weight gain Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
17	1	0.158492	-1.669492	0.2317708	0.1333723
18	1	0.106325	-2.128842	0.2375146	0.09502
19	1	0.2064097	-1.346704	0.2171021	0.1638048
20	1	0.081403	-2.423436	0.2835621	0.0747765
21	1	0.0172705	-4.041336	0.355739	0.0169722
22	1	0.081403	-2.423436	0.2835621	0.0747765
23	1	0.3427012	-0.65128	0.2455984	0.2252571
24	1	0.1249473	-1.946392	0.2309461	0.1093354
25	1	0.0654839	-2.658225	0.285244	0.0611957
26	1	0.1269248	-1.928427	0.2558144	0.1108149
27	1	0.077574	-2.475775	0.2765814	0.0715562
28	1	0.2622814	-1.034145	0.2163603	0.1934899
29	1	0.0603003	-2.746223	0.3021542	0.0566642
30	1	0.1529559	-1.711603	0.2251134	0.1295604
31	1	0.4244953	-0.304346	0.2285288	0.244299
32	1	0.0603003	-2.746223	0.3021542	0.0566642
33	1	0.1269248	-1.928427	0.2558144	0.1108149
34	0	0.1529559	-1.711603	0.2251134	0.1295604
35	1	0.2317193	-1.198629	0.2428364	0.1780255
36	0	0.4417553	-0.234041	0.2569597	0.2466076
37	1	0.2411676	-1.146289	0.2483584	0.1830058
38	1	0.1485553	-1.745977	0.2508726	0.1264866
39	0	0.3848931	-0.46883	0.248897	0.2367504
40	1	0.1080442	-2.110876	0.2617932	0.0963706
41	0	0.3427012	-0.65128	0.2455984	0.2252571

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=HBA70 Parameter=HbA1c <7.0% without severe hypo and with minimal weight gain Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
42	0	0.3386658	-0.669246	0.2198571	0.2239713
43	1	0.4244953	-0.304346	0.2285288	0.244299
44	0	0.3101634	-0.799355	0.2150575	0.2139621
45	1	0.2133931	-1.304593	0.2266575	0.1678565
46	1	0.0982484	-2.21684	0.2483229	0.0885956
47	0	0.5835718	0.3374535	0.2647005	0.2430158
48	0	0.2622814	-1.034145	0.2163603	0.1934899
49	1	0.0800696	-2.441401	0.254657	0.0736585
50	0	0.5386736	0.1550039	0.2561766	0.2485044
51	0	0.5835718	0.3374535	0.2647005	0.2430158
52	1	0.2622814	-1.034145	0.2163603	0.1934899
53	0	0.3806486	-0.486796	0.2235753	0.2357553
54	1	0.1781175	-1.529154	0.2204752	0.1463917
55	1	0.106325	-2.128842	0.2375146	0.09502
56	0	0.1843661	-1.487042	0.2285833	0.1503752
57	1	0.0901921	-2.311292	0.2451142	0.0820575
58	1	0.0592903	-2.764189	0.2737287	0.055775
59	1	0.1307831	-1.894053	0.2309404	0.1136789
60	0	0.0382894	-3.223539	0.2954332	0.0368234
61	0	0.5733034	0.2953419	0.2458296	0.2446266
62	1	0.0832269	-2.39929	0.2559191	0.0763002
63	1	0.1249473	-1.946392	0.2309461	0.1093354
64	1	0.5281932	0.1128923	0.23789	0.2492051
65	0	0.4244953	-0.304346	0.2285288	0.244299
66	1	0.4244953	-0.304346	0.2285288	0.244299

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=HBA70 Parameter=HbA1c <7.0% without severe hypo and with minimal weight gain Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
67	1	0.1705841	-1.581493	0.2212559	0.1414852
68	1	0.4244953	-0.304346	0.2285288	0.244299
69	1	0.2809623	-0.939693	0.2266991	0.2020225
70	1	0.0144318	-4.223785	0.3691718	0.0142235
71	1	0.319245	-0.757244	0.2286657	0.2173276
72	1	0.2725338	-0.981805	0.2143678	0.1982591
73	0	0.2990774	-0.851695	0.2174376	0.2096301
74	1	0.3101634	-0.799355	0.2150575	0.2139621
75	0	0.1843661	-1.487042	0.2285833	0.1503752
76	0	0.2064097	-1.346704	0.2171021	0.1638048
77	1	0.2990774	-0.851695	0.2174376	0.2096301
78	1	0.4373296	-0.252007	0.2251281	0.2460724
79	1	0.0351775	-3.311538	0.3057893	0.03394
80	0	0.493139	-0.027446	0.2485504	0.2499529
81	1	0.0337759	-3.353649	0.3096115	0.0326351
82	1	0.1356451	-1.851941	0.2361691	0.1172455
83	1	0.4373296	-0.252007	0.2251281	0.2460724
84	1	0.3504855	-0.616906	0.2171098	0.2276454
85	0	0.1356451	-1.851941	0.2361691	0.1172455
86	1	0.0382894	-3.223539	0.2954332	0.0368234
87	1	0.0982484	-2.21684	0.2483229	0.0885956
88	1	0.2990774	-0.851695	0.2174376	0.2096301
89	0	0.6172262	0.4777915	0.2546831	0.236258
90	0	0.3806486	-0.486796	0.2235753	0.2357553
91	1	0.1307831	-1.894053	0.2309404	0.1136789

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
92	1	0.2064097	-1.346704	0.2171021	0.1638048
93	1	0.1781175	-1.529154	0.2204752	0.1463917
94	1	0.1529559	-1.711603	0.2251134	0.1295604
95	0	0.319245	-0.757244	0.2286657	0.2173276
96	0	0.2064097	-1.346704	0.2171021	0.1638048
97	1	0.3386658	-0.669246	0.2198571	0.2239713
98	1	0.1552981	-1.693638	0.2572212	0.1311806
99	1	0.2133931	-1.304593	0.2266575	0.1678565
100	1	0.2008359	-1.381078	0.2443385	0.1605008
101	1	0.6990316	0.8426906	0.2747695	0.2103864
102	1	0.284606	-0.921728	0.2599728	0.2036054
103	1	0.1269248	-1.928427	0.2558144	0.1108149
104	0	0.3930627	-0.434456	0.2204865	0.2385644
105	1	0.1131926	-2.058537	0.2685213	0.1003801
106	1	0.2093681	-1.328738	0.2501695	0.1655331
107	1	0.1781175	-1.529154	0.2204752	0.1463917
108	1	0.0901921	-2.311292	0.2451142	0.0820575
109	1	0.3806486	-0.486796	0.2235753	0.2357553
110	0	0.187083	-1.469076	0.2617185	0.152083
111	0	0.5776924	0.3133075	0.2751816	0.2439639
112	0	0.5326679	0.130858	0.2681454	0.2489328
113	1	0.3973568	-0.416491	0.2529379	0.2394644
114	0	0.2093681	-1.328738	0.2501695	0.1655331
115	1	0.0715066	-2.563774	0.2937137	0.0663934
116	1	0.1269248	-1.928427	0.2558144	0.1108149

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=HBA70 Parameter=HbA1c <7.0% without severe hypo and with minimal weight gain Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
117	1	0.1552981	-1.693638	0.2572212	0.1311806
118	1	0.0507542	-2.928673	0.3113155	0.0481782
119	1	0.3545862	-0.59894	0.2500351	0.2288548
120	0	0.4521644	-0.19193	0.2732063	0.2477118
121	1	0.132839	-1.876087	0.2623697	0.1151928
122	0	0.248958	-1.104177	0.2594199	0.1869779
123	1	0.2657724	-1.016179	0.2425458	0.1951374
124	1	0.0168654	-4.065482	0.3834263	0.016581
125	0	0.1174891	-2.016425	0.2733567	0.1036854
126	1	0.0654839	-2.658225	0.285244	0.0611957
127	1	0.173141	-1.563528	0.24703	0.1431632
128	1	0.1485553	-1.745977	0.2508726	0.1264866
129	1	0.0321088	-3.405989	0.307397	0.0310778
130	1	0.0998516	-2.198875	0.279251	0.0898812
131	1	0.0100639	-4.588685	0.396907	0.0099626
132	1	0.173141	-1.563528	0.24703	0.1431632
133	1	0.0389565	-3.205574	0.3154507	0.0374389
134	1	0.1529559	-1.711603	0.2251134	0.1295604
135	1	0.2761102	-0.963839	0.2477291	0.1998733
136	1	0.2093681	-1.328738	0.2501695	0.1655331
137	1	0.5648742	0.2609679	0.2727297	0.2457913
138	1	0.1529559	-1.711603	0.2251134	0.1295604
139	1	0.2164243	-1.286627	0.2600044	0.1695848
140	1	0.2411676	-1.146289	0.2483584	0.1830058
141	0	0.2008359	-1.381078	0.2443385	0.1605008

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=HBA70 Parameter=HbA1c <7.0% without severe hypo and with minimal weight gain Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
142	0	0.5648742	0.2609679	0.2727297	0.2457913
143	1	0.2725338	-0.981805	0.2143678	0.1982591
144	1	0.319245	-0.757244	0.2286657	0.2173276
145	1	0.1356451	-1.851941	0.2361691	0.1172455
146	1	0.1307831	-1.894053	0.2309404	0.1136789
147	1	0.4244953	-0.304346	0.2285288	0.244299
148	1	0.0762981	-2.493741	0.2536522	0.0704767
149	1	0.2725338	-0.981805	0.2143678	0.1982591
150	1	0.1156391	-2.034391	0.241712	0.1022667
151	0	0.1462972	-1.763943	0.225499	0.1248943
152	1	0.0676191	-2.623851	0.2643304	0.0630468
153	0	0.6172262	0.4777915	0.2546831	0.236258
154	1	0.026898	-3.588438	0.3198372	0.0261745
155	1	0.1114017	-2.076502	0.237869	0.0989914
156	1	0.158492	-1.669492	0.2317708	0.1333723
157	1	0.2622814	-1.034145	0.2163603	0.1934899
158	1	0.2622814	-1.034145	0.2163603	0.1934899
159	0	0.2133931	-1.304593	0.2266575	0.1678565
160	1	0.1356451	-1.851941	0.2361691	0.1172455
161	1	0.2133931	-1.304593	0.2266575	0.1678565
162	0	0.5151336	0.0605527	0.2418194	0.249771
163	1	0.1705841	-1.581493	0.2212559	0.1414852
164	0	0.4244953	-0.304346	0.2285288	0.244299
165	1	0.3101634	-0.799355	0.2150575	0.2139621
166	1	0.0901921	-2.311292	0.2451142	0.0820575

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=HBA70 Parameter=HbA1c <7.0% without severe hypo and with minimal weight gain Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
167	1	0.2725338	-0.981805	0.2143678	0.1982591
168	1	0.1114017	-2.076502	0.237869	0.0989914
169	1	0.0800696	-2.441401	0.254657	0.0736585
170	1	0.158492	-1.669492	0.2317708	0.1333723
171	1	0.3806486	-0.486796	0.2235753	0.2357553
172	0	0.2809623	-0.939693	0.2266991	0.2020225
173	1	0.0419232	-3.129088	0.2944879	0.0401657
174	1	0.0337759	-3.353649	0.3096115	0.0326351
175	1	0.1529559	-1.711603	0.2251134	0.1295604
176	1	0.1307831	-1.894053	0.2309404	0.1136789
177	1	0.0901921	-2.311292	0.2451142	0.0820575
178	1	0.0246881	-3.676437	0.32992	0.0240786
179	1	0.106325	-2.128842	0.2375146	0.09502
180	1	0.2378951	-1.164255	0.2150536	0.181301
181	1	0.1843661	-1.487042	0.2285833	0.1503752
182	1	0.2725338	-0.981805	0.2143678	0.1982591
183	1	0.2622814	-1.034145	0.2163603	0.1934899
184	1	0.026898	-3.588438	0.3198372	0.0261745
185	1	0.106325	-2.128842	0.2375146	0.09502
186	1	0.1529559	-1.711603	0.2251134	0.1295604
187	1	0.0498956	-2.946639	0.2837779	0.0474061
188	1	0.245614	-1.122143	0.2260259	0.1852878
189	1	0.0542364	-2.85864	0.2731825	0.0512948
190	1	0.0832269	-2.39929	0.2559191	0.0763002
191	1	0.3973568	-0.416491	0.2529379	0.2394644

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=HBA70 Parameter=HbA1c <7.0% without severe hypo and with minimal weight gain Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
192	1	0.2725338	-0.981805	0.2143678	0.1982591
193	1	0.0246881	-3.676437	0.32992	0.0240786
194	1	0.5733034	0.2953419	0.2458296	0.2446266
195	1	0.064393	-2.676191	0.2630375	0.0602465
196	1	0.3545862	-0.59894	0.2500351	0.2288548
197	1	0.0236941	-3.718548	0.3352581	0.0231327
198	0	0.1307831	-1.894053	0.2309404	0.1136789
199	0	0.2133931	-1.304593	0.2266575	0.1678565
200	1	0.0283024	-3.536099	0.3222317	0.0275014
201	1	0.0498956	-2.946639	0.2837779	0.0474061
202	1	0.1529559	-1.711603	0.2251134	0.1295604
203	1	0.3386658	-0.669246	0.2198571	0.2239713
204	1	0.245614	-1.122143	0.2260259	0.1852878
205	1	0.2622814	-1.034145	0.2163603	0.1934899
206	1	0.0294838	-3.493987	0.3176189	0.0286145
207	1	0.0498956	-2.946639	0.2837779	0.0474061
208	1	0.0542364	-2.85864	0.2731825	0.0512948
209	1	0.158492	-1.669492	0.2317708	0.1333723
210	1	0.0479367	-2.98875	0.2858032	0.0456388
211	1	0.0064959	-5.030069	0.4454098	0.0064537
212	1	0.0321088	-3.405989	0.307397	0.0310778
213	1	0.1462972	-1.763943	0.225499	0.1248943
214	1	0.0916772	-2.293326	0.2687399	0.0832725
215	1	0.2990774	-0.851695	0.2174376	0.2096301
216	1	0.2164243	-1.286627	0.2600044	0.1695848

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=HBA70 Parameter=HbA1c <7.0% without severe hypo and with minimal weight gain Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
217	1	0.2761102	-0.963839	0.2477291	0.1998733
218	1	0.0846079	-2.381324	0.2860578	0.0774494
219	1	0.040964	-3.153234	0.3226513	0.039286
220	1	0.2093681	-1.328738	0.2501695	0.1655331
221	0	0.6172262	0.4777915	0.2546831	0.236258
222	0	0.319245	-0.757244	0.2286657	0.2173276
223	1	0.4695635	-0.121897	0.2346394	0.2490736
224	0	0.1979679	-1.399044	0.2182873	0.1587766
225	1	0.319245	-0.757244	0.2286657	0.2173276
226	0	0.319245	-0.757244	0.2286657	0.2173276
227	1	0.2622814	-1.034145	0.2163603	0.1934899
228	1	0.0479367	-2.98875	0.2858032	0.0456388
229	1	0.0165701	-4.083447	0.362353	0.0162955
230	0	0.1705841	-1.581493	0.2212559	0.1414852
231	0	0.026898	-3.588438	0.3198372	0.0261745
232	1	0.1307831	-1.894053	0.2309404	0.1136789
233	1	0.0037012	-5.595384	0.4765665	0.0036875
234	1	0.0982484	-2.21684	0.2483229	0.0885956
235	1	0.0762981	-2.493741	0.2536522	0.0704767
236	1	0.6047871	0.4254518	0.2590187	0.2390197
237	1	0.0901921	-2.311292	0.2451142	0.0820575
238	1	0.2725338	-0.981805	0.2143678	0.1982591
239	1	0.1249473	-1.946392	0.2309461	0.1093354
240	1	0.0294838	-3.493987	0.3176189	0.0286145
241	1	0.2809623	-0.939693	0.2266991	0.2020225

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
242	1	0.0246881	-3.676437	0.32992	0.0240786
243	1	0.2064097	-1.346704	0.2171021	0.1638048
244	1	0.0283024	-3.536099	0.3222317	0.0275014
245	0	0.1705841	-1.581493	0.2212559	0.1414852
246	1	0.0405173	-3.164666	0.3501693	0.0388756
247	1	0.0482358	-2.982216	0.3427027	0.0459091
248	1	0.0270695	-3.581905	0.3692996	0.0263368
249	1	0.0805522	-2.434868	0.3247607	0.0740636
250	1	0.0385308	-3.217005	0.3529951	0.0370461
251	1	0.0238458	-3.712014	0.3764079	0.0232771
252	1	0.0353999	-3.305004	0.3541905	0.0341468
253	1	0.1715105	-1.574959	0.3175716	0.1420947
254	1	0.2635476	-1.027611	0.3218182	0.1940902
255	1	0.2468267	-1.115609	0.3200967	0.1859033
256	1	0.0458889	-3.034556	0.3458371	0.0437831
257	1	0.0101292	-4.582151	0.4220718	0.0100266
258	1	0.0545725	-2.852106	0.3393992	0.0515944
259	1	0.0385308	-3.217005	0.3529951	0.0370461
260	1	0.0092247	-4.676602	0.4311491	0.0091396
261	1	0.0199482	-3.894464	0.386289	0.0195503
262	1	0.0545725	-2.852106	0.3393992	0.0515944
263	1	0.0248459	-3.669903	0.3708808	0.0242286
264	1	0.0339898	-3.347115	0.3583052	0.0328344
265	1	0.0284826	-3.529565	0.3670659	0.0276714
266	1	0.0032724	-5.71896	0.5070225	0.0032617

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
267	1	0.0067653	-4.989161	0.4547989	0.0067195
268	1	0.0339898	-3.347115	0.3583052	0.0328344
269	0	0.0421864	-3.122554	0.3468229	0.0404067
270	1	0.1471151	-1.757409	0.3180065	0.1254723
271	1	0.4947722	-0.020912	0.3505235	0.2499727
272	1	0.0458889	-3.034556	0.3458371	0.0437831
273	1	0.0647878	-2.669657	0.333723	0.0605903
274	1	0.0207884	-3.852352	0.3801178	0.0203562
275	1	0.0405173	-3.164666	0.3501693	0.0388756
276	1	0.1990074	-1.39251	0.3180662	0.1594034
277	1	0.2635476	-1.027611	0.3218182	0.1940902
278	1	0.2635476	-1.027611	0.3218182	0.1940902
279	1	0.0988288	-2.210306	0.3214394	0.0890616
280	1	0.0207884	-3.852352	0.3801178	0.0203562
281	1	0.0189503	-3.946804	0.3879713	0.0185912
282	1	0.5402969	0.1615378	0.3582388	0.2483762
283	1	0.6286517	0.5264369	0.3755582	0.2334487
284	1	0.4047261	-0.385811	0.3371975	0.2409229
285	1	0.0226573	-3.764354	0.3783604	0.022144
286	1	0.0166769	-4.076914	0.3966688	0.0163988
287	0	0.2738311	-0.975271	0.3154781	0.1988476
288	1	0.0166769	-4.076914	0.3966688	0.0163988
289	1	0.0027281	-5.901409	0.5206785	0.0027207
290	1	8.3282E-8	-16.30103	1.4309206	8.3282E-8
291	0	0.2738311	-0.975271	0.3154781	0.1988476

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
292	1	0.0385308	-3.217005	0.3529951	0.0370461
293	1	0.116309	-2.027857	0.3189089	0.1027812
294	1	0.0339898	-3.347115	0.3583052	0.0328344
295	1	0.0458889	-3.034556	0.3458371	0.0437831
296	1	0.0199482	-3.894464	0.386289	0.0195503
297	0	0.1790761	-1.52262	0.3119689	0.1470078
298	0	0.3401307	-0.662712	0.3291363	0.2244418
299	1	0.0596558	-2.757655	0.3342586	0.056097
300	1	0.0988288	-2.210306	0.3214394	0.0890616
301	1	0.3115631	-0.792822	0.3184993	0.2144916
302	1	0.0076981	-4.859051	0.4429541	0.0076389
303	1	0.0907297	-2.304758	0.3248103	0.0824978
304	1	0.0482358	-2.982216	0.3427027	0.0459091
305	1	0.0502063	-2.940105	0.3401648	0.0476856
306	1	0.0502063	-2.940105	0.3401648	0.0476856
307	1	0.1120502	-2.069968	0.3169217	0.0994949
308	1	0.012132	-4.399701	0.4109072	0.0119848
309	1	0.0296713	-3.487453	0.3622242	0.0287909
310	1	0.1853507	-1.480508	0.3168377	0.1509958
311	0	0.1990074	-1.39251	0.3180662	0.1594034
312	1	0.0482358	-2.982216	0.3427027	0.0459091
313	1	0.0680322	-2.617317	0.3299555	0.0634038
314	1	0.0132332	-4.311703	0.4086859	0.0130581
315	1	0.0988288	-2.210306	0.3214394	0.0890616
316	1	0.1120502	-2.069968	0.3169217	0.0994949

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
317	1	0.0647878	-2.669657	0.333723	0.0605903
318	1	0.0707513	-2.575206	0.3291447	0.0657455
319	1	0.0458889	-3.034556	0.3458371	0.0437831
320	1	0.012132	-4.399701	0.4109072	0.0119848
321	0	0.0680322	-2.617317	0.3299555	0.0634038
322	1	0.0907297	-2.304758	0.3248103	0.0824978
323	1	0.0596558	-2.757655	0.3342586	0.056097
324	1	0.2074821	-1.34017	0.3121984	0.1644333
325	1	0.0707513	-2.575206	0.3291447	0.0657455
326	1	0.0502063	-2.940105	0.3401648	0.0476856
327	0	0.0081084	-4.806712	0.4424493	0.0080427
328	1	0.0405173	-3.164666	0.3501693	0.0388756
329	1	0.0573368	-2.799767	0.3359502	0.0540493
330	1	0.0226573	-3.764354	0.3783604	0.022144
331	1	0.0951411	-2.252418	0.3204045	0.0860893
332	1	0.2144919	-1.298059	0.3180073	0.1684851
333	1	0.0767599	-2.487207	0.328848	0.0708678
334	1	0.0596558	-2.757655	0.3342586	0.056097
335	1	0.0023718	-6.041747	0.5232683	0.0023661
336	1	0.0482358	-2.982216	0.3427027	0.0459091
337	1	0.0482358	-2.982216	0.3427027	0.0459091
338	1	0.2144919	-1.298059	0.3180073	0.1684851
339	0	0.0573368	-2.799767	0.3359502	0.0540493
340	0	0.3004489	-0.845161	0.3250438	0.2101794
341	1	0.0707513	-2.575206	0.3291447	0.0657455

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
342	1	0.2738311	-0.975271	0.3154781	0.1988476
343	1	0.5402969	0.1615378	0.3582388	0.2483762
344	1	0.0238458	-3.712014	0.3764079	0.0232771
345	1	0.0101292	-4.582151	0.4220718	0.0100266
346	1	0.3004489	-0.845161	0.3250438	0.2101794
347	1	0.3519743	-0.610372	0.3224096	0.2280884
348	1	0.2822841	-0.93316	0.323088	0.2025998
349	1	0.0162934	-4.100569	0.3420102	0.0160279
350	0	0.2521978	-1.086925	0.2236293	0.1885941
351	1	0.0612854	-2.728971	0.2558842	0.0575295
352	0	0.2881317	-0.904475	0.226374	0.2051118
353	0	0.189721	-1.451824	0.2220631	0.153727
354	0	0.101413	-2.181622	0.2345306	0.0911284
355	1	0.3585444	-0.581688	0.2235917	0.2299903
356	0	0.1575748	-1.676385	0.2189762	0.132745
357	1	0.3724758	-0.52161	0.246621	0.2337376
358	1	0.3103441	-0.798511	0.2300492	0.2140306
359	1	0.1599743	-1.658419	0.2293763	0.1343825
360	0	0.0623271	-2.711005	0.2665008	0.0584424
361	1	0.1114853	-2.075658	0.2359403	0.0990564
362	1	0.0873758	-2.346106	0.2518239	0.0797413
363	1	0.4058201	-0.381272	0.2386225	0.2411301
364	1	0.2224564	-1.251409	0.234031	0.1729696
365	1	0.2224564	-1.251409	0.234031	0.1729696
366	1	0.1420024	-1.798757	0.2375597	0.1218377

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
367	1	0.2918307	-0.886509	0.2379386	0.2066655
368	1	0.1860369	-1.47597	0.2268468	0.1514272
369	1	0.103062	-2.163656	0.2459627	0.0924402
370	1	0.0101748	-4.577612	0.3891232	0.0100713
371	1	0.0873758	-2.346106	0.2518239	0.0797413
372	1	0.2380482	-1.16341	0.225285	0.1813812
373	1	0.0946524	-2.258108	0.2417083	0.0856933
374	1	0.4375374	-0.251162	0.246185	0.2460984
375	1	0.0623271	-2.711005	0.2665008	0.0584424
376	1	0.0676723	-2.623007	0.2563303	0.0630928
377	1	0.0402967	-3.170355	0.284709	0.0386729
378	1	0.6595042	0.6610854	0.2919401	0.2245584
379	1	0.1599743	-1.658419	0.2293763	0.1343825
380	0	0.2380482	-1.16341	0.225285	0.1813812
381	1	0.05703	-2.805456	0.2650142	0.0537776
382	1	0.1308791	-1.893208	0.2313081	0.1137497
383	0	0.4504574	-0.198823	0.2447892	0.2475455
384	1	0.1398276	-1.816723	0.2257805	0.1202758
385	1	0.3626867	-0.563722	0.2335601	0.2311451
386	1	0.1114853	-2.075658	0.2359403	0.0990564
387	0	0.0106078	-4.535501	0.3801361	0.0104953
388	0	0.0198373	-3.900154	0.3313629	0.0194438
389	1	0.0946524	-2.258108	0.2417083	0.0856933
390	0	0.1530653	-1.710759	0.2278812	0.1296363
391	1	0.0121865	-4.395163	0.3752481	0.012038

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
392	1	0.128849	-1.911174	0.2285222	0.1122469
393	0	0.5239245	0.0957711	0.2599935	0.2494276
394	1	0.101413	-2.181622	0.2345306	0.0911284
395	1	0.1632458	-1.634273	0.223269	0.1365966
396	0	0.2691526	-0.998926	0.2243875	0.1967095
397	1	0.0623271	-2.711005	0.2665008	0.0584424
398	1	0.2193644	-1.269374	0.2221839	0.1712437
399	1	0.101413	-2.181622	0.2345306	0.0911284
400	1	0.2193644	-1.269374	0.2221839	0.1712437
401	0	0.0515919	-2.91142	0.2648563	0.0489302
402	1	0.2348049	-1.181376	0.2225821	0.1796716
403	1	0.0698736	-2.588633	0.2499868	0.0649913
404	1	0.1507508	-1.728725	0.225092	0.128025
405	1	0.2881317	-0.904475	0.226374	0.2051118
406	1	0.0665476	-2.640972	0.2536801	0.062119
407	1	0.4116554	-0.357126	0.2418573	0.2421952
408	1	0.0178785	-4.006118	0.3325464	0.0175588
409	0	0.3103441	-0.798511	0.2300492	0.2140306
410	1	0.1657147	-1.616308	0.2351365	0.1382534
411	0	0.4375374	-0.251162	0.246185	0.2460984
412	1	0.2224564	-1.251409	0.234031	0.1729696
413	0	0.2065481	-1.34586	0.2248439	0.163886
414	1	0.0710503	-2.570667	0.2593155	0.0660021
415	1	0.0676723	-2.623007	0.2563303	0.0630928
416	0	0.3216561	-0.746171	0.2296752	0.2181935

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
417	0	0.6711575	0.713425	0.289289	0.2207051
418	1	0.57351	0.2961863	0.271308	0.2445963
419	1	0.2380482	-1.16341	0.225285	0.1813812
420	0	0.8061613	1.4252576	0.3301079	0.1562652
421	1	0.346598	-0.634027	0.2318098	0.2264678
422	0	0.6255118	0.5130098	0.2707437	0.2342468
423	1	0.1149361	-2.041284	0.2280253	0.1017258
424	0	0.8620317	1.8322683	0.375046	0.118933
425	1	0.101413	-2.181622	0.2345306	0.0911284
426	0	0.1756249	-1.546275	0.2229375	0.1447808
427	0	0.5019432	0.0077727	0.2574524	0.2499962
428	1	0.0433608	-3.09387	0.274612	0.0414807
429	1	0.1756249	-1.546275	0.2229375	0.1447808
430	1	0.134839	-1.858834	0.2228849	0.1166574
431	1	0.0471613	-3.005871	0.2719624	0.0449371
432	0	0.2795718	-0.946587	0.2166782	0.2014114
433	1	0.1632458	-1.634273	0.223269	0.1365966
434	1	0.2122383	-1.311486	0.2151013	0.1671932
435	0	0.4914161	-0.034339	0.2428774	0.2499263
436	0	0.1575748	-1.676385	0.2189762	0.132745
437	0	0.3724758	-0.52161	0.246621	0.2337376
438	1	0.134839	-1.858834	0.2228849	0.1166574
439	1	0.103062	-2.163656	0.2459627	0.0924402
440	0	0.1167763	-2.023318	0.2381044	0.1031396
441	1	0.2193644	-1.269374	0.2221839	0.1712437

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
442	1	0.0738804	-2.528555	0.258696	0.0684221
443	1	0.244339	-1.129036	0.215206	0.1846375
444	1	0.0416472	-3.135981	0.2798354	0.0399127
445	1	0.0623271	-2.711005	0.2665008	0.0584424
446	1	0.2224564	-1.251409	0.234031	0.1729696
447	1	0.1097181	-2.093624	0.2331718	0.0976801
448	1	0.0479753	-2.987906	0.2745004	0.0456736
449	0	0.8978005	2.1730214	0.3904256	0.0917547
450	1	0.0515919	-2.91142	0.2648563	0.0489302
451	1	0.0171539	-4.048229	0.3412913	0.0168596
452	1	0.0292872	-3.50088	0.3029924	0.0284295
453	1	0.0676723	-2.623007	0.2563303	0.0630928
454	1	0.1211903	-1.981207	0.2411862	0.1065032
455	1	0.0479753	-2.987906	0.2745004	0.0456736
456	1	0.0976394	-2.223734	0.2343162	0.0881059
457	1	0.0524781	-2.893455	0.275159	0.0497241
458	1	0.0338034	-3.352805	0.295565	0.0326608
459	1	0.0946524	-2.258108	0.2417083	0.0856933
460	1	0.5818957	0.3305602	0.260654	0.2432931
461	1	0.0495699	-2.953532	0.2691572	0.0471127
462	1	0.0310443	-3.440803	0.3054934	0.0300806
463	1	0.0423702	-3.118016	0.2882913	0.040575
464	1	0.189721	-1.451824	0.2220631	0.153727
465	1	0.2832046	-0.928621	0.2270282	0.2029997
466	1	0.2036193	-1.363825	0.2220959	0.1621585

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
467	1	0.2122383	-1.311486	0.2151013	0.1671932
468	1	0.0471613	-3.005871	0.2719624	0.0449371
469	1	0.1756249	-1.546275	0.2229375	0.1447808
470	1	0.0676723	-2.623007	0.2563303	0.0630928
471	1	0.0213804	-3.823668	0.3199541	0.0209233
472	1	0.128849	-1.911174	0.2285222	0.1122469
473	1	0.0873758	-2.346106	0.2518239	0.0797413
474	1	0.019491	-3.918119	0.3291296	0.0191111
475	1	0.1097181	-2.093624	0.2331718	0.0976801
476	1	0.101413	-2.181622	0.2345306	0.0911284
477	1	0.244339	-1.129036	0.215206	0.1846375
478	1	0.2691526	-0.998926	0.2243875	0.1967095
479	1	0.189721	-1.451824	0.2220631	0.153727
480	1	0.0396076	-3.188321	0.2822316	0.0380388
481	1	0.4014954	-0.399238	0.2289132	0.2402969
482	1	0.2348049	-1.181376	0.2225821	0.1796716
483	1	0.0332216	-3.370771	0.2931492	0.0321179
484	0	0.1507508	-1.728725	0.225092	0.128025
485	0	0.3585444	-0.581688	0.2235917	0.2299903
486	1	0.0305084	-3.458769	0.2961583	0.0295777
487	1	0.1097181	-2.093624	0.2331718	0.0976801
488	1	0.0178785	-4.006118	0.3325464	0.0175588
489	0	0.2521978	-1.086925	0.2236293	0.1885941
490	1	0.0396076	-3.188321	0.2822316	0.0380388
491	1	0.3889857	-0.451578	0.2373076	0.2376758

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=HBA70 Parameter=HbA1c <7.0% without severe hypo and with minimal weight gain Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
492	1	0.0698736	-2.588633	0.2499868	0.0649913
493	1	0.244339	-1.129036	0.215206	0.1846375
494	1	0.0255504	-3.641218	0.3078064	0.0248976
495	1	0.189721	-1.451824	0.2220631	0.153727
496	0	0.2122383	-1.311486	0.2151013	0.1671932
497	1	0.0931241	-2.276073	0.2389697	0.084452
498	1	0.2036193	-1.363825	0.2220959	0.1621585
499	1	0.3585444	-0.581688	0.2235917	0.2299903
500	0	0.4014954	-0.399238	0.2289132	0.2402969
501	1	0.2795718	-0.946587	0.2166782	0.2014114
502	1	0.0162934	-4.100569	0.3420102	0.0160279
503	1	0.4564415	-0.174677	0.2491846	0.2481027
504	1	0.0788175	-2.458523	0.2458347	0.0726053
505	1	0.1833318	-1.493935	0.2163659	0.1497212
506	1	0.6255118	0.5130098	0.2707437	0.2342468
507	1	0.0788175	-2.458523	0.2458347	0.0726053
508	1	0.346598	-0.634027	0.2318098	0.2264678
509	1	0.0332216	-3.370771	0.2931492	0.0321179
510	1	0.0332216	-3.370771	0.2931492	0.0321179
511	0	0.2795718	-0.946587	0.2166782	0.2014114
512	0	0.5691099	0.2782206	0.26933	0.2452238
513	1	0.0495699	-2.953532	0.2691572	0.0471127
514	1	0.0560715	-2.823422	0.262418	0.0529275
515	1	0.101413	-2.181622	0.2345306	0.0911284
516	1	0.0612854	-2.728971	0.2558842	0.0575295

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=HBA70 Parameter=HbA1c <7.0% without severe hypo and with minimal weight gain Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
517	1	0.0560715	-2.823422	0.262418	0.0529275
518	1	0.0471613	-3.005871	0.2719624	0.0449371
519	0	0.4460142	-0.216788	0.235372	0.2470855
520	1	0.128849	-1.911174	0.2285222	0.1122469
521	1	0.0859538	-2.364072	0.2406337	0.0785657
522	1	0.2795718	-0.946587	0.2166782	0.2014114
523	1	0.0698736	-2.588633	0.2499868	0.0649913
524	1	0.0396076	-3.188321	0.2822316	0.0380388
525	0	0.0612854	-2.728971	0.2558842	0.0575295
526	1	0.0433608	-3.09387	0.274612	0.0414807
527	1	0.0931241	-2.276073	0.2389697	0.084452
528	1	0.0433608	-3.09387	0.274612	0.0414807
529	1	0.5019432	0.0077727	0.2574524	0.2499962
530	1	0.189721	-1.451824	0.2220631	0.153727
531	1	0.4914161	-0.034339	0.2428774	0.2499263
532	1	0.101413	-2.181622	0.2345306	0.0911284
533	1	0.128849	-1.911174	0.2285222	0.1122469
534	1	0.3065121	-0.816477	0.2274805	0.2125624
535	1	0.4116554	-0.357126	0.2418573	0.2421952
536	1	0.0976394	-2.223734	0.2343162	0.0881059
537	1	0.3585444	-0.581688	0.2235917	0.2299903
538	1	0.0976394	-2.223734	0.2343162	0.0881059
539	1	0.1632458	-1.634273	0.223269	0.1365966
540	1	0.0099955	-4.595578	0.3827162	0.0098956
541	1	0.0726605	-2.546521	0.2477807	0.067381

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Parameter Code=HBA70 Parameter=HbA1c <7.0% without severe hypo and with minimal weight gain Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
542	1	0.0698736	-2.588633	0.2499868	0.0649913
543	1	0.134839	-1.858834	0.2228849	0.1166574
544	0	0.1192898	-1.999172	0.2295547	0.1050598
545	1	0.0433608	-3.09387	0.274612	0.0414807
546	1	0.0612854	-2.728971	0.2558842	0.0575295
547	1	0.2881317	-0.904475	0.226374	0.2051118
548	1	0.0560715	-2.823422	0.262418	0.0529275
549	1	0.0433608	-3.09387	0.274612	0.0414807
550	1	0.0416472	-3.135981	0.2798354	0.0399127
551	1	0.1575748	-1.676385	0.2189762	0.132745
552	1	0.0363926	-3.276319	0.2850708	0.0350682
553	1	0.0515919	-2.91142	0.2648563	0.0489302
554	1	0.0245226	-3.68333	0.3153392	0.0239213
555	1	0.0612854	-2.728971	0.2558842	0.0575295
556	1	0.101413	-2.181622	0.2345306	0.0911284
557	1	0.0069608	-4.960477	0.4116065	0.0069123
558	1	0.1632458	-1.634273	0.223269	0.1365966
559	1	0.1632458	-1.634273	0.223269	0.1365966
560	0	0.4460142	-0.216788	0.235372	0.2470855
561	1	0.0560715	-2.823422	0.262418	0.0529275
562	1	0.0292872	-3.50088	0.3029924	0.0284295
563	1	0.2152576	-1.29352	0.2256019	0.1689218
564	1	0.2036193	-1.363825	0.2220959	0.1621585
565	0	0.3177487	-0.764137	0.2194903	0.2167845
566	1	0.0305084	-3.458769	0.2961583	0.0295777

Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=HBA70 Parameter=HbA1c <7.0% without severe hypo and with minimal weight gain Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
567	0	0.0992337	-2.205768	0.2441719	0.0893864
568	1	0.0788175	-2.458523	0.2458347	0.0726053
569	1	0.3585444	-0.581688	0.2235917	0.2299903
570	1	0.1097181	-2.093624	0.2331718	0.0976801
571	1	0.0124807	-4.371017	0.3588765	0.0123249
572	1	0.3065121	-0.816477	0.2274805	0.2125624
573	1	0.101413	-2.181622	0.2345306	0.0911284
574	1	0.0931241	-2.276073	0.2389697	0.084452
575	1	0.0931241	-2.276073	0.2389697	0.084452
576	1	0.0726605	-2.546521	0.2477807	0.067381
577	1	0.0827024	-2.406183	0.2416679	0.0758627
578	1	0.0698736	-2.588633	0.2499868	0.0649913
579	1	0.346598	-0.634027	0.2318098	0.2264678
580	1	0.3065121	-0.816477	0.2274805	0.2125624
581	1	0.0976394	-2.223734	0.2343162	0.0881059
582	1	0.1833318	-1.493935	0.2163659	0.1497212
583	1	0.1632458	-1.634273	0.223269	0.1365966
584	0	0.3506777	-0.616062	0.2342934	0.2277029
585	1	0.0992337	-2.205768	0.2441719	0.0893864
586	1	0.0992337	-2.205768	0.2441719	0.0893864
587	1	0.0084923	-4.760062	0.4032533	0.0084202
588	0	0.5064342	0.0257383	0.2675128	0.2499586
589	1	0.0623271	-2.711005	0.2665008	0.0584424
590	0	0.1530653	-1.710759	0.2278812	0.1296363
591	1	0.1599743	-1.658419	0.2293763	0.1343825

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
592	1	0.2476714	-1.111071	0.2256627	0.1863303
593	1	0.0338034	-3.352805	0.295565	0.0326608
594	1	0.0524781	-2.893455	0.275159	0.0497241
595	1	0.0801318	-2.440557	0.2485331	0.0737107
596	1	0.0623271	-2.711005	0.2665008	0.0584424
597	1	0.1211903	-1.981207	0.2411862	0.1065032
598	0	0.2918307	-0.886509	0.2379386	0.2066655
599	1	0.0217596	-3.805702	0.3286676	0.0212861
600	1	0.0992337	-2.205768	0.2441719	0.0893864
601	1	0.0479753	-2.987906	0.2745004	0.0456736
602	1	0.1924983	-1.433858	0.233954	0.1554427
603	0	0.3889857	-0.451578	0.2373076	0.2376758
604	1	0.0623271	-2.711005	0.2665008	0.0584424
605	1	0.0298023	-3.482915	0.3108758	0.0289141
606	1	0.0710503	-2.570667	0.2593155	0.0660021
607	1	0.0338034	-3.352805	0.295565	0.0326608
608	1	0.0788175	-2.458523	0.2458347	0.0726053
609	1	0.2224564	-1.251409	0.234031	0.1729696
610	0	0.3506777	-0.616062	0.2342934	0.2277029
611	1	0.0423702	-3.118016	0.2882913	0.040575
612	1	0.2727012	-0.980961	0.22703	0.1983353
613	1	0.1860369	-1.47597	0.2268468	0.1514272
614	0	0.4609022	-0.156711	0.2595997	0.2484714
615	1	0.4160133	-0.339161	0.2526095	0.2429462
616	1	0.1211903	-1.981207	0.2411862	0.1065032

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
617	0	0.3103441	-0.798511	0.2300492	0.2140306
618	0	0.1860369	-1.47597	0.2268468	0.1514272
619	1	0.1530653	-1.710759	0.2278812	0.1296363
620	1	0.2918307	-0.886509	0.2379386	0.2066655
621	1	0.0946524	-2.258108	0.2417083	0.0856933
622	1	0.0623271	-2.711005	0.2665008	0.0584424
623	1	0.0946524	-2.258108	0.2417083	0.0856933
624	1	0.0840756	-2.388217	0.2512705	0.0770069
625	1	0.3216561	-0.746171	0.2296752	0.2181935
626	1	0.1211903	-1.981207	0.2411862	0.1065032
627	1	0.1782412	-1.528309	0.2257143	0.1464713
628	0	0.1369486	-1.840869	0.2331486	0.1181937
629	1	0.0106078	-4.535501	0.3801361	0.0104953
630	0	0.4504574	-0.198823	0.2447892	0.2475455
631	1	0.3932642	-0.433612	0.2396975	0.2386075
632	1	0.0738804	-2.528555	0.258696	0.0684221
633	1	0.1860369	-1.47597	0.2268468	0.1514272
634	1	0.1114853	-2.075658	0.2359403	0.0990564
635	1	0.2832046	-0.928621	0.2270282	0.2029997
636	1	0.0441122	-3.075904	0.2845927	0.0421663
637	1	0.0738804	-2.528555	0.258696	0.0684221
638	1	0.3216561	-0.746171	0.2296752	0.2181935
639	0	0.1114853	-2.075658	0.2359403	0.0990564
640	1	0.2224564	-1.251409	0.234031	0.1729696
641	0	0.3506777	-0.616062	0.2342934	0.2277029

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
642	1	0.058907	-2.771082	0.2591798	0.055437
643	1	0.2556011	-1.068959	0.2353662	0.1902692
644	1	0.134839	-1.858834	0.2228849	0.1166574
645	1	0.103062	-2.163656	0.2459627	0.0924402
646	1	0.0788175	-2.458523	0.2458347	0.0726053
647	1	0.1924983	-1.433858	0.233954	0.1554427
648	1	0.0045971	-5.377716	0.4404821	0.004576
649	1	0.134839	-1.858834	0.2228849	0.1166574
650	1	0.0665476	-2.640972	0.2536801	0.062119
651	1	0.0249561	-3.665364	0.3229485	0.0243333
652	1	0.2727012	-0.980961	0.22703	0.1983353
653	1	0.2065481	-1.34586	0.2248439	0.163886
654	1	0.0560715	-2.823422	0.262418	0.0529275
655	1	0.1575748	-1.676385	0.2189762	0.132745
656	1	0.0665476	-2.640972	0.2536801	0.062119
657	0	0.1833318	-1.493935	0.2163659	0.1497212
658	1	0.1833318	-1.493935	0.2163659	0.1497212
659	1	0.0931241	-2.276073	0.2389697	0.084452
660	1	0.0086981	-4.735916	0.3864719	0.0086224
661	1	0.0441122	-3.075904	0.2845927	0.0421663
662	1	0.0162934	-4.100569	0.3420102	0.0160279
663	1	0.1575748	-1.676385	0.2189762	0.132745
664	1	0.0976394	-2.223734	0.2343162	0.0881059
665	0	0.1833318	-1.493935	0.2163659	0.1497212
666	1	0.0124807	-4.371017	0.3588765	0.0123249

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
667	1	0.1632458	-1.634273	0.223269	0.1365966
668	1	0.058907	-2.771082	0.2591798	0.055437
669	1	0.244339	-1.129036	0.215206	0.1846375
670	1	0.0042875	-5.447748	0.4509946	0.0042691
671	1	0.1114853	-2.075658	0.2359403	0.0990564
672	1	0.0073886	-4.9004	0.4077847	0.007334
673	1	0.0029806	-5.812647	0.4807165	0.0029717
674	1	0.05703	-2.805456	0.2650142	0.0537776
675	1	0.2380482	-1.16341	0.225285	0.1813812
676	1	0.0504231	-2.935566	0.2779065	0.0478807
677	1	0.2152576	-1.29352	0.2256019	0.1689218
678	1	0.0370279	-3.258354	0.2947274	0.0356568
679	1	0.0402967	-3.170355	0.284709	0.0386729
680	1	0.1860369	-1.47597	0.2268468	0.1514272
681	1	0.2380482	-1.16341	0.225285	0.1813812
682	1	0.1530653	-1.710759	0.2278812	0.1296363
683	1	0.0840756	-2.388217	0.2512705	0.0770069
684	1	0.1167763	-2.023318	0.2381044	0.1031396
685	1	0.4609022	-0.156711	0.2595997	0.2484714
686	1	0.0801318	-2.440557	0.2485331	0.0737107
687	1	0.1657147	-1.616308	0.2351365	0.1382534
688	1	0.1167763	-2.023318	0.2381044	0.1031396
689	1	0.1369486	-1.840869	0.2331486	0.1181937
690	1	0.1860369	-1.47597	0.2268468	0.1514272
691	1	0.1599743	-1.658419	0.2293763	0.1343825

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Parameter Code=HBA70 Parameter=HbA1c <7.0% without severe hypo and with minimal weight gain Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
692	1	0.1308791	-1.893208	0.2313081	0.1137497
693	0	0.0738804	-2.528555	0.258696	0.0684221
694	1	0.1120502	-2.069968	0.3169217	0.0994949
695	1	0.2074821	-1.34017	0.3121984	0.1644333
696	1	0.0707513	-2.575206	0.3291447	0.0657455
697	1	0.3946225	-0.427922	0.327177	0.2388956
698	1	0.0101292	-4.582151	0.4220718	0.0100266
699	1	0.0680322	-2.617317	0.3299555	0.0634038
700	0	0.136413	-1.845407	0.3172904	0.1178045
701	1	0.0458889	-3.034556	0.3458371	0.0437831
702	1	0.0166769	-4.076914	0.3966688	0.0163988
703	1	0.1790761	-1.52262	0.3119689	0.1470078
704	1	0.0545725	-2.852106	0.3393992	0.0515944
705	0	0.2738311	-0.975271	0.3154781	0.1988476
706	1	0.0573368	-2.799767	0.3359502	0.0540493
707	1	0.1069474	-2.122308	0.3216413	0.0955097
708	1	0.2468267	-1.115609	0.3200967	0.1859033
709	0	0.2738311	-0.975271	0.3154781	0.1988476
710	1	0.0323125	-3.399455	0.3608303	0.0312684
711	1	0.3206666	-0.75071	0.3269565	0.2178395
712	1	0.136413	-1.845407	0.3172904	0.1178045
713	0	0.1538043	-1.705069	0.3126854	0.1301486
714	0	0.3115631	-0.792822	0.3184993	0.2144916
715	1	0.1790761	-1.52262	0.3119689	0.1470078
716	1	0.0421864	-3.122554	0.3468229	0.0404067

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Parameter Code=HBA70 Parameter=HbA1c <7.0% without severe hypo and with minimal weight gain Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
717	1	0.0907297	-2.304758	0.3248103	0.0824978
718	1	0.0951411	-2.252418	0.3204045	0.0860893
719	0	0.1256634	-1.939859	0.319367	0.1098721
720	1	0.1538043	-1.705069	0.3126854	0.1301486
721	1	0.0166769	-4.076914	0.3966688	0.0163988
722	1	0.1069474	-2.122308	0.3216413	0.0955097
723	1	0.3004489	-0.845161	0.3250438	0.2101794
724	1	0.2296904	-1.21006	0.3194857	0.1769327
725	1	0.0392329	-3.198217	0.2841018	0.0376937
726	1	0.0419596	-3.128184	0.3067272	0.0401989
727	1	0.054615	-2.851283	0.2867215	0.0516322
728	1	0.0172858	-4.040432	0.3635863	0.016987
729	1	0.1257539	-1.939035	0.2529005	0.1099398
730	1	0.0352082	-3.310633	0.3170533	0.0339686
731	1	0.0295097	-3.493083	0.3279554	0.0286389
732	1	0.0329052	-3.380666	0.2955253	0.0318224
733	1	0.2255899	-1.233383	0.2177849	0.1746991
734	1	0.0533816	-2.875429	0.2742276	0.050532
735	1	0.078102	-2.468418	0.2452255	0.0720021
736	1	0.0085583	-4.752264	0.3954144	0.008485
737	1	0.009398	-4.657813	0.3875892	0.0093097
738	1	0.0158528	-4.12843	0.3641025	0.0156015
739	1	0.1231232	-1.963181	0.2320893	0.1079639
740	1	0.0315911	-3.422778	0.3083678	0.0305931
741	1	0.0555501	-2.833318	0.2631411	0.0524643

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=HBA70 Parameter=HbA1c <7.0% without severe hypo and with minimal weight gain Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
742	1	0.054615	-2.851283	0.2867215	0.0516322
743	1	0.054615	-2.851283	0.2867215	0.0516322
744	1	0.1047402	-2.145631	0.2386442	0.0937697
745	1	0.2255899	-1.233383	0.2177849	0.1746991
746	1	0.0300286	-3.475117	0.300774	0.0291269
747	0	0.0907976	-2.303934	0.2636033	0.0825534
748	1	0.6436204	0.5911125	0.269617	0.2293732
749	1	0.2135449	-1.303688	0.2493179	0.1679435
750	1	0.364491	-0.555924	0.220361	0.2316373
751	1	0.0217608	-3.805643	0.3534959	0.0212873
752	1	0.054615	-2.851283	0.2867215	0.0516322
753	1	0.0358236	-3.292668	0.2888173	0.0345403
754	1	0.0092322	-4.675779	0.4037511	0.009147
755	1	0.1610249	-1.650622	0.2157589	0.1350959
756	1	0.0507978	-2.927769	0.2666241	0.0482174
757	1	0.4077016	-0.373475	0.2257455	0.241481
758	1	0.026462	-3.605227	0.3207837	0.0257618
759	1	0.078102	-2.468418	0.2452255	0.0720021
760	1	0.0185215	-3.970126	0.3468389	0.0181785
761	0	0.2165777	-1.285723	0.2117971	0.1696718
762	0	0.1953157	-1.415833	0.2194378	0.1571675
763	1	0.1610249	-1.650622	0.2157589	0.1350959
764	1	0.084678	-2.38042	0.2388062	0.0775076
765	0	0.2955699	-0.868484	0.2185339	0.2082083
766	1	0.2224668	-1.251349	0.2476534	0.1729753

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
767	1	0.1442128	-1.780732	0.2266507	0.1234155
768	1	0.0230771	-3.745565	0.3199222	0.0225446
769	1	0.0251465	-3.657567	0.3132177	0.0245142
770	1	0.0751233	-2.51053	0.2547439	0.0694798
771	1	0.1378728	-1.833071	0.2197383	0.1188639
772	0	0.1442128	-1.780732	0.2266507	0.1234155
773	1	0.1378728	-1.833071	0.2197383	0.1188639
774	1	0.0358236	-3.292668	0.2888173	0.0345403
775	1	0.0888239	-2.32808	0.2462263	0.0809342
776	0	0.6315269	0.5387729	0.2680155	0.2327007
777	0	0.1494883	-1.73862	0.2213795	0.1271415
778	1	0.2491271	-1.103273	0.2118895	0.1870628
779	1	0.0329052	-3.380666	0.2955253	0.0318224
780	1	0.0392329	-3.198217	0.2841018	0.0376937
781	1	0.0648377	-2.668834	0.2781684	0.0606337
782	0	0.4077016	-0.373475	0.2257455	0.241481
783	1	0.0633889	-2.69298	0.2641065	0.0593707
784	1	0.6933172	0.8156736	0.2906844	0.2126285
785	1	0.084678	-2.38042	0.2388062	0.0775076
786	1	0.0907976	-2.303934	0.2636033	0.0825534
787	1	0.0648377	-2.668834	0.2781684	0.0606337
788	1	0.0715666	-2.56287	0.2472334	0.0664449
789	1	0.0907976	-2.303934	0.2636033	0.0825534
790	1	0.0888239	-2.32808	0.2462263	0.0809342
791	1	0.1175829	-2.015521	0.2249638	0.1037572

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
792	1	0.0392329	-3.198217	0.2841018	0.0376937
793	1	0.0751233	-2.51053	0.2547439	0.0694798
794	1	0.1231232	-1.963181	0.2320893	0.1079639
795	1	0.1231232	-1.963181	0.2320893	0.1079639
796	1	0.2672105	-1.008822	0.2175636	0.195809
797	1	0.2165777	-1.285723	0.2117971	0.1696718
798	0	0.3044127	-0.826372	0.2199818	0.2117456
799	0	0.1030675	-2.163596	0.2660165	0.0924446
800	1	0.1991386	-1.391687	0.245147	0.1594824
801	0	0.3823846	-0.479439	0.2558821	0.2361666
802	1	0.1472185	-1.756586	0.2491601	0.1255452
803	0	0.3603397	-0.57389	0.2567703	0.230495
804	0	0.7540806	1.1204955	0.3254577	0.185443
805	0	0.460917	-0.156651	0.2636421	0.2484725
806	1	0.0832959	-2.398386	0.2724408	0.0763577
807	1	0.0181977	-3.988092	0.3659707	0.0178666
808	1	0.0260031	-3.623193	0.3414305	0.0253269
809	0	0.1357512	-1.851037	0.255995	0.1173228
810	1	0.1357512	-1.851037	0.255995	0.1173228
811	1	0.1420097	-1.798697	0.2553812	0.1218429
812	0	0.5214557	0.0858754	0.2500866	0.2495397
813	0	0.3443603	-0.643923	0.223698	0.2257763
814	1	0.1610249	-1.650622	0.2157589	0.1350959
815	1	0.1277423	-1.92107	0.2256202	0.1114242
816	1	0.0112579	-4.475364	0.3734553	0.0111312

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
817	1	0.1157316	-2.033487	0.2604603	0.1023378
818	1	0.0275688	-3.563116	0.3074855	0.0268087
819	1	0.0751233	-2.51053	0.2547439	0.0694798
820	1	0.1231232	-1.963181	0.2320893	0.1079639
821	1	0.0888239	-2.32808	0.2462263	0.0809342
822	0	0.3233598	-0.738374	0.2162121	0.2187982
823	0	0.364491	-0.555924	0.220361	0.2316373
824	1	0.0922917	-2.285969	0.2376295	0.0837739
825	1	0.0193028	-3.928015	0.3327819	0.0189302
826	1	0.0633889	-2.69298	0.2641065	0.0593707
827	1	0.0648377	-2.668834	0.2781684	0.0606337
828	0	0.4306931	-0.279024	0.2347564	0.2451966
829	0	0.2165777	-1.285723	0.2117971	0.1696718
830	1	0.0300286	-3.475117	0.300774	0.0291269
831	1	0.0633889	-2.69298	0.2641065	0.0593707
832	0	0.465384	-0.138686	0.235583	0.2488017
833	1	0.1872206	-1.468172	0.2130953	0.152169
834	0	0.2847901	-0.920824	0.2133707	0.2036847
835	0	0.2020193	-1.373721	0.2167717	0.1612075
836	1	0.1030675	-2.163596	0.2660165	0.0924446
837	1	0.165723	-1.616248	0.2516606	0.1382589
838	1	0.045925	-3.033733	0.2960262	0.0438159
839	1	0.0270912	-3.581081	0.3277847	0.0263573
840	1	0.1030675	-2.163596	0.2660165	0.0924446
841	1	0.0593407	-2.763285	0.2880474	0.0558194

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
842	0	0.2224668	-1.251349	0.2476534	0.1729753
843	1	0.0217608	-3.805643	0.3534959	0.0212873
844	1	0.045925	-3.033733	0.2960262	0.0438159
845	0	0.0873806	-2.346046	0.2728067	0.0797452
846	0	0.3006219	-0.844338	0.2480968	0.2102484
847	1	0.291843	-0.88645	0.2483833	0.2066707
848	0	0.3194415	-0.75634	0.2531837	0.2173986
849	1	0.6689094	0.7032568	0.3086652	0.2214696
850	1	0.0648377	-2.668834	0.2781684	0.0606337
851	1	0.1716275	-1.574136	0.2465635	0.1421715
852	1	0.3194415	-0.75634	0.2531837	0.2173986
853	1	0.1357512	-1.851037	0.255995	0.1173228
854	1	0.0533816	-2.875429	0.2742276	0.050532
855	1	0.0633889	-2.69298	0.2641065	0.0593707
856	1	0.0999329	-2.19797	0.2313508	0.0899463
857	1	0.2847901	-0.920824	0.2133707	0.2036847
858	1	0.0555501	-2.833318	0.2631411	0.0524643
859	1	0.0329052	-3.380666	0.2955253	0.0318224
860	1	0.0419596	-3.128184	0.3067272	0.0401989
861	1	0.3823846	-0.479439	0.2558821	0.2361666
862	1	0.0623306	-2.710945	0.2889863	0.0584455
863	0	0.2491271	-1.103273	0.2118895	0.1870628
864	1	0.1845021	-1.486138	0.2503864	0.1504611
865	1	0.4978561	-0.008576	0.2398695	0.2499954
866	1	0.1872206	-1.468172	0.2130953	0.152169

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
867	0	0.6007672	0.4086629	0.2598245	0.239846
868	0	0.4306931	-0.279024	0.2347564	0.2451966
869	1	0.2165777	-1.285723	0.2117971	0.1696718
870	1	0.1047402	-2.145631	0.2386442	0.0937697
871	1	0.1070261	-2.121485	0.257735	0.0955715
872	0	0.1087552	-2.103519	0.2310644	0.0969275
873	1	0.1953157	-1.415833	0.2194378	0.1571675
874	1	0.1953157	-1.415833	0.2194378	0.1571675
875	1	0.2020193	-1.373721	0.2167717	0.1612075
876	1	0.1277423	-1.92107	0.2256202	0.1114242
877	1	0.3349158	-0.686034	0.220922	0.2227472
878	0	0.2491271	-1.103273	0.2118895	0.1870628
879	1	0.1741968	-1.556171	0.2184126	0.1438523
880	0	0.5433593	0.1738737	0.2484182	0.24812
881	0	0.4758752	-0.096574	0.241933	0.249418
882	1	0.1741968	-1.556171	0.2184126	0.1438523
883	1	0.1087552	-2.103519	0.2310644	0.0969275
884	1	0.1682218	-1.598282	0.2224104	0.1399233
885	1	0.0315911	-3.422778	0.3083678	0.0305931
886	1	0.1610249	-1.650622	0.2157589	0.1350959
887	1	0.0315911	-3.422778	0.3083678	0.0305931
888	0	0.3866364	-0.461473	0.2286489	0.2371487
889	1	0.2255899	-1.233383	0.2177849	0.1746991
890	1	0.2847901	-0.920824	0.2133707	0.2036847
891	0	0.3233598	-0.738374	0.2162121	0.2187982

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
892	1	0.1231232	-1.963181	0.2320893	0.1079639
893	0	0.364491	-0.555924	0.220361	0.2316373
894	1	0.0999329	-2.19797	0.2313508	0.0899463
895	1	0.1047402	-2.145631	0.2386442	0.0937697
896	1	0.4203991	-0.321135	0.2295162	0.2436637
897	1	0.0206741	-3.857982	0.3512703	0.0202467
898	1	0.2020193	-1.373721	0.2167717	0.1612075
899	1	0.2165777	-1.285723	0.2117971	0.1696718
900	1	0.4077016	-0.373475	0.2257455	0.241481
901	1	0.1277423	-1.92107	0.2256202	0.1114242
902	1	0.1741968	-1.556171	0.2184126	0.1438523
903	1	0.4306931	-0.279024	0.2347564	0.2451966
904	1	0.0715666	-2.56287	0.2472334	0.0664449
905	0	0.4160279	-0.339101	0.2582012	0.2429487
906	1	0.1211966	-1.981147	0.2601861	0.106508
907	1	0.3233598	-0.738374	0.2162121	0.2187982
908	1	0.0768182	-2.486384	0.2704382	0.0709172
909	1	0.0499385	-2.945734	0.2970372	0.0474447
910	1	0.03703	-3.258294	0.3187129	0.0356588
911	0	0.2165777	-1.285723	0.2117971	0.1696718
912	1	0.2556125	-1.068899	0.2474225	0.1902747
913	1	0.0593407	-2.763285	0.2880474	0.0558194
914	1	0.5388983	0.1559081	0.2813435	0.2484869
915	1	0.3403155	-0.661888	0.2514328	0.2245009
916	1	0.0441147	-3.075844	0.3081649	0.0421686

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Parameter Code=HBA70 Parameter=HbA1c <7.0% without severe hypo and with minimal weight gain Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
917	1	0.5064492	0.0257982	0.2700689	0.2499584
918	1	0.1741968	-1.556171	0.2184126	0.1438523
919	1	0.078102	-2.468418	0.2452255	0.0720021
920	0	0.5169709	0.0679097	0.2753026	0.249712
921	1	0.1682218	-1.598282	0.2224104	0.1399233
922	1	0.0648377	-2.668834	0.2781684	0.0606337
923	0	0.3443603	-0.643923	0.223698	0.2257763
924	0	0.1378728	-1.833071	0.2197383	0.1188639
925	0	0.5169709	0.0679097	0.2753026	0.249712
926	1	0.084678	-2.38042	0.2388062	0.0775076
927	1	0.0751233	-2.51053	0.2547439	0.0694798
928	1	0.1845021	-1.486138	0.2503864	0.1504611
929	1	0.0659355	-2.650868	0.2537598	0.061588
930	1	0.3403155	-0.661888	0.2514328	0.2245009
931	1	0.281145	-0.938789	0.2507264	0.2021025
932	1	0.2491271	-1.103273	0.2118895	0.1870628
933	1	0.015209	-4.170542	0.3788147	0.0149777
934	1	0.0226756	-3.763531	0.3394525	0.0221614
935	1	0.1716275	-1.574136	0.2465635	0.1421715
936	1	0.1231232	-1.963181	0.2320893	0.1079639
937	1	0.1070261	-2.121485	0.257735	0.0955715
938	1	0.281145	-0.938789	0.2507264	0.2021025
939	1	0.0507978	-2.927769	0.2666241	0.0482174
940	1	0.0555501	-2.833318	0.2631411	0.0524643
941	0	0.1030675	-2.163596	0.2660165	0.0924446

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Parameter Code=HBA70 Parameter=HbA1c <7.0% without severe hypo and with minimal weight gain Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
942	1	0.0467186	-3.015767	0.2732822	0.044536
943	1	0.0715666	-2.56287	0.2472334	0.0664449
944	1	0.1277423	-1.92107	0.2256202	0.1114242
945	1	0.4758752	-0.096574	0.241933	0.249418
946	1	0.0385613	-3.216182	0.306014	0.0370743
947	1	0.084678	-2.38042	0.2388062	0.0775076
948	1	0.2165777	-1.285723	0.2117971	0.1696718
949	1	0.364491	-0.555924	0.220361	0.2316373
950	0	0.0873806	-2.346046	0.2728067	0.0797452
951	1	0.078102	-2.468418	0.2452255	0.0720021
952	1	0.045925	-3.033733	0.2960262	0.0438159
953	1	0.1953157	-1.415833	0.2194378	0.1571675
954	0	0.4203991	-0.321135	0.2295162	0.2436637
955	1	0.0715666	-2.56287	0.2472334	0.0664449
956	0	0.1741968	-1.556171	0.2184126	0.1438523
957	1	0.3006219	-0.844338	0.2480968	0.2102484
958	1	0.0467186	-3.015767	0.2732822	0.044536
959	0	0.364491	-0.555924	0.220361	0.2316373
960	0	0.084678	-2.38042	0.2388062	0.0775076
961	1	0.1494883	-1.73862	0.2213795	0.1271415
962	1	0.2298361	-1.209237	0.2449313	0.1770114
963	1	0.0467186	-3.015767	0.2732822	0.044536
964	1	0.1953157	-1.415833	0.2194378	0.1571675
965	1	0.0768182	-2.486384	0.2704382	0.0709172
966	1	0.465384	-0.138686	0.235583	0.2488017

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
967	1	0.0329052	-3.380666	0.2955253	0.0318224
968	1	0.0659355	-2.650868	0.2537598	0.061588
969	1	0.0329052	-3.380666	0.2955253	0.0318224
970	1	0.0221466	-3.787677	0.333623	0.0216561
971	1	0.3724897	-0.52155	0.2538095	0.2337411
972	1	0.0715666	-2.56287	0.2472334	0.0664449
973	1	0.0419596	-3.128184	0.3067272	0.0401989
974	1	0.0217608	-3.805643	0.3534959	0.0212873
975	0	0.2135449	-1.303688	0.2493179	0.1679435
976	1	0.0226756	-3.763531	0.3394525	0.0221614
977	1	0.757397	1.1384611	0.3029711	0.1837468
978	1	0.1925076	-1.433798	0.2490728	0.1554484
979	1	0.0134808	-4.292914	0.3595874	0.0132991
980	1	0.0623306	-2.710945	0.2889863	0.0584455
981	1	0.1472185	-1.756586	0.2491601	0.1255452
982	0	0.5169709	0.0679097	0.2753026	0.249712
983	1	0.1442128	-1.780732	0.2266507	0.1234155
984	1	0.3443603	-0.643923	0.223698	0.2257763
985	1	0.2255899	-1.233383	0.2177849	0.1746991
986	1	0.1586126	-1.668587	0.2526223	0.1334546
987	1	0.2491271	-1.103273	0.2118895	0.1870628
988	1	0.3349158	-0.686034	0.220922	0.2227472
989	1	0.1047402	-2.145631	0.2386442	0.0937697
990	1	0.0922917	-2.285969	0.2376295	0.0837739
991	1	0.1047402	-2.145631	0.2386442	0.0937697

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
992	0	0.4203991	-0.321135	0.2295162	0.2436637
993	1	0.364491	-0.555924	0.220361	0.2316373
994	1	0.0154804	-4.152576	0.3603899	0.0152408
995	1	0.1872206	-1.468172	0.2130953	0.152169
996	1	0.0426877	-3.110218	0.2774105	0.0408655
997	1	0.0751233	-2.51053	0.2547439	0.0694798
998	1	0.3403155	-0.661888	0.2514328	0.2245009
999	1	0.0633889	-2.69298	0.2641065	0.0593707
1000	1	0.5214557	0.0858754	0.2500866	0.2495397
1001	1	0.2298361	-1.209237	0.2449313	0.1770114
1002	1	0.0419596	-3.128184	0.3067272	0.0401989
1003	1	0.3349158	-0.686034	0.220922	0.2227472
1004	1	0.1610249	-1.650622	0.2157589	0.1350959
1005	1	0.5563134	0.2262134	0.2508284	0.2468288
1006	1	0.2020193	-1.373721	0.2167717	0.1612075
1007	1	0.0329052	-3.380666	0.2955253	0.0318224
1008	1	0.1231232	-1.963181	0.2320893	0.1079639
1009	1	0.3349158	-0.686034	0.220922	0.2227472
1010	1	0.0358236	-3.292668	0.2888173	0.0345403
1011	1	0.1277423	-1.92107	0.2256202	0.1114242
1012	1	0.3443603	-0.643923	0.223698	0.2257763
1013	1	0.078102	-2.468418	0.2452255	0.0720021
1014	1	0.364491	-0.555924	0.220361	0.2316373
1015	1	0.3866364	-0.461473	0.2286489	0.2371487
1016	1	0.1378728	-1.833071	0.2197383	0.1188639

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=HBA70 Parameter=HbA1c <7.0% without severe hypo and with minimal weight gain Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
1017	1	0.2491271	-1.103273	0.2118895	0.1870628
1018	1	0.2590459	-1.050934	0.2174817	0.1919411
1019	1	0.4262936	-0.296989	0.2613877	0.2445674
1020	1	0.2330316	-1.191272	0.2164869	0.1787279
1021	1	0.0999329	-2.19797	0.2313508	0.0899463
1022	1	0.3866364	-0.461473	0.2286489	0.2371487
1023	0	0.4203991	-0.321135	0.2295162	0.2436637
1024	0	0.2255899	-1.233383	0.2177849	0.1746991
1025	1	0.0448785	-3.057879	0.2850264	0.0428645

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=HBAB7SHY Parameter=HbA1c <7.0% without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Model Information

Data Set	WORK.ENDPOINT
Distribution	Binomial
Link Function	Logit
Dependent Variable	aval

Number of Observations Read	1025
Number of Observations Used	1025
Number of Events	282
Number of Trials	1025

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Response Profile

Ordered Value	aval	Total Frequency
1	0	282
2	1	743

PROC GENMOD is modeling the probability that aval='0'. One way to change this to model the probability that aval='1' is to

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Parameter Code=HBAB7SHY Parameter=HbA1c <7.0% without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

specify the DESCENDING option in the PROC statement.

Parameter Information

Parameter	Effect	TRTPN	REGION1	BOLAD1
Prm1	Intercept			
Prm2	TRTPN	2		
Prm3	TRTPN	3		
Prm4	TRTPN	4		
Prm5	REGION1		ASIA (EXCLUDING JAPAN)	
Prm6	REGION1		EUROPE	
Prm7	REGION1		JAPAN	
Prm8	REGION1		NORTH AMERICA	
Prm9	BOLAD1			BOLUS INSULIN ALGORITHM (SLIDING SCALE)
Prm10	BOLAD1			CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY
Prm11	HBA1CBL			

Criteria For Assessing Goodness Of Fit

Criterion	DF	Value	Value/DF
Log Likelihood		-474.0373	
Full Log Likelihood		-474.0373	
AIC (smaller is better)		964.0745	
AICC (smaller is better)		964.2163	
BIC (smaller is better)		1003.5341	

Algorithm converged.

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The GENMOD Procedure

Analysis Of Maximum Likelihood Parameter Estimates

Parameter		DF	Estimate	Standard Error	Wald 95% Confidence Limits		Wald Chi-Square
Intercept		1	14.4937	1.1955	12.1507	16.8367	146.99
TRTPN	2	1	-0.1889	0.1976	-0.5762	0.1985	0.91
TRTPN	3	1	-0.1998	0.1946	-0.5812	0.1816	1.05
TRTPN	4	0	0.0000	0.0000	0.0000	0.0000	.
REGION1	ASIA (EXCLUDING JAPAN)	1	-0.3942	0.3056	-0.9931	0.2047	1.66
REGION1	EUROPE	1	-0.5421	0.2129	-0.9593	-0.1249	6.49
REGION1	JAPAN	1	0.1134	0.2224	-0.3226	0.5493	0.26
REGION1	NORTH AMERICA	0	0.0000	0.0000	0.0000	0.0000	.
BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	1	0.1532	0.1800	-0.1996	0.5060	0.72
BOLAD1	CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY	0	0.0000	0.0000	0.0000	0.0000	.
HBA1CBL	Scale	1	-2.0997	0.1631	-2.4194	-1.7800	165.70
		0	1.0000	0.0000	1.0000	1.0000	

Analysis Of Maximum Likelihood Parameter Estimates

Parameter		Pr > ChiSq
Intercept		<.0001
TRTPN	2	0.3392
TRTPN	3	0.3045
TRTPN	4	.
REGION1	ASIA (EXCLUDING JAPAN)	0.1971
REGION1	EUROPE	0.0109
REGION1	JAPAN	0.6102
REGION1	NORTH AMERICA	.
BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.3947
BOLAD1	CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY	.
HBA1CBL		<.0001

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The GENMOD Procedure

Analysis Of Maximum Likelihood Parameter Estimates

Parameter Pr > ChiSq

Scale

NOTE: The scale parameter was held fixed.

Coefficients for TRTPN Least Squares Means Using WORK.ENDPOINT Margins

Parameter	Geographic Region Grouping Method 1
Intercept	
Planned Treatment (N) 2	
Planned Treatment (N) 3	
Planned Treatment (N) 4	
Geographic Region Grouping Method 1 ASIA (EXCLUDING JAPAN)	ASIA (EXCLUDING JAPAN)

Coefficients for TRTPN Least Squares Means Using WORK.ENDPOINT Margins

Bolus Adjustment Method at Timepoint 1	Planned Treatment (N)	Row		
		Row1	Row2	Row3
		1	1	1
	2	1		
	3		1	
	4			1
		0.1307	0.1307	0.1307

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Parameter Code=HBAB7SHY Parameter=HbA1c <7.0% without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Coefficients for TRTPN Least Squares Means Using WORK.ENDPOINT Margins

Parameter	Geographic Region Grouping Method 1
Geographic Region Grouping Method 1 EUROPE	EUROPE
Geographic Region Grouping Method 1 JAPAN	JAPAN
Geographic Region Grouping Method 1 NORTH AMERICA	NORTH AMERICA
Bolus Adjustment Method at Timepoint 1 BOLUS INSULIN ALGORITHM (SLIDING SCALE)	
Bolus Adjustment Method at Timepoint 1 CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY	
HbA1c at Baseline	

Coefficients for TRTPN Least Squares Means Using WORK.ENDPOINT Margins

	Planned Treatment (N)	Row1	Row2	Row3
Bolus Adjustment Method at Timepoint 1				
		0.3366	0.3366	0.3366
		0.239	0.239	0.239
		0.2937	0.2937	0.2937
BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.5824	0.5824	0.5824
CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0.4176	0.4176	0.4176
		7.4245	7.4245	7.4245

Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

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The GENMOD Procedure

TRTPN Least Squares Means

Planned Treatment (N)	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
2	WORK.ENDPOINT	-1.4023	0.1507	-9.31	<.0001	0.05	-1.6977	-1.1069
3	WORK.ENDPOINT	-1.4132	0.1474	-9.59	<.0001	0.05	-1.7022	-1.1243
4	WORK.ENDPOINT	-1.2134	0.1434	-8.46	<.0001	0.05	-1.4945	-0.9323

Differences of TRTPN Least Squares Means

Planned Treatment (N)	Planned Treatment (N)	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
2	4	WORK.ENDPOINT	-0.1889	0.1976	-0.96	0.3392	0.05	-0.5762	0.1985
3	4	WORK.ENDPOINT	-0.1998	0.1946	-1.03	0.3045	0.05	-0.5812	0.1816

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) / NovoRapid (meal)	WORK.ENDPOINT	-0.1889	0.1976	-0.96	0.3392	0.05	-0.5762	0.1985

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The GENMOD Procedure

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
TRTPN	Faster aspart (post) / NovoRapid (meal)	WORK.ENDPOINT	-0.1998	0.1946	-1.03	0.3045	0.05	-0.5812	0.1816

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
1	1	0.5866108	0.3499721	0.2473295	0.2424986
2	0	0.5866108	0.3499721	0.2473295	0.2424986
3	1	0.3318353	-0.699896	0.2353805	0.2217206
4	1	0.2870266	-0.909869	0.2363193	0.2046423
5	1	0.2870266	-0.909869	0.2363193	0.2046423
6	1	0.3666279	-0.546711	0.2014153	0.2322119
7	0	0.3773434	-0.50084	0.2227517	0.2349554
8	1	0.1749841	-1.550707	0.2339304	0.1443647
9	1	0.0847351	-2.379684	0.271747	0.077555
10	0	0.6182358	0.4820667	0.2022123	0.2360203
11	0	0.63644	0.5599456	0.2528278	0.2313841
12	0	0.7249152	0.9689753	0.2545997	0.1994131
13	0	0.5322255	0.1290811	0.230089	0.2489615
14	0	0.722882	0.9588025	0.2515319	0.2003236
15	1	0.148077	-1.749764	0.2508774	0.1261502
16	1	0.2421491	-1.140933	0.2317406	0.1835129

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
17	1	0.3193665	-0.756684	0.2027691	0.2173716
18	1	0.1982095	-1.397523	0.2097206	0.1589225
19	1	0.4114856	-0.357828	0.1936008	0.2421652
20	1	0.1212307	-1.980827	0.2545147	0.1065338
21	1	0.0297034	-3.486341	0.3108905	0.0288211
22	1	0.1212307	-1.980827	0.2545147	0.1065338
23	1	0.4797879	-0.080892	0.2264978	0.2495915
24	1	0.2336976	-1.187549	0.2044336	0.179083
25	1	0.0838922	-2.390602	0.2615071	0.0768543
26	1	0.1749841	-1.550707	0.2339304	0.1443647
27	1	0.1015036	-2.180628	0.2533222	0.0912006
28	1	0.465634	-0.137681	0.1970458	0.248819
29	1	0.0847351	-2.379684	0.271747	0.077555
30	0	0.3147997	-0.777775	0.1974078	0.2157008
31	0	0.6686783	0.7022131	0.2145523	0.2215476
32	1	0.0847351	-2.379684	0.271747	0.077555
33	1	0.1749841	-1.550707	0.2339304	0.1443647
34	0	0.3147997	-0.777775	0.1974078	0.2157008
35	1	0.3294192	-0.710813	0.2226546	0.2209022
36	0	0.6315461	0.5388554	0.2389525	0.2326956
37	1	0.3749562	-0.511012	0.2258	0.2343641
38	1	0.2073894	-1.340734	0.22943	0.164379
39	0	0.5322255	0.1290811	0.230089	0.2489615
40	1	0.1467051	-1.760681	0.2394595	0.1251827
41	0	0.4797879	-0.080892	0.2264978	0.2495915

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=HBAB7SHY Parameter=HbA1c <7.0% without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
42	0	0.5701017	0.282266	0.2033854	0.2450858
43	1	0.6686783	0.7022131	0.2145523	0.2215476
44	0	0.5676067	0.2720931	0.1980895	0.2454293
45	0	0.4166022	-0.336737	0.201378	0.2430448
46	1	0.1999503	-1.386605	0.2143586	0.1599702
47	0	0.8253502	1.5530248	0.2537009	0.1441473
48	0	0.465634	-0.137681	0.1970458	0.248819
49	1	0.1655266	-1.617669	0.2198469	0.1381276
50	0	0.7929913	1.3430512	0.2441105	0.1641561
51	0	0.8253502	1.5530248	0.2537009	0.1441473
52	1	0.465634	-0.137681	0.1970458	0.248819
53	0	0.6206339	0.4922395	0.2084061	0.2354475
54	1	0.3617444	-0.567801	0.194832	0.2308854
55	0	0.1982095	-1.397523	0.2097206	0.1589225
56	0	0.3666279	-0.546711	0.2014153	0.2322119
57	1	0.1669365	-1.607496	0.2161122	0.1390687
58	1	0.1174787	-2.016526	0.2357395	0.1036775
59	1	0.2713571	-0.987748	0.2012768	0.1977224
60	0	0.0655366	-2.657364	0.2613338	0.0612415
61	0	0.8222892	1.5319345	0.2390053	0.1461297
62	1	0.1684603	-1.596579	0.2205114	0.1400815
63	1	0.2336976	-1.187549	0.2044336	0.179083
64	0	0.7895078	1.321961	0.2298098	0.1661852
65	0	0.6686783	0.7022131	0.2145523	0.2215476
66	1	0.6686783	0.7022131	0.2145523	0.2215476

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=HBAB7SHY Parameter=HbA1c <7.0% without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
67	1	0.3169981	-0.767602	0.1975102	0.2165103
68	0	0.6686783	0.7022131	0.2145523	0.2215476
69	0	0.5207905	0.0832098	0.2052303	0.2495678
70	1	0.024214	-3.696314	0.3234965	0.0236276
71	0	0.5727753	0.2931834	0.2090476	0.2447038
72	0	0.5155249	0.0621196	0.1952467	0.249759
73	0	0.5180652	0.0722924	0.1995752	0.2496736
74	1	0.5676067	0.2720931	0.1980895	0.2454293
75	0	0.3666279	-0.546711	0.2014153	0.2322119
76	0	0.4114856	-0.357828	0.1936008	0.2421652
77	0	0.5180652	0.0722924	0.1995752	0.2496736
78	1	0.7113632	0.9020138	0.2139787	0.2053256
79	1	0.0662084	-2.646446	0.2645485	0.0618248
80	0	0.7564064	1.1330776	0.2352612	0.1842557
81	1	0.0649163	-2.667537	0.2683454	0.0607022
82	1	0.2755471	-0.966658	0.2054132	0.1996209
83	0	0.7113632	0.9020138	0.2139787	0.2053256
84	1	0.6182358	0.4820667	0.2022123	0.2360203
85	0	0.2755471	-0.966658	0.2054132	0.1996209
86	1	0.0655366	-2.657364	0.2613338	0.0612415
87	1	0.1999503	-1.386605	0.2143586	0.1599702
88	0	0.5180652	0.0722924	0.1995752	0.2496736
89	0	0.8509293	1.7419081	0.2489311	0.1268487
90	0	0.6206339	0.4922395	0.2084061	0.2354475
91	1	0.2713571	-0.987748	0.2012768	0.1977224

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=HBAB7SHY Parameter=HbA1c <7.0% without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
92	1	0.4114856	-0.357828	0.1936008	0.2421652
93	1	0.3617444	-0.567801	0.194832	0.2308854
94	1	0.3147997	-0.777775	0.1974078	0.2157008
95	0	0.5727753	0.2931834	0.2090476	0.2447038
96	0	0.4114856	-0.357828	0.1936008	0.2421652
97	1	0.5701017	0.282266	0.2033854	0.2450858
98	1	0.2421491	-1.140933	0.2317406	0.1835129
99	1	0.4166022	-0.336737	0.201378	0.2430448
100	1	0.2847976	-0.920787	0.2237498	0.2036879
101	0	0.8967714	2.1618552	0.2706464	0.0925724
102	1	0.4304664	-0.279949	0.2368855	0.2451651
103	1	0.1749841	-1.550707	0.2339304	0.1443647
104	0	0.6664206	0.6920403	0.2075386	0.2223042
105	1	0.1735204	-1.56088	0.2411979	0.1434111
106	1	0.3271759	-0.720986	0.2266264	0.2201318
107	0	0.3617444	-0.567801	0.194832	0.2308854
108	0	0.1669365	-1.607496	0.2161122	0.1390687
109	0	0.6206339	0.4922395	0.2084061	0.2354475
110	0	0.2870266	-0.909869	0.2363193	0.2046423
111	0	0.7629237	1.1687761	0.2591361	0.1808711
112	0	0.722882	0.9588025	0.2515319	0.2003236
113	0	0.5814873	0.3288818	0.2341185	0.2433598
114	0	0.3271759	-0.720986	0.2266264	0.2201318
115	0	0.1025036	-2.169711	0.2639671	0.0919967
116	1	0.1749841	-1.550707	0.2339304	0.1443647

Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=HBAB7SHY Parameter=HbA1c <7.0% without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
117	0	0.2421491	-1.140933	0.2317406	0.1835129
118	1	0.069807	-2.589658	0.2802613	0.064934
119	0	0.5296921	0.1189083	0.2303407	0.2491184
120	0	0.63644	0.5599456	0.2528278	0.2313841
121	1	0.2057222	-1.350907	0.2359534	0.1634006
122	0	0.3799119	-0.489922	0.2355701	0.2355788
123	1	0.3773434	-0.50084	0.2227517	0.2349554
124	1	0.0204204	-3.870589	0.347598	0.0200034
125	0	0.1765658	-1.53979	0.2456992	0.1453903
126	1	0.0838922	-2.390602	0.2615071	0.0768543
127	0	0.2440208	-1.13076	0.2260199	0.1844747
128	1	0.2073894	-1.340734	0.22943	0.164379
129	1	0.053792	-2.867337	0.272415	0.0508984
130	1	0.148077	-1.749764	0.2508774	0.1261502
131	1	0.0160438	-4.116261	0.3496292	0.0157864
132	1	0.2440208	-1.13076	0.2260199	0.1844747
133	1	0.0465073	-3.020522	0.2902074	0.0443444
134	1	0.3147997	-0.777775	0.1974078	0.2157008
135	1	0.4253035	-0.301039	0.2261502	0.2444204
136	1	0.3271759	-0.720986	0.2266264	0.2201318
137	0	0.7249152	0.9689753	0.2545997	0.1994131
138	1	0.3147997	-0.777775	0.1974078	0.2157008
139	1	0.3318353	-0.699896	0.2353805	0.2217206
140	1	0.3749562	-0.511012	0.2258	0.2343641
141	0	0.2847976	-0.920787	0.2237498	0.2036879

Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=HBAB7SHY Parameter=HbA1c <7.0% without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
142	0	0.7249152	0.9689753	0.2545997	0.1994131
143	1	0.5155249	0.0621196	0.1952467	0.249759
144	1	0.5727753	0.2931834	0.2090476	0.2447038
145	1	0.2755471	-0.966658	0.2054132	0.1996209
146	1	0.2713571	-0.987748	0.2012768	0.1977224
147	1	0.6686783	0.7022131	0.2145523	0.2215476
148	1	0.1397378	-1.81747	0.2235137	0.1202111
149	1	0.5155249	0.0621196	0.1952467	0.249759
150	1	0.2356584	-1.176632	0.2092989	0.1801235
151	0	0.2733731	-0.977575	0.2003388	0.1986403
152	1	0.1385194	-1.827642	0.2280432	0.1193317
153	0	0.8509293	1.7419081	0.2489311	0.1268487
154	1	0.0440529	-3.077311	0.2840012	0.0421123
155	1	0.2318807	-1.197722	0.2063661	0.1781121
156	1	0.3193665	-0.756684	0.2027691	0.2173716
157	1	0.465634	-0.137681	0.1970458	0.248819
158	1	0.465634	-0.137681	0.1970458	0.248819
159	0	0.4166022	-0.336737	0.201378	0.2430448
160	1	0.2755471	-0.966658	0.2054132	0.1996209
161	0	0.4166022	-0.336737	0.201378	0.2430448
162	0	0.7543892	1.1221602	0.2298442	0.1852861
163	0	0.3169981	-0.767602	0.1975102	0.2165103
164	0	0.6686783	0.7022131	0.2145523	0.2215476
165	1	0.5676067	0.2720931	0.1980895	0.2454293
166	1	0.1669365	-1.607496	0.2161122	0.1390687

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
167	0	0.5155249	0.0621196	0.1952467	0.249759
168	1	0.2318807	-1.197722	0.2063661	0.1781121
169	1	0.1655266	-1.617669	0.2198469	0.1381276
170	1	0.3193665	-0.756684	0.2027691	0.2173716
171	1	0.6206339	0.4922395	0.2084061	0.2354475
172	0	0.5207905	0.0832098	0.2052303	0.2495678
173	1	0.0804334	-2.436473	0.2542627	0.0739639
174	1	0.0649163	-2.667537	0.2683454	0.0607022
175	1	0.3147997	-0.777775	0.1974078	0.2157008
176	1	0.2713571	-0.987748	0.2012768	0.1977224
177	1	0.1669365	-1.607496	0.2161122	0.1390687
178	1	0.044515	-3.066394	0.2868015	0.0425334
179	1	0.1982095	-1.397523	0.2097206	0.1589225
180	0	0.4631037	-0.147854	0.1937401	0.2486387
181	1	0.3666279	-0.546711	0.2014153	0.2322119
182	1	0.5155249	0.0621196	0.1952467	0.249759
183	1	0.465634	-0.137681	0.1970458	0.248819
184	1	0.0440529	-3.077311	0.2840012	0.0421123
185	1	0.1982095	-1.397523	0.2097206	0.1589225
186	1	0.3147997	-0.777775	0.1974078	0.2157008
187	1	0.097396	-2.226499	0.2446329	0.08791
188	0	0.4683514	-0.126764	0.2026579	0.2489984
189	1	0.0964404	-2.237417	0.2409618	0.0871397
190	1	0.1684603	-1.596579	0.2205114	0.1400815
191	1	0.5814873	0.3288818	0.2341185	0.2433598

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=HBAB7SHY Parameter=HbA1c <7.0% without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
192	1	0.5155249	0.0621196	0.1952467	0.249759
193	1	0.044515	-3.066394	0.2868015	0.0425334
194	1	0.8222892	1.5319345	0.2390053	0.1461297
195	0	0.1163515	-2.027443	0.2318284	0.1028139
196	1	0.5296921	0.1189083	0.2303407	0.2491184
197	1	0.0436265	-3.087484	0.2918987	0.0417232
198	0	0.2713571	-0.987748	0.2012768	0.1977224
199	0	0.4166022	-0.336737	0.201378	0.2430448
200	1	0.0532766	-2.87751	0.2798946	0.0504382
201	1	0.097396	-2.226499	0.2446329	0.08791
202	0	0.3147997	-0.777775	0.1974078	0.2157008
203	1	0.5701017	0.282266	0.2033854	0.2450858
204	1	0.4683514	-0.126764	0.2026579	0.2489984
205	1	0.465634	-0.137681	0.1970458	0.248819
206	1	0.0543504	-2.85642	0.2754169	0.0513964
207	1	0.097396	-2.226499	0.2446329	0.08791
208	1	0.0964404	-2.237417	0.2409618	0.0871397
209	1	0.3193665	-0.756684	0.2027691	0.2173716
210	1	0.0955576	-2.24759	0.2468647	0.0864263
211	1	0.005939	-5.120258	0.4142348	0.0059037
212	1	0.053792	-2.867337	0.272415	0.0508984
213	1	0.2733731	-0.977575	0.2003388	0.1986403
214	1	0.1223186	-1.970655	0.245948	0.1073568
215	1	0.5180652	0.0722924	0.1995752	0.2496736
216	1	0.3318353	-0.699896	0.2353805	0.2217206

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=HBAB7SHY Parameter=HbA1c <7.0% without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
217	0	0.4253035	-0.301039	0.2261502	0.2444204
218	1	0.1234955	-1.959737	0.2569883	0.1082444
219	1	0.0562146	-2.820722	0.2904582	0.0530546
220	1	0.3271759	-0.720986	0.2266264	0.2201318
221	0	0.8509293	1.7419081	0.2489311	0.1268487
222	0	0.5727753	0.2931834	0.2090476	0.2447038
223	1	0.7134474	0.9121867	0.2217306	0.2044402
224	0	0.3640964	-0.557628	0.1960027	0.2315302
225	0	0.5727753	0.2931834	0.2090476	0.2447038
226	0	0.5727753	0.2931834	0.2090476	0.2447038
227	1	0.465634	-0.137681	0.1970458	0.248819
228	1	0.0955576	-2.24759	0.2468647	0.0864263
229	1	0.0291015	-3.507431	0.3170631	0.0282546
230	0	0.3169981	-0.767602	0.1975102	0.2165103
231	0	0.0440529	-3.077311	0.2840012	0.0421123
232	1	0.2713571	-0.987748	0.2012768	0.1977224
233	1	0.0045547	-5.38702	0.4320784	0.004534
234	1	0.1999503	-1.386605	0.2143586	0.1599702
235	1	0.1397378	-1.81747	0.2235137	0.1202111
236	1	0.8237709	1.5421073	0.2485006	0.1451724
237	1	0.1669365	-1.607496	0.2161122	0.1390687
238	1	0.5155249	0.0621196	0.1952467	0.249759
239	1	0.2336976	-1.187549	0.2044336	0.179083
240	1	0.0543504	-2.85642	0.2754169	0.0513964
241	1	0.5207905	0.0832098	0.2052303	0.2495678

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
242	1	0.044515	-3.066394	0.2868015	0.0425334
243	1	0.4114856	-0.357828	0.1936008	0.2421652
244	1	0.0532766	-2.87751	0.2798946	0.0504382
245	0	0.3169981	-0.767602	0.1975102	0.2165103
246	0	0.0882493	-2.335201	0.2868911	0.0804614
247	1	0.106669	-2.125227	0.280304	0.0952907
248	0	0.0495032	-2.954948	0.3098131	0.0470526
249	1	0.1831266	-1.495306	0.2656213	0.1495912
250	1	0.0734406	-2.535001	0.2944239	0.0680471
251	0	0.0490267	-2.965121	0.3109788	0.0466231
252	1	0.074187	-2.524084	0.2948699	0.0686833
253	0	0.3440631	-0.645239	0.2667995	0.2256837
254	0	0.4961704	-0.015319	0.2749412	0.2499853
255	1	0.4988997	-0.004401	0.2764202	0.2499988
256	1	0.0890713	-2.325028	0.2878094	0.0811376
257	1	0.0180943	-3.993899	0.3584464	0.0177669
258	1	0.1076422	-2.115054	0.2819845	0.0960554
259	1	0.0734406	-2.535001	0.2944239	0.0680471
260	1	0.0145603	-4.21479	0.3696642	0.0143483
261	1	0.0401138	-3.175095	0.3202694	0.0385047
262	1	0.1076422	-2.115054	0.2819845	0.0960554
263	1	0.0500194	-2.944031	0.3100885	0.0475174
264	1	0.0727514	-2.545174	0.294236	0.0674586
265	1	0.0597966	-2.755148	0.3022834	0.056221
266	1	0.0050928	-5.27483	0.4364484	0.0050668

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=HBAB7SHY Parameter=HbA1c <7.0% without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
267	1	0.0117169	-4.434936	0.3859219	0.0115796
268	1	0.0727514	-2.545174	0.294236	0.0674586
269	0	0.0899611	-2.31411	0.2883455	0.0818681
270	1	0.2983405	-0.855213	0.2660377	0.2093334
271	1	0.7782402	1.2554401	0.3160277	0.1725824
272	1	0.0890713	-2.325028	0.2878094	0.0811376
273	1	0.1295345	-1.905081	0.2769989	0.1127553
274	1	0.0409338	-3.154005	0.3186791	0.0392582
275	1	0.0882493	-2.335201	0.2868911	0.0804614
276	1	0.3928696	-0.435266	0.2685518	0.2385231
277	1	0.4961704	-0.015319	0.2749412	0.2499853
278	0	0.4961704	-0.015319	0.2749412	0.2499853
279	0	0.2202444	-1.264243	0.2685139	0.1717368
280	1	0.0409338	-3.154005	0.3186791	0.0392582
281	1	0.0330893	-3.374896	0.3277368	0.0319944
282	1	0.8123593	1.4654137	0.3250337	0.1524317
283	1	0.8682257	1.8853608	0.3446594	0.1144099
284	1	0.6975151	0.835493	0.2998719	0.2109878
285	1	0.0405073	-3.164922	0.3184835	0.0388665
286	1	0.0327654	-3.385068	0.3301051	0.0316918
287	0	0.5459902	0.1844821	0.2694321	0.2478849
288	1	0.0327654	-3.385068	0.3301051	0.0316918
289	1	0.0041322	-5.484804	0.4496726	0.0041151
290	1	2.6311E-8	-17.4533	1.3227881	2.6311E-8
291	0	0.5459902	0.1844821	0.2694321	0.2478849

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
292	1	0.0734406	-2.535001	0.2944239	0.0680471
293	1	0.2584062	-1.054269	0.2673713	0.1916324
294	1	0.0727514	-2.545174	0.294236	0.0674586
295	1	0.0890713	-2.325028	0.2878094	0.0811376
296	1	0.0401138	-3.175095	0.3202694	0.0385047
297	0	0.3904458	-0.445439	0.2604573	0.2379979
298	0	0.5997992	0.4046285	0.2849453	0.2400401
299	1	0.1307705	-1.894163	0.2777217	0.1136696
300	1	0.2202444	-1.264243	0.2685139	0.1717368
301	1	0.5973548	0.3944556	0.2743049	0.240522
302	1	0.0118353	-4.424763	0.3811719	0.0116952
303	1	0.1846533	-1.485134	0.269724	0.1505564
304	1	0.106669	-2.125227	0.280304	0.0952907
305	1	0.1086954	-2.104137	0.2826131	0.0968807
306	1	0.1086954	-2.104137	0.2826131	0.0968807
307	1	0.2543852	-1.075359	0.2605218	0.1896734
308	1	0.022228	-3.783925	0.3477841	0.0217339
309	1	0.0609934	-2.734058	0.3021349	0.0572732
310	1	0.3954767	-0.424348	0.2698952	0.2390749
311	0	0.3928696	-0.435266	0.2685518	0.2385231
312	1	0.106669	-2.125227	0.280304	0.0952907
313	1	0.1537769	-1.70528	0.269619	0.1301296
314	1	0.0219919	-3.794843	0.3478035	0.0215083
315	1	0.2202444	-1.264243	0.2685139	0.1717368
316	1	0.2543852	-1.075359	0.2605218	0.1896734

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
317	1	0.1295345	-1.905081	0.2769989	0.1127553
318	1	0.1565415	-1.68419	0.2737164	0.1320362
319	1	0.0890713	-2.325028	0.2878094	0.0811376
320	1	0.022228	-3.783925	0.3477841	0.0217339
321	0	0.1537769	-1.70528	0.269619	0.1301296
322	1	0.1846533	-1.485134	0.269724	0.1505564
323	1	0.1307705	-1.894163	0.2777217	0.1136696
324	0	0.4414042	-0.235465	0.2624711	0.2465665
325	1	0.1565415	-1.68419	0.2737164	0.1320362
326	1	0.1086954	-2.104137	0.2826131	0.0968807
327	0	0.014415	-4.224963	0.3740029	0.0142073
328	1	0.0882493	-2.335201	0.2868911	0.0804614
329	1	0.1283918	-1.915254	0.2745293	0.1119073
330	1	0.0405073	-3.164922	0.3184835	0.0388665
331	1	0.2166438	-1.285333	0.2625778	0.1697093
332	0	0.4466106	-0.214375	0.2726898	0.2471496
333	1	0.1551054	-1.695107	0.2728986	0.1310477
334	1	0.1307705	-1.894163	0.2777217	0.1136696
335	1	0.0034234	-5.673687	0.45594	0.0034117
336	1	0.106669	-2.125227	0.280304	0.0952907
337	0	0.106669	-2.125227	0.280304	0.0952907
338	1	0.4466106	-0.214375	0.2726898	0.2471496
339	0	0.1283918	-1.915254	0.2745293	0.1119073
340	0	0.5485107	0.1946549	0.2795124	0.2476467
341	0	0.1565415	-1.68419	0.2737164	0.1320362

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=HBAB7SHY Parameter=HbA1c <7.0% without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
342	0	0.5459902	0.1844821	0.2694321	0.2478849
343	0	0.8123593	1.4654137	0.3250337	0.1524317
344	1	0.0490267	-2.965121	0.3109788	0.0466231
345	1	0.0180943	-3.993899	0.3584464	0.0177669
346	1	0.5485107	0.1946549	0.2795124	0.2476467
347	1	0.646669	0.6044292	0.2800443	0.2284882
348	0	0.5512129	0.2055723	0.2810493	0.2473772
349	1	0.0190259	-3.942744	0.3108686	0.0186639
350	0	0.4104088	-0.362276	0.2037017	0.2419734
351	1	0.0951738	-2.252038	0.2251009	0.0861158
352	0	0.4619979	-0.152302	0.2076909	0.2485558
353	0	0.313841	-0.782223	0.1995208	0.2153448
354	0	0.1649131	-1.622117	0.206936	0.1377168
355	1	0.5613284	0.2465549	0.2095854	0.2462388
356	0	0.2663372	-1.013287	0.196099	0.1954017
357	1	0.4761398	-0.095513	0.2296005	0.2494307
358	1	0.3713621	-0.526378	0.2141486	0.2334523
359	1	0.2015806	-1.376445	0.2115449	0.1609458
360	0	0.0681668	-2.615196	0.2459803	0.0635201
361	1	0.1196032	-1.996193	0.2210512	0.1052983
362	1	0.1001779	-2.195249	0.2321349	0.0901423
363	1	0.5233255	0.09337	0.2236116	0.2494559
364	1	0.2818289	-0.935408	0.2163303	0.2024014
365	1	0.2818289	-0.935408	0.2163303	0.2024014
366	0	0.1728834	-1.565328	0.2189705	0.1429947

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=HBAB7SHY Parameter=HbA1c <7.0% without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
367	0	0.3739143	-0.51546	0.2206656	0.2341024
368	1	0.2374934	-1.166471	0.2095351	0.1810903
369	1	0.1207576	-1.985275	0.2266604	0.1061752
370	1	0.0086972	-4.736022	0.3614728	0.0086215
371	1	0.1001779	-2.195249	0.2321349	0.0901423
372	1	0.2796245	-0.946325	0.2098981	0.2014346
373	1	0.0991981	-2.206166	0.2267627	0.0893578
374	1	0.5258626	0.1035428	0.2292472	0.2493311
375	1	0.0681668	-2.615196	0.2459803	0.0635201
376	1	0.0674766	-2.626113	0.2411081	0.0629235
377	1	0.0371107	-3.256034	0.2686854	0.0357335
378	0	0.7601333	1.1534106	0.2726807	0.1823307
379	0	0.2015806	-1.376445	0.2115449	0.1609458
380	0	0.2796245	-0.946325	0.2098981	0.2014346
381	1	0.055405	-2.836087	0.2495741	0.0523353
382	1	0.1435369	-1.786219	0.216421	0.122934
383	0	0.5752597	0.3033435	0.2299583	0.244336
384	1	0.2310894	-1.20217	0.2006271	0.1776871
385	1	0.4708821	-0.116604	0.2183016	0.2491521
386	1	0.1196032	-1.996193	0.2210512	0.1052983
387	0	0.0088809	-4.714932	0.3543064	0.008802
388	0	0.0163679	-4.095928	0.3136666	0.0161
389	1	0.0991981	-2.206166	0.2267627	0.0893578
390	0	0.1713278	-1.576246	0.2129428	0.1419746
391	1	0.0107075	-4.526048	0.3482845	0.0105928

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Parameter Code=HBAB7SHY Parameter=HbA1c <7.0% without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
392	1	0.1941822	-1.423061	0.2057795	0.1564755
393	0	0.708198	0.8866484	0.2447265	0.2066536
394	1	0.1649131	-1.622117	0.206936	0.1377168
395	1	0.2704785	-0.992196	0.1994087	0.1973199
396	0	0.4077697	-0.373193	0.2057633	0.2414936
397	1	0.0681668	-2.615196	0.2459803	0.0635201
398	1	0.360718	-0.572249	0.2009612	0.2306005
399	1	0.1649131	-1.622117	0.206936	0.1377168
400	1	0.360718	-0.572249	0.2009612	0.2306005
401	0	0.0785646	-2.462011	0.2331323	0.0723922
402	1	0.3582043	-0.583167	0.2031639	0.229894
403	1	0.1127299	-2.063154	0.2202936	0.1000219
404	1	0.2291553	-1.213087	0.2031738	0.1766431
405	1	0.4619979	-0.152302	0.2076909	0.2485558
406	1	0.0942378	-2.262955	0.2278794	0.0853571
407	0	0.6171854	0.4776187	0.2263885	0.2362676
408	1	0.0236178	-3.721853	0.2959849	0.02306
409	0	0.3713621	-0.526378	0.2141486	0.2334523
410	1	0.2049963	-1.355355	0.2168706	0.1629728
411	0	0.5258626	0.1035428	0.2292472	0.2493311
412	1	0.2818289	-0.935408	0.2163303	0.2024014
413	0	0.2393405	-1.156299	0.2096526	0.1820566
414	1	0.0811881	-2.426313	0.2386729	0.0745966
415	1	0.0674766	-2.626113	0.2411081	0.0629235
416	0	0.4190737	-0.326577	0.2141056	0.2434509

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
417	0	0.7946541	1.3532113	0.2743288	0.1631789
418	1	0.6755648	0.7334635	0.2530576	0.219177
419	1	0.2796245	-0.946325	0.2098981	0.2014346
420	0	0.9279932	2.556264	0.3220426	0.0668218
421	1	0.5116864	0.0467541	0.2146178	0.2498634
422	0	0.8185265	1.5063962	0.2618286	0.1485409
423	1	0.1925953	-1.433234	0.2022083	0.1555024
424	0	0.9524521	2.9973014	0.3627796	0.0452871
425	1	0.1649131	-1.622117	0.206936	0.1377168
426	0	0.2683297	-1.003114	0.2018567	0.1963289
427	0	0.710449	0.8975658	0.2435636	0.2057112
428	0	0.0646469	-2.671985	0.241998	0.0604676
429	1	0.2683297	-1.003114	0.2018567	0.1963289
430	0	0.2273632	-1.22326	0.1985081	0.1756692
431	1	0.0639898	-2.682902	0.2447729	0.0598951
432	0	0.4567602	-0.173392	0.1999344	0.2481303
433	1	0.2704785	-0.992196	0.1994087	0.1973199
434	1	0.355869	-0.593339	0.1953203	0.2292263
435	0	0.7060913	0.8764755	0.2320463	0.2075264
436	0	0.2663372	-1.013287	0.196099	0.1954017
437	0	0.4761398	-0.095513	0.2296005	0.2494307
438	1	0.2273632	-1.22326	0.1985081	0.1756692
439	1	0.1207576	-1.985275	0.2266604	0.1061752
440	0	0.1422908	-1.796392	0.2191808	0.1220441
441	0	0.360718	-0.572249	0.2009612	0.2306005

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
442	1	0.0827753	-2.405223	0.2386009	0.0759236
443	0	0.4053154	-0.383366	0.1969665	0.2410348
444	1	0.0633832	-2.693075	0.2469	0.0593658
445	1	0.0681668	-2.615196	0.2459803	0.0635201
446	1	0.2818289	-0.935408	0.2163303	0.2024014
447	1	0.1634151	-1.633034	0.2096257	0.1367106
448	1	0.0453879	-3.046061	0.2587923	0.0433278
449	0	0.9540429	3.0329998	0.3724623	0.0438451
450	1	0.0785646	-2.462011	0.2331323	0.0723922
451	1	0.0231363	-3.742943	0.3038414	0.022601
452	1	0.0425733	-3.113022	0.2681552	0.0407608
453	1	0.0674766	-2.626113	0.2411081	0.0629235
454	1	0.1448842	-1.775302	0.2222509	0.1238928
455	1	0.0453879	-3.046061	0.2587923	0.0433278
456	1	0.1620291	-1.643207	0.2071306	0.1357757
457	1	0.0559791	-2.82517	0.2541935	0.0528455
458	1	0.030295	-3.466008	0.2791816	0.0293773
459	1	0.0991981	-2.206166	0.2267627	0.0893578
460	0	0.7852323	1.2964227	0.2512353	0.1686425
461	1	0.0770514	-2.483101	0.2372426	0.0711144
462	1	0.0306174	-3.45509	0.2830748	0.02968
463	1	0.0449491	-3.056233	0.2658543	0.0429287
464	1	0.313841	-0.782223	0.1995208	0.2153448
465	1	0.3689903	-0.536551	0.2110899	0.2328365
466	1	0.3114948	-0.79314	0.2018534	0.2144658

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=HBAB7SHY Parameter=HbA1c <7.0% without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
467	1	0.355869	-0.593339	0.1953203	0.2292263
468	1	0.0639898	-2.682902	0.2447729	0.0598951
469	1	0.2683297	-1.003114	0.2018567	0.1963289
470	1	0.0674766	-2.626113	0.2411081	0.0629235
471	1	0.0289761	-3.511879	0.2841372	0.0281365
472	1	0.1941822	-1.423061	0.2057795	0.1564755
473	1	0.1001779	-2.195249	0.2321349	0.0901423
474	1	0.0233674	-3.73277	0.2986436	0.0228213
475	1	0.1634151	-1.633034	0.2096257	0.1367106
476	1	0.1649131	-1.622117	0.206936	0.1377168
477	1	0.4053154	-0.383366	0.1969665	0.2410348
478	0	0.4077697	-0.373193	0.2057633	0.2414936
479	1	0.313841	-0.782223	0.1995208	0.2153448
480	1	0.0525069	-2.892876	0.2543705	0.0497499
481	1	0.6121903	0.4565284	0.2161027	0.2374133
482	1	0.3582043	-0.583167	0.2031639	0.229894
483	1	0.0429899	-3.102849	0.2646262	0.0411417
484	0	0.2291553	-1.213087	0.2031738	0.1766431
485	0	0.5613284	0.2465549	0.2095854	0.2462388
486	1	0.0434413	-3.091932	0.2618859	0.0415541
487	1	0.1634151	-1.633034	0.2096257	0.1367106
488	1	0.0236178	-3.721853	0.2959849	0.02306
489	0	0.4104088	-0.362276	0.2037017	0.2419734
490	1	0.0525069	-2.892876	0.2543705	0.0497499
491	0	0.5638317	0.2567277	0.2207265	0.2459255

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=HBAB7SHY Parameter=HbA1c <7.0% without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
492	1	0.1127299	-2.063154	0.2202936	0.1000219
493	1	0.4053154	-0.383366	0.1969665	0.2410348
494	1	0.0355059	-3.301905	0.2727509	0.0342452
495	1	0.313841	-0.782223	0.1995208	0.2153448
496	0	0.355869	-0.593339	0.1953203	0.2292263
497	1	0.1366959	-1.843008	0.2146458	0.1180102
498	1	0.3114948	-0.79314	0.2018534	0.2144658
499	1	0.5613284	0.2465549	0.2095854	0.2462388
500	0	0.6121903	0.4565284	0.2161027	0.2374133
501	1	0.4567602	-0.173392	0.1999344	0.2481303
502	1	0.0190259	-3.942744	0.3108686	0.0186639
503	1	0.6654311	0.6875922	0.2345665	0.2226326
504	1	0.1137515	-2.052981	0.2207597	0.1008121
505	0	0.3093173	-0.803313	0.1950291	0.2136401
506	0	0.8185265	1.5063962	0.2618286	0.1485409
507	1	0.1137515	-2.052981	0.2207597	0.1008121
508	1	0.5116864	0.0467541	0.2146178	0.2498634
509	1	0.0429899	-3.102849	0.2646262	0.0411417
510	1	0.0429899	-3.102849	0.2646262	0.0411417
511	0	0.4567602	-0.173392	0.1999344	0.2481303
512	0	0.7496266	1.0966219	0.2543206	0.1876865
513	1	0.0770514	-2.483101	0.2372426	0.0711144
514	1	0.0777779	-2.472929	0.2359138	0.0717285
515	0	0.1649131	-1.622117	0.206936	0.1377168
516	1	0.0951738	-2.252038	0.2251009	0.0861158

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=HBAB7SHY Parameter=HbA1c <7.0% without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
517	1	0.0777779	-2.472929	0.2359138	0.0717285
518	1	0.0639898	-2.682902	0.2447729	0.0598951
519	0	0.6607195	0.666502	0.2236221	0.2241693
520	1	0.1941822	-1.423061	0.2057795	0.1564755
521	1	0.1379894	-1.832091	0.2119111	0.1189483
522	1	0.4567602	-0.173392	0.1999344	0.2481303
523	1	0.1127299	-2.063154	0.2202936	0.1000219
524	0	0.0525069	-2.892876	0.2543705	0.0497499
525	0	0.0951738	-2.252038	0.2251009	0.0861158
526	1	0.0646469	-2.671985	0.241998	0.0604676
527	1	0.1366959	-1.843008	0.2146458	0.1180102
528	1	0.0646469	-2.671985	0.241998	0.0604676
529	0	0.710449	0.8975658	0.2435636	0.2057112
530	0	0.313841	-0.782223	0.1995208	0.2153448
531	1	0.7060913	0.8764755	0.2320463	0.2075264
532	1	0.1649131	-1.622117	0.206936	0.1377168
533	1	0.1941822	-1.423061	0.2057795	0.1564755
534	1	0.4592855	-0.163219	0.2096034	0.2483423
535	0	0.6171854	0.4776187	0.2263885	0.2362676
536	1	0.1620291	-1.643207	0.2071306	0.1357757
537	1	0.5613284	0.2465549	0.2095854	0.2462388
538	1	0.1620291	-1.643207	0.2071306	0.1357757
539	1	0.2704785	-0.992196	0.1994087	0.1973199
540	1	0.0124579	-4.372863	0.3428137	0.0123027
541	1	0.1148567	-2.042064	0.2179961	0.1016647

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=HBAB7SHY Parameter=HbA1c <7.0% without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
542	1	0.1127299	-2.063154	0.2202936	0.1000219
543	1	0.2273632	-1.22326	0.1985081	0.1756692
544	0	0.1958962	-1.412143	0.2031522	0.1575209
545	1	0.0646469	-2.671985	0.241998	0.0604676
546	1	0.0951738	-2.252038	0.2251009	0.0861158
547	1	0.4619979	-0.152302	0.2076909	0.2485558
548	1	0.0777779	-2.472929	0.2359138	0.0717285
549	1	0.0646469	-2.671985	0.241998	0.0604676
550	1	0.0633832	-2.693075	0.2469	0.0593658
551	1	0.2663372	-1.013287	0.196099	0.1954017
552	1	0.0530527	-2.881958	0.25161	0.0502381
553	1	0.0785646	-2.462011	0.2331323	0.0723922
554	1	0.0347907	-3.322996	0.2796054	0.0335803
555	1	0.0951738	-2.252038	0.2251009	0.0861158
556	1	0.1649131	-1.622117	0.206936	0.1377168
557	1	0.008221	-4.792811	0.3701122	0.0081534
558	1	0.2704785	-0.992196	0.1994087	0.1973199
559	1	0.2704785	-0.992196	0.1994087	0.1973199
560	0	0.6607195	0.666502	0.2236221	0.2241693
561	1	0.0777779	-2.472929	0.2359138	0.0717285
562	1	0.0425733	-3.113022	0.2681552	0.0407608
563	1	0.2775799	-0.956498	0.2087841	0.2005293
564	1	0.3114948	-0.79314	0.2018534	0.2144658
565	0	0.5091443	0.0365813	0.2041662	0.2499164
566	1	0.0434413	-3.091932	0.2618859	0.0415541

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=HBAB7SHY Parameter=HbA1c <7.0% without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
567	0	0.1185362	-2.006366	0.2246841	0.1044854
568	1	0.1137515	-2.052981	0.2207597	0.1008121
569	1	0.5613284	0.2465549	0.2095854	0.2462388
570	1	0.1634151	-1.633034	0.2096257	0.1367106
571	1	0.0156455	-4.1418	0.3208576	0.0154008
572	0	0.4592855	-0.163219	0.2096034	0.2483423
573	1	0.1649131	-1.622117	0.206936	0.1377168
574	1	0.1366959	-1.843008	0.2146458	0.1180102
575	1	0.1366959	-1.843008	0.2146458	0.1180102
576	1	0.1148567	-2.042064	0.2179961	0.1016647
577	1	0.1354999	-1.853181	0.2131903	0.1171397
578	1	0.1127299	-2.063154	0.2202936	0.1000219
579	1	0.5116864	0.0467541	0.2146178	0.2498634
580	1	0.4592855	-0.163219	0.2096034	0.2483423
581	1	0.1620291	-1.643207	0.2071306	0.1357757
582	1	0.3093173	-0.803313	0.1950291	0.2136401
583	1	0.2704785	-0.992196	0.1994087	0.1973199
584	0	0.4215523	-0.316404	0.2180803	0.243846
585	1	0.1185362	-2.006366	0.2246841	0.1044854
586	1	0.1185362	-2.006366	0.2246841	0.1044854
587	1	0.0070616	-4.945995	0.3749069	0.0070117
588	0	0.6305105	0.5344073	0.2504836	0.232967
589	1	0.0681668	-2.615196	0.2459803	0.0635201
590	0	0.1713278	-1.576246	0.2129428	0.1419746
591	1	0.2015806	-1.376445	0.2115449	0.1609458

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Parameter Code=HBAB7SHY Parameter=HbA1c <7.0% without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
592	0	0.3215791	-0.746524	0.2093055	0.218166
593	1	0.030295	-3.466008	0.2791816	0.0293773
594	1	0.0559791	-2.82517	0.2541935	0.0528455
595	1	0.0819502	-2.41614	0.2334762	0.0752344
596	1	0.0681668	-2.615196	0.2459803	0.0635201
597	1	0.1448842	-1.775302	0.2222509	0.1238928
598	0	0.3739143	-0.51546	0.2206656	0.2341024
599	1	0.0203316	-3.875037	0.305183	0.0199182
600	1	0.1185362	-2.006366	0.2246841	0.1044854
601	1	0.0453879	-3.046061	0.2587923	0.0433278
602	1	0.2413337	-1.145381	0.2159856	0.1830918
603	0	0.5638317	0.2567277	0.2207265	0.2459255
604	1	0.0681668	-2.615196	0.2459803	0.0635201
605	1	0.0299976	-3.476181	0.2871963	0.0290978
606	1	0.0811881	-2.426313	0.2386729	0.0745966
607	1	0.030295	-3.466008	0.2791816	0.0293773
608	1	0.1137515	-2.052981	0.2207597	0.1008121
609	1	0.2818289	-0.935408	0.2163303	0.2024014
610	0	0.4215523	-0.316404	0.2180803	0.243846
611	1	0.0449491	-3.056233	0.2658543	0.0429287
612	0	0.3238025	-0.736351	0.2114057	0.2189544
613	1	0.2374934	-1.166471	0.2095351	0.1810903
614	0	0.5804044	0.3244338	0.2426273	0.2435351
615	1	0.5285839	0.1144602	0.2356398	0.249183
616	1	0.1448842	-1.775302	0.2222509	0.1238928

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
617	0	0.3713621	-0.526378	0.2141486	0.2334523
618	0	0.2374934	-1.166471	0.2095351	0.1810903
619	1	0.1713278	-1.576246	0.2129428	0.1419746
620	1	0.3739143	-0.51546	0.2206656	0.2341024
621	1	0.0991981	-2.206166	0.2267627	0.0893578
622	1	0.0681668	-2.615196	0.2459803	0.0635201
623	1	0.0991981	-2.206166	0.2267627	0.0893578
624	1	0.0982928	-2.216339	0.2312094	0.0886313
625	1	0.4190737	-0.326577	0.2141056	0.2434509
626	1	0.1448842	-1.775302	0.2222509	0.1238928
627	1	0.2032228	-1.366272	0.2106736	0.1619233
628	0	0.1698884	-1.586419	0.2147782	0.1410263
629	1	0.0088809	-4.714932	0.3543064	0.008802
630	0	0.5752597	0.3033435	0.2299583	0.244336
631	1	0.4734174	-0.106431	0.223138	0.2492934
632	1	0.0827753	-2.405223	0.2386009	0.0759236
633	1	0.2374934	-1.166471	0.2095351	0.1810903
634	1	0.1196032	-1.996193	0.2210512	0.1052983
635	1	0.3689903	-0.536551	0.2110899	0.2328365
636	1	0.0458632	-3.035143	0.2631626	0.0437598
637	1	0.0827753	-2.405223	0.2386009	0.0759236
638	1	0.4190737	-0.326577	0.2141056	0.2434509
639	0	0.1196032	-1.996193	0.2210512	0.1052983
640	1	0.2818289	-0.935408	0.2163303	0.2024014
641	0	0.4215523	-0.316404	0.2180803	0.243846

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
642	1	0.0933731	-2.273128	0.2283432	0.0846546
643	1	0.3261975	-0.725434	0.2178991	0.2197927
644	1	0.2273632	-1.22326	0.1985081	0.1756692
645	1	0.1207576	-1.985275	0.2266604	0.1061752
646	1	0.1137515	-2.052981	0.2207597	0.1008121
647	1	0.2413337	-1.145381	0.2159856	0.1830918
648	1	0.0044404	-5.412558	0.4045961	0.0044207
649	1	0.2273632	-1.22326	0.1985081	0.1756692
650	1	0.0942378	-2.262955	0.2278794	0.0853571
651	1	0.0244552	-3.686154	0.2986327	0.0238571
652	1	0.3238025	-0.736351	0.2114057	0.2189544
653	1	0.2393405	-1.156299	0.2096526	0.1820566
654	1	0.0777779	-2.472929	0.2359138	0.0717285
655	1	0.2663372	-1.013287	0.196099	0.1954017
656	1	0.0942378	-2.262955	0.2278794	0.0853571
657	0	0.3093173	-0.803313	0.1950291	0.2136401
658	1	0.3093173	-0.803313	0.1950291	0.2136401
659	1	0.1366959	-1.843008	0.2146458	0.1180102
660	1	0.0103359	-4.561747	0.3470169	0.010229
661	1	0.0458632	-3.035143	0.2631626	0.0437598
662	1	0.0190259	-3.942744	0.3108686	0.0186639
663	1	0.2663372	-1.013287	0.196099	0.1954017
664	1	0.1620291	-1.643207	0.2071306	0.1357757
665	0	0.3093173	-0.803313	0.1950291	0.2136401
666	1	0.0156455	-4.1418	0.3208576	0.0154008

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
667	1	0.2704785	-0.992196	0.1994087	0.1973199
668	1	0.0933731	-2.273128	0.2283432	0.0846546
669	1	0.4053154	-0.383366	0.1969665	0.2410348
670	1	0.0031262	-5.764799	0.4219023	0.0031164
671	1	0.1196032	-1.996193	0.2210512	0.1052983
672	1	0.0058533	-5.134879	0.3806889	0.005819
673	1	0.0020564	-6.184747	0.4502377	0.0020522
674	1	0.055405	-2.836087	0.2495741	0.0523353
675	1	0.2796245	-0.946325	0.2098981	0.2014346
676	1	0.054875	-2.84626	0.2560764	0.0518637
677	1	0.2775799	-0.956498	0.2087841	0.2005293
678	1	0.0375028	-3.245117	0.2728129	0.0360963
679	1	0.0371107	-3.256034	0.2686854	0.0357335
680	1	0.2374934	-1.166471	0.2095351	0.1810903
681	1	0.2796245	-0.946325	0.2098981	0.2014346
682	1	0.1713278	-1.576246	0.2129428	0.1419746
683	1	0.0982928	-2.216339	0.2312094	0.0886313
684	1	0.1422908	-1.796392	0.2191808	0.1220441
685	1	0.5804044	0.3244338	0.2426273	0.2435351
686	1	0.0819502	-2.41614	0.2334762	0.0752344
687	1	0.2049963	-1.355355	0.2168706	0.1629728
688	1	0.1422908	-1.796392	0.2191808	0.1220441
689	1	0.1698884	-1.586419	0.2147782	0.1410263
690	1	0.2374934	-1.166471	0.2095351	0.1810903
691	1	0.2015806	-1.376445	0.2115449	0.1609458

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
692	1	0.1435369	-1.786219	0.216421	0.122934
693	0	0.0827753	-2.405223	0.2386009	0.0759236
694	1	0.2543852	-1.075359	0.2605218	0.1896734
695	1	0.4414042	-0.235465	0.2624711	0.2465665
696	1	0.1565415	-1.68419	0.2737164	0.1320362
697	1	0.6930469	0.8144028	0.2865983	0.2127329
698	1	0.0180943	-3.993899	0.3584464	0.0177669
699	1	0.1537769	-1.70528	0.269619	0.1301296
700	0	0.3006309	-0.844295	0.2672214	0.210252
701	1	0.0890713	-2.325028	0.2878094	0.0811376
702	1	0.0327654	-3.385068	0.3301051	0.0316918
703	1	0.3904458	-0.445439	0.2604573	0.2379979
704	1	0.1076422	-2.115054	0.2819845	0.0960554
705	0	0.5459902	0.1844821	0.2694321	0.2478849
706	1	0.1283918	-1.915254	0.2745293	0.1119073
707	1	0.2183752	-1.27516	0.2675081	0.1706875
708	1	0.4988997	-0.004401	0.2764202	0.2499988
709	0	0.5459902	0.1844821	0.2694321	0.2478849
710	1	0.0603711	-2.744975	0.3017759	0.0567264
711	1	0.6024169	0.4155459	0.2865334	0.2395108
712	1	0.3006309	-0.844295	0.2672214	0.210252
713	0	0.341771	-0.655412	0.2594553	0.2249636
714	0	0.5973548	0.3944556	0.2743049	0.240522
715	1	0.3904458	-0.445439	0.2604573	0.2379979
716	0	0.0899611	-2.31411	0.2883455	0.0818681

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
717	1	0.1846533	-1.485134	0.269724	0.1505564
718	1	0.2166438	-1.285333	0.2625778	0.1697093
719	0	0.2563196	-1.065186	0.2662747	0.1906198
720	1	0.341771	-0.655412	0.2594553	0.2249636
721	1	0.0327654	-3.385068	0.3301051	0.0316918
722	1	0.2183752	-1.27516	0.2675081	0.1706875
723	1	0.5485107	0.1946549	0.2795124	0.2476467
724	1	0.443914	-0.225292	0.2712753	0.2468544
725	1	0.0515142	-2.91301	0.2543177	0.0488605
726	1	0.0717064	-2.560769	0.2695188	0.0665646
727	1	0.1062241	-2.129904	0.2475125	0.0949405
728	1	0.026323	-3.610636	0.3218564	0.0256301
729	0	0.2534991	-1.080036	0.221735	0.1892373
730	1	0.0589258	-2.770742	0.2788662	0.0554536
731	1	0.0483047	-2.980716	0.2888329	0.0459714
732	1	0.0421691	-3.122983	0.2649249	0.0403909
733	1	0.3487835	-0.624391	0.1977361	0.2271336
734	1	0.074872	-2.514153	0.2435425	0.0692661
735	1	0.1117374	-2.073115	0.2190161	0.0992522
736	1	0.0080525	-4.813689	0.3646931	0.0079876
737	1	0.010023	-4.592798	0.3516233	0.0099225
738	1	0.0266043	-3.599719	0.317091	0.0258965
739	1	0.1878128	-1.464285	0.2067895	0.1525392
740	1	0.0413254	-3.144074	0.2750077	0.0396176
741	1	0.076346	-2.493063	0.2350712	0.0705172

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
742	1	0.1062241	-2.129904	0.2475125	0.0949405
743	1	0.1062241	-2.129904	0.2475125	0.0949405
744	1	0.1578572	-1.674259	0.2121505	0.1329383
745	1	0.3487835	-0.624391	0.1977361	0.2271336
746	1	0.0340963	-3.343874	0.2747725	0.0329338
747	0	0.182428	-1.499983	0.2289288	0.149148
748	0	0.8138684	1.4753448	0.2592168	0.1514866
749	1	0.3867408	-0.461033	0.2250523	0.2371723
750	1	0.5039256	0.0157027	0.2048956	0.2499846
751	1	0.0391333	-3.200862	0.3066023	0.0376019
752	1	0.1062241	-2.129904	0.2475125	0.0949405
753	1	0.0417303	-3.133901	0.2634655	0.0399889
754	1	0.0143488	-4.22964	0.354069	0.0141429
755	1	0.2237164	-1.244139	0.1964363	0.1736674
756	1	0.062155	-2.713954	0.2425669	0.0582917
757	1	0.5561808	0.2256763	0.210738	0.2468437
758	1	0.0337629	-3.354047	0.2865873	0.032623
759	0	0.1117374	-2.073115	0.2190161	0.0992522
760	1	0.0224448	-3.773994	0.3110221	0.0219411
761	0	0.3048746	-0.824192	0.1938823	0.2119261
762	0	0.302723	-0.834364	0.1980327	0.2110818
763	1	0.2237164	-1.244139	0.1964363	0.1736674
764	1	0.1106585	-2.084033	0.2167179	0.0984132
765	0	0.4490664	-0.204444	0.2011497	0.2474058
766	1	0.4350608	-0.261232	0.2234422	0.2457829

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
767	1	0.2219547	-1.254311	0.2026034	0.1726908
768	1	0.0281151	-3.54293	0.2877447	0.0273246
769	1	0.0278183	-3.553848	0.2865623	0.0270445
770	1	0.1096613	-2.094206	0.2260445	0.0976357
771	1	0.1893695	-1.454112	0.1997095	0.1535087
772	0	0.2219547	-1.254311	0.2026034	0.1726908
773	1	0.1893695	-1.454112	0.1997095	0.1535087
774	1	0.0417303	-3.133901	0.2634655	0.0399889
775	1	0.1319035	-1.884232	0.2185999	0.114505
776	0	0.7816903	1.2755441	0.2540357	0.1706506
777	0	0.2256181	-1.233221	0.1994313	0.1747146
778	1	0.3510976	-0.614218	0.1946538	0.2278281
779	1	0.0421691	-3.122983	0.2649249	0.0403909
780	1	0.0515142	-2.91301	0.2543177	0.0488605
781	1	0.1278693	-1.919931	0.2403725	0.1115187
782	0	0.5561808	0.2256763	0.210738	0.2468437
783	1	0.0907774	-2.304179	0.2343896	0.0825369
784	0	0.8463699	1.7064086	0.2795334	0.1300279
785	1	0.1106585	-2.084033	0.2167179	0.0984132
786	1	0.182428	-1.499983	0.2289288	0.149148
787	1	0.1278693	-1.919931	0.2403725	0.1115187
788	1	0.0916206	-2.294006	0.2244813	0.0832262
789	1	0.182428	-1.499983	0.2289288	0.149148
790	1	0.1319035	-1.884232	0.2185999	0.114505
791	1	0.1592143	-1.664086	0.2042368	0.1338651

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
792	1	0.0515142	-2.91301	0.2543177	0.0488605
793	1	0.1096613	-2.094206	0.2260445	0.0976357
794	1	0.1878128	-1.464285	0.2067895	0.1525392
795	0	0.1878128	-1.464285	0.2067895	0.1525392
796	1	0.4029167	-0.393327	0.2002294	0.2405748
797	0	0.3048746	-0.824192	0.1938823	0.2119261
798	0	0.4542896	-0.183353	0.2037201	0.2479106
799	0	0.2123028	-1.3111	0.2317232	0.1672303
800	1	0.3893333	-0.450116	0.21976	0.2377529
801	0	0.6455996	0.5997521	0.2397581	0.2288008
802	1	0.2952412	-0.870063	0.2198718	0.2080738
803	0	0.5935984	0.3788612	0.238226	0.2412393
804	0	0.9218984	2.468424	0.3199789	0.0720018
805	0	0.730785	0.998609	0.250926	0.1967383
806	1	0.1517586	-1.720874	0.239704	0.1287279
807	1	0.0319585	-3.410836	0.3180322	0.0309372
808	1	0.0478392	-2.990889	0.2956309	0.0455506
809	0	0.2514387	-1.090954	0.2272854	0.1882173
810	1	0.2514387	-1.090954	0.2272854	0.1882173
811	1	0.2908719	-0.891153	0.2249256	0.2062655
812	0	0.7040199	0.8665144	0.2377697	0.2083759
813	0	0.5066546	0.0266201	0.2084325	0.2499557
814	1	0.2237164	-1.244139	0.1964363	0.1736674
815	1	0.1910511	-1.443195	0.2025424	0.1545506
816	1	0.012336	-4.382825	0.33824	0.0121838

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
817	1	0.214009	-1.300927	0.2303467	0.1682091
818	1	0.0344577	-3.332957	0.2760888	0.0332704
819	1	0.1096613	-2.094206	0.2260445	0.0976357
820	1	0.1878128	-1.464285	0.2067895	0.1525392
821	1	0.1319035	-1.884232	0.2185999	0.114505
822	0	0.4515845	-0.194271	0.200215	0.2476559
823	0	0.5039256	0.0157027	0.2048956	0.2499846
824	1	0.1343373	-1.863142	0.2124171	0.1162908
825	1	0.0229123	-3.752904	0.2998352	0.0223873
826	1	0.0907774	-2.304179	0.2343896	0.0825369
827	1	0.1278693	-1.919931	0.2403725	0.1115187
828	0	0.6098228	0.4465673	0.22119	0.237939
829	0	0.3048746	-0.824192	0.1938823	0.2119261
830	1	0.0340963	-3.343874	0.2747725	0.0329338
831	1	0.0907774	-2.304179	0.2343896	0.0825369
832	0	0.6537243	0.6354506	0.2226436	0.2263688
833	1	0.2622774	-1.034165	0.1944806	0.193488
834	0	0.400293	-0.404244	0.196779	0.2400585
835	0	0.3071932	-0.813274	0.1971498	0.2128256
836	1	0.2123028	-1.3111	0.2317232	0.1672303
837	0	0.3359981	-0.681179	0.2232435	0.2231034
838	1	0.0878737	-2.339878	0.2554957	0.0801519
839	1	0.0488091	-2.969798	0.2837565	0.0464268
840	1	0.2123028	-1.3111	0.2317232	0.1672303
841	1	0.105192	-2.140822	0.2529524	0.0941267

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
842	0	0.4350608	-0.261232	0.2234422	0.2457829
843	1	0.0391333	-3.200862	0.3066023	0.0376019
844	1	0.0878737	-2.339878	0.2554957	0.0801519
845	0	0.1793035	-1.521074	0.2367402	0.1471537
846	0	0.5448305	0.179805	0.2284989	0.2479902
847	1	0.5395956	0.1587148	0.2283499	0.2484322
848	0	0.5421218	0.1688876	0.2332973	0.2482258
849	0	0.8639716	1.8486761	0.296512	0.1175247
850	1	0.1278693	-1.919931	0.2403725	0.1115187
851	1	0.3407196	-0.660089	0.2192099	0.2246297
852	1	0.5421218	0.1688876	0.2332973	0.2482258
853	1	0.2514387	-1.090954	0.2272854	0.1882173
854	1	0.074872	-2.514153	0.2435425	0.0692661
855	1	0.0907774	-2.304179	0.2343896	0.0825369
856	1	0.1330727	-1.874059	0.2099371	0.1153644
857	1	0.400293	-0.404244	0.196779	0.2400585
858	1	0.076346	-2.493063	0.2350712	0.0705172
859	1	0.0421691	-3.122983	0.2649249	0.0403909
860	1	0.0717064	-2.560769	0.2695188	0.0665646
861	0	0.6455996	0.5997521	0.2397581	0.2288008
862	1	0.1255358	-1.941021	0.2496855	0.1097765
863	0	0.3510976	-0.614218	0.1946538	0.2278281
864	0	0.3382715	-0.671007	0.2246176	0.2238439
865	1	0.6560235	0.6456234	0.2255295	0.2256567
866	1	0.2622774	-1.034165	0.1944806	0.193488

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
867	0	0.7799494	1.2653713	0.2489766	0.1716284
868	0	0.6098228	0.4465673	0.22119	0.237939
869	1	0.3048746	-0.824192	0.1938823	0.2119261
870	1	0.1578572	-1.674259	0.2121505	0.1329383
871	1	0.2158511	-1.29001	0.2247695	0.1692594
872	0	0.1606812	-1.653168	0.2068965	0.1348628
873	1	0.302723	-0.834364	0.1980327	0.2110818
874	1	0.302723	-0.834364	0.1980327	0.2110818
875	1	0.3071932	-0.813274	0.1971498	0.2128256
876	1	0.1910511	-1.443195	0.2025424	0.1545506
877	0	0.5013825	0.0055299	0.2047932	0.2499981
878	0	0.3510976	-0.614218	0.1946538	0.2278281
879	1	0.2643953	-1.023248	0.1976218	0.1944904
880	0	0.7017399	0.855597	0.2342825	0.209301
881	0	0.6584829	0.6565408	0.2290494	0.2248832
882	1	0.2643953	-1.023248	0.1976218	0.1944904
883	1	0.1606812	-1.653168	0.2068965	0.1348628
884	1	0.2603139	-1.044338	0.1996659	0.1925506
885	1	0.0413254	-3.144074	0.2750077	0.0396176
886	1	0.2237164	-1.244139	0.1964363	0.1736674
887	1	0.0413254	-3.144074	0.2750077	0.0396176
888	0	0.558874	0.2365937	0.214286	0.2465338
889	1	0.3487835	-0.624391	0.1977361	0.2271336
890	1	0.400293	-0.404244	0.196779	0.2400585
891	0	0.4515845	-0.194271	0.200215	0.2476559

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NN1218-4131

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=HBAB7SHY Parameter=HbA1c <7.0% without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
892	1	0.1878128	-1.464285	0.2067895	0.1525392
893	0	0.5039256	0.0157027	0.2048956	0.2499846
894	0	0.1330727	-1.874059	0.2099371	0.1153644
895	1	0.1578572	-1.674259	0.2121505	0.1329383
896	1	0.6047931	0.425477	0.2156263	0.2390184
897	1	0.0322748	-3.400663	0.3103821	0.0312331
898	1	0.3071932	-0.813274	0.1971498	0.2128256
899	0	0.3048746	-0.824192	0.1938823	0.2119261
900	1	0.5561808	0.2256763	0.210738	0.2468437
901	1	0.1910511	-1.443195	0.2025424	0.1545506
902	1	0.2643953	-1.023248	0.1976218	0.1944904
903	1	0.6098228	0.4465673	0.22119	0.237939
904	1	0.0916206	-2.294006	0.2244813	0.0832262
905	0	0.6875383	0.7886355	0.2438454	0.2148294
906	0	0.2495289	-1.101127	0.2277664	0.1872642
907	1	0.4515845	-0.194271	0.200215	0.2476559
908	1	0.1531693	-1.709957	0.234153	0.1297085
909	1	0.0870026	-2.350795	0.2608574	0.0794331
910	1	0.0710322	-2.570942	0.2752804	0.0659866
911	0	0.3048746	-0.824192	0.1938823	0.2119261
912	0	0.4871881	-0.051259	0.2253197	0.2498359
913	1	0.105192	-2.140822	0.2529524	0.0941267
914	1	0.7718445	1.2187554	0.2671496	0.1761006
915	0	0.5962294	0.3897786	0.2336274	0.2407399
916	1	0.0861979	-2.360968	0.2660232	0.0787678

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=HBAB7SHY Parameter=HbA1c <7.0% without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
917	0	0.7700481	1.2085826	0.2588421	0.177074
918	1	0.2643953	-1.023248	0.1976218	0.1944904
919	1	0.1117374	-2.073115	0.2190161	0.0992522
920	0	0.7737613	1.2296728	0.2634071	0.1750547
921	1	0.2603139	-1.044338	0.1996659	0.1925506
922	1	0.1278693	-1.919931	0.2403725	0.1115187
923	0	0.5066546	0.0266201	0.2084325	0.2499557
924	0	0.1893695	-1.454112	0.1997095	0.1535087
925	0	0.7737613	1.2296728	0.2634071	0.1750547
926	1	0.1106585	-2.084033	0.2167179	0.0984132
927	1	0.1096613	-2.094206	0.2260445	0.0976357
928	1	0.3382715	-0.671007	0.2246176	0.2238439
929	1	0.0925332	-2.283089	0.2265992	0.0839708
930	0	0.5962294	0.3897786	0.2336274	0.2407399
931	1	0.48973	-0.041086	0.2294249	0.2498945
932	1	0.3510976	-0.614218	0.1946538	0.2278281
933	1	0.0260635	-3.620809	0.3298729	0.0253842
934	1	0.0399341	-3.179772	0.294384	0.0383393
935	1	0.3407196	-0.660089	0.2192099	0.2246297
936	1	0.1878128	-1.464285	0.2067895	0.1525392
937	1	0.2158511	-1.29001	0.2247695	0.1692594
938	1	0.48973	-0.041086	0.2294249	0.2498945
939	1	0.062155	-2.713954	0.2425669	0.0582917
940	1	0.076346	-2.493063	0.2350712	0.0705172
941	0	0.2123028	-1.3111	0.2317232	0.1672303

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=HBAB7SHY Parameter=HbA1c <7.0% without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
942	0	0.0627944	-2.703036	0.2443398	0.0588513
943	1	0.0916206	-2.294006	0.2244813	0.0832262
944	1	0.1910511	-1.443195	0.2025424	0.1545506
945	1	0.6584829	0.6565408	0.2290494	0.2248832
946	1	0.0724365	-2.549851	0.2642458	0.0671894
947	1	0.1106585	-2.084033	0.2167179	0.0984132
948	1	0.3048746	-0.824192	0.1938823	0.2119261
949	1	0.5039256	0.0157027	0.2048956	0.2499846
950	0	0.1793035	-1.521074	0.2367402	0.1471537
951	1	0.1117374	-2.073115	0.2190161	0.0992522
952	1	0.0878737	-2.339878	0.2554957	0.0801519
953	1	0.302723	-0.834364	0.1980327	0.2110818
954	0	0.6047931	0.425477	0.2156263	0.2390184
955	1	0.0916206	-2.294006	0.2244813	0.0832262
956	0	0.2643953	-1.023248	0.1976218	0.1944904
957	1	0.5448305	0.179805	0.2284989	0.2479902
958	1	0.0627944	-2.703036	0.2443398	0.0588513
959	0	0.5039256	0.0157027	0.2048956	0.2499846
960	0	0.1106585	-2.084033	0.2167179	0.0984132
961	0	0.2256181	-1.233221	0.1994313	0.1747146
962	1	0.4402513	-0.240142	0.2215132	0.2464301
963	1	0.0627944	-2.703036	0.2443398	0.0588513
964	1	0.302723	-0.834364	0.1980327	0.2110818
965	1	0.1531693	-1.709957	0.234153	0.1297085
966	0	0.6537243	0.6354506	0.2226436	0.2263688

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=HBAB7SHY Parameter=HbA1c <7.0% without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
967	1	0.0421691	-3.122983	0.2649249	0.0403909
968	1	0.0925332	-2.283089	0.2265992	0.0839708
969	1	0.0421691	-3.122983	0.2649249	0.0403909
970	1	0.0275445	-3.564021	0.2986092	0.0267858
971	0	0.6407595	0.5786619	0.2376752	0.2301868
972	1	0.0916206	-2.294006	0.2244813	0.0832262
973	1	0.0717064	-2.560769	0.2695188	0.0665646
974	1	0.0391333	-3.200862	0.3066023	0.0376019
975	0	0.3867408	-0.461033	0.2250523	0.2371723
976	1	0.0399341	-3.179772	0.294384	0.0383393
977	0	0.8914139	2.1052655	0.2932544	0.0967952
978	0	0.3843309	-0.471206	0.2227464	0.2366207
979	1	0.0151745	-4.172851	0.3251242	0.0149442
980	1	0.1255358	-1.941021	0.2496855	0.1097765
981	1	0.2952412	-0.870063	0.2198718	0.2080738
982	0	0.7737613	1.2296728	0.2634071	0.1750547
983	1	0.2219547	-1.254311	0.2026034	0.1726908
984	1	0.5066546	0.0266201	0.2084325	0.2499557
985	1	0.3487835	-0.624391	0.1977361	0.2271336
986	0	0.2929747	-0.88098	0.2253659	0.2071405
987	1	0.3510976	-0.614218	0.1946538	0.2278281
988	1	0.5013825	0.0055299	0.2047932	0.2499981
989	1	0.1578572	-1.674259	0.2121505	0.1329383
990	1	0.1343373	-1.863142	0.2124171	0.1162908
991	1	0.1578572	-1.674259	0.2121505	0.1329383

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=HBAB7SHY Parameter=HbA1c <7.0% without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
992	0	0.6047931	0.425477	0.2156263	0.2390184
993	1	0.5039256	0.0157027	0.2048956	0.2499846
994	1	0.0182716	-3.983968	0.3237811	0.0179377
995	1	0.2622774	-1.034165	0.1944806	0.193488
996	1	0.0509834	-2.923927	0.2527059	0.0483841
997	1	0.1096613	-2.094206	0.2260445	0.0976357
998	1	0.5962294	0.3897786	0.2336274	0.2407399
999	1	0.0907774	-2.304179	0.2343896	0.0825369
1000	1	0.7040199	0.8665144	0.2377697	0.2083759
1001	0	0.4402513	-0.240142	0.2215132	0.2464301
1002	1	0.0717064	-2.560769	0.2695188	0.0665646
1003	1	0.5013825	0.0055299	0.2047932	0.2499981
1004	1	0.2237164	-1.244139	0.1964363	0.1736674
1005	0	0.7418101	1.0553977	0.2394107	0.1915279
1006	1	0.3071932	-0.813274	0.1971498	0.2128256
1007	1	0.0421691	-3.122983	0.2649249	0.0403909
1008	1	0.1878128	-1.464285	0.2067895	0.1525392
1009	1	0.5013825	0.0055299	0.2047932	0.2499981
1010	1	0.0417303	-3.133901	0.2634655	0.0399889
1011	1	0.1910511	-1.443195	0.2025424	0.1545506
1012	1	0.5066546	0.0266201	0.2084325	0.2499557
1013	1	0.1117374	-2.073115	0.2190161	0.0992522
1014	1	0.5039256	0.0157027	0.2048956	0.2499846
1015	1	0.558874	0.2365937	0.214286	0.2465338
1016	1	0.1893695	-1.454112	0.1997095	0.1535087

Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=HBAB7SHY Parameter=HbA1c <7.0% without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
1017	1	0.3510976	-0.614218	0.1946538	0.2278281
1018	1	0.3978534	-0.414417	0.1987821	0.2395661
1019	0	0.6920511	0.8097257	0.2468162	0.2131164
1020	1	0.3535889	-0.603301	0.1980249	0.2285638
1021	1	0.1330727	-1.874059	0.2099371	0.1153644
1022	1	0.558874	0.2365937	0.214286	0.2465338
1023	0	0.6047931	0.425477	0.2156263	0.2390184
1024	0	0.3487835	-0.624391	0.1977361	0.2271336
1025	1	0.0615646	-2.724126	0.2534158	0.0577744

Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=HBA_BL7 Parameter=HbA1c <7.0% Study Identifier=NN1218-4131

The GENMOD Procedure

Model Information

Data Set	WORK.ENDPOINT
Distribution	Binomial
Link Function	Logit
Dependent Variable	aval

Number of Observations Read	1025
Number of Observations Used	1025
Number of Events	306
Number of Trials	1025

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Response Profile

Ordered Value	aval	Total Frequency
1	0	306
2	1	719

PROC GENMOD is modeling the probability that aval='0'. One way to change this to model the probability that aval='1' is to

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The GENMOD Procedure

specify the DESCENDING option in the PROC statement.

Parameter Information

Parameter	Effect	TRTPN	REGION1	BOLAD1
Prm1	Intercept			
Prm2	TRTPN	2		
Prm3	TRTPN	3		
Prm4	TRTPN	4		
Prm5	REGION1		ASIA (EXCLUDING JAPAN)	
Prm6	REGION1		EUROPE	
Prm7	REGION1		JAPAN	
Prm8	REGION1		NORTH AMERICA	
Prm9	BOLAD1			BOLUS INSULIN ALGORITHM (SLIDING SCALE)
Prm10	BOLAD1			CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY
Prm11	HBA1CBL			

Criteria For Assessing Goodness Of Fit

Criterion	DF	Value	Value/DF
Log Likelihood		-482.3799	
Full Log Likelihood		-482.3799	
AIC (smaller is better)		980.7597	
AICC (smaller is better)		980.9014	
BIC (smaller is better)		1020.2193	

Algorithm converged.

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The GENMOD Procedure

Analysis Of Maximum Likelihood Parameter Estimates

Parameter		DF	Estimate	Standard Error	Wald 95% Confidence Limits		Wald Chi-Square
Intercept		1	15.1734	1.2000	12.8214	17.5254	159.88
TRTPN	2	1	-0.1270	0.1952	-0.5096	0.2556	0.42
TRTPN	3	1	-0.2227	0.1931	-0.6012	0.1559	1.33
TRTPN	4	0	0.0000	0.0000	0.0000	0.0000	.
REGION1	ASIA (EXCLUDING JAPAN)	1	-0.0192	0.2941	-0.5956	0.5571	0.00
REGION1	EUROPE	1	-0.6181	0.2124	-1.0343	-0.2018	8.47
REGION1	JAPAN	1	0.1142	0.2214	-0.3198	0.5482	0.27
REGION1	NORTH AMERICA	0	0.0000	0.0000	0.0000	0.0000	.
BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	1	0.2248	0.1793	-0.1267	0.5762	1.57
BOLAD1	CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY	0	0.0000	0.0000	0.0000	0.0000	.
HBA1CBL	Scale	1	-2.1840	0.1635	-2.5045	-1.8635	178.38
		0	1.0000	0.0000	1.0000	1.0000	

Analysis Of Maximum Likelihood Parameter Estimates

Parameter		Pr > ChiSq
Intercept		<.0001
TRTPN	2	0.5154
TRTPN	3	0.2489
TRTPN	4	.
REGION1	ASIA (EXCLUDING JAPAN)	0.9479
REGION1	EUROPE	0.0036
REGION1	JAPAN	0.6060
REGION1	NORTH AMERICA	.
BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.2100
BOLAD1	CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY	.
HBA1CBL		<.0001

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The GENMOD Procedure

Analysis Of Maximum Likelihood Parameter Estimates

Parameter Pr > ChiSq

Scale

NOTE: The scale parameter was held fixed.

Coefficients for TRTPN Least Squares Means Using WORK.ENDPOINT Margins

Parameter	Geographic Region Grouping Method 1
Intercept	
Planned Treatment (N) 2	
Planned Treatment (N) 3	
Planned Treatment (N) 4	
Geographic Region Grouping Method 1 ASIA (EXCLUDING JAPAN)	ASIA (EXCLUDING JAPAN)

Coefficients for TRTPN Least Squares Means Using WORK.ENDPOINT Margins

Bolus Adjustment Method at Timepoint 1	Planned Treatment (N)	Row		
		Row1	Row2	Row3
	2	1	1	1
	3	1	1	
	4			1
		0.1307	0.1307	0.1307

Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

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The GENMOD Procedure

Coefficients for TRTPN Least Squares Means Using WORK.ENDPOINT Margins

Parameter	Geographic Region Grouping Method 1
Geographic Region Grouping Method 1 EUROPE	EUROPE
Geographic Region Grouping Method 1 JAPAN	JAPAN
Geographic Region Grouping Method 1 NORTH AMERICA	NORTH AMERICA
Bolus Adjustment Method at Timepoint 1 BOLUS INSULIN ALGORITHM (SLIDING SCALE)	
Bolus Adjustment Method at Timepoint 1 CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY	
HbA1c at Baseline	

Coefficients for TRTPN Least Squares Means Using WORK.ENDPOINT Margins

	Planned Treatment (N)	Row1	Row2	Row3
Bolus Adjustment Method at Timepoint 1				
		0.3366	0.3366	0.3366
		0.239	0.239	0.239
		0.2937	0.2937	0.2937
BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.5824	0.5824	0.5824
CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0.4176	0.4176	0.4176
		7.4245	7.4245	7.4245

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TRTPN Least Squares Means

Planned Treatment (N)	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
2	WORK.ENDPOINT	-1.2210	0.1466	-8.33	<.0001	0.05	-1.5083	-0.9337
3	WORK.ENDPOINT	-1.3167	0.1455	-9.05	<.0001	0.05	-1.6019	-1.0316
4	WORK.ENDPOINT	-1.0940	0.1412	-7.75	<.0001	0.05	-1.3707	-0.8173

Differences of TRTPN Least Squares Means

Planned Treatment (N)	Planned Treatment (N)	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
2	4	WORK.ENDPOINT	-0.1270	0.1952	-0.65	0.5154	0.05	-0.5096	0.2556
3	4	WORK.ENDPOINT	-0.2227	0.1931	-1.15	0.2489	0.05	-0.6012	0.1559

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) / NovoRapid (meal)	WORK.ENDPOINT	-0.1270	0.1952	-0.65	0.5154	0.05	-0.5096	0.2556

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Parameter Code=HBA_BL7 Parameter=HbA1c <7.0% Study Identifier=NN1218-4131

The GENMOD Procedure

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
TRTPN	Faster aspart (post) / NovoRapid (meal)	WORK.ENDPOINT	-0.2227	0.1931	-1.15	0.2489	0.05	-0.6012	0.1559

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
1	1	0.6289716	0.5278077	0.2467083	0.2333663
2	0	0.6289716	0.5278077	0.2467083	0.2333663
3	0	0.362577	-0.564197	0.2334649	0.2311149
4	1	0.3137604	-0.782597	0.2341762	0.2153148
5	1	0.3137604	-0.782597	0.2341762	0.2153148
6	1	0.4159537	-0.339406	0.199416	0.2429362
7	0	0.3913845	-0.441496	0.2220115	0.2382027
8	1	0.1774821	-1.533501	0.2333347	0.1459822
9	1	0.0901829	-2.311403	0.2685915	0.08205
10	0	0.6595245	0.6611762	0.2027628	0.2245519
11	0	0.678352	0.7462085	0.2524702	0.2181906
12	0	0.7478747	1.0873095	0.2540328	0.1885581
13	0	0.5532241	0.2137062	0.2293757	0.2471672
14	0	0.7486807	1.0915886	0.2513774	0.1881579
15	1	0.1602727	-1.656201	0.2480262	0.1345853
16	1	0.2511629	-1.09242	0.2305628	0.1880801

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Parameter Code=HBA_BL7 Parameter=HbA1c <7.0% Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
17	1	0.364055	-0.557807	0.2002882	0.2315189
18	0	0.2127027	-1.30871	0.2081968	0.1674603
19	1	0.447092	-0.212427	0.1927806	0.2472007
20	1	0.1228167	-1.966023	0.2532219	0.1077327
21	1	0.0323888	-3.397018	0.3054757	0.0313397
22	1	0.1228167	-1.966023	0.2532219	0.1077327
23	1	0.4988263	-0.004695	0.2257662	0.2499986
24	0	0.25156	-1.09031	0.2030494	0.1882776
25	1	0.0826326	-2.407104	0.2611445	0.0758044
26	1	0.1774821	-1.533501	0.2333347	0.1459822
27	1	0.1007696	-2.188703	0.252896	0.090615
28	1	0.5004236	0.0016946	0.196639	0.2499998
29	1	0.0901829	-2.311403	0.2685915	0.08205
30	0	0.3431633	-0.649229	0.1959566	0.2254023
31	0	0.7058469	0.8752979	0.2150436	0.2076271
32	1	0.0901829	-2.311403	0.2685915	0.08205
33	1	0.1774821	-1.533501	0.2333347	0.1459822
34	0	0.3431633	-0.649229	0.1959566	0.2254023
35	1	0.3407627	-0.659897	0.2219249	0.2246435
36	0	0.6580884	0.6547869	0.2385495	0.2250081
37	1	0.3924042	-0.437217	0.2248402	0.2384232
38	1	0.2116347	-1.3151	0.2287887	0.1668455
39	0	0.5532241	0.2137062	0.2293757	0.2471672
40	1	0.1478075	-1.751901	0.2389157	0.1259605
41	0	0.4988263	-0.004695	0.2257662	0.2499986

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=HBA_BL7 Parameter=HbA1c <7.0% Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
42	0	0.6079007	0.4384962	0.2034348	0.2383574
43	0	0.7058469	0.8752979	0.2150436	0.2076271
44	0	0.6089201	0.4427753	0.1983014	0.2381364
45	0	0.4697855	-0.121006	0.1998822	0.2490871
46	1	0.2291689	-1.21301	0.2106423	0.1766505
47	0	0.8634921	1.844602	0.25631	0.1178735
48	0	0.5004236	0.0016946	0.196639	0.2499998
49	1	0.1790448	-1.522832	0.2174535	0.1469878
50	0	0.8356486	1.6262011	0.2463643	0.13734
51	0	0.8634921	1.844602	0.25631	0.1178735
52	1	0.5004236	0.0016946	0.196639	0.2499998
53	0	0.658563	0.6568971	0.20868	0.2248578
54	1	0.3939286	-0.430828	0.193686	0.2387489
55	0	0.2127027	-1.30871	0.2081968	0.1674603
56	0	0.4159537	-0.339406	0.199416	0.2429362
57	1	0.1784167	-1.527111	0.2144704	0.1465842
58	1	0.1337487	-1.868212	0.2311671	0.11586
59	1	0.2957477	-0.86763	0.1995458	0.208281
60	0	0.0679183	-2.619116	0.2593801	0.0633054
61	0	0.8523535	1.7531804	0.241001	0.125847
62	1	0.192879	-1.431411	0.2164672	0.1556767
63	1	0.25156	-1.09031	0.2030494	0.1882776
64	0	0.8227045	1.5347795	0.2315559	0.1458618
65	0	0.7058469	0.8752979	0.2150436	0.2076271
66	1	0.7058469	0.8752979	0.2150436	0.2076271

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Parameter Code=HBA_BL7 Parameter=HbA1c <7.0% Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
67	1	0.3421995	-0.653508	0.1964682	0.225099
68	0	0.7058469	0.8752979	0.2150436	0.2076271
69	0	0.5782994	0.3157961	0.2047673	0.2438692
70	1	0.0262007	-3.615419	0.3180431	0.0255142
71	0	0.6304614	0.5341969	0.2090939	0.2329798
72	0	0.5558595	0.2243745	0.1951126	0.2468797
73	0	0.5548028	0.2200954	0.1993964	0.2469967
74	1	0.6089201	0.4427753	0.1983014	0.2381364
75	0	0.4159537	-0.339406	0.199416	0.2429362
76	0	0.447092	-0.212427	0.1927806	0.2472007
77	0	0.5548028	0.2200954	0.1993964	0.2469967
78	1	0.749881	1.0979778	0.2151647	0.1875595
79	1	0.0742329	-2.523415	0.2594602	0.0687224
80	0	0.8034188	1.4078003	0.2371302	0.1579371
81	1	0.0681897	-2.614836	0.2653827	0.0635398
82	1	0.3151377	-0.776208	0.2024817	0.2158259
83	0	0.749881	1.0979778	0.2151647	0.1875595
84	1	0.6595245	0.6611762	0.2027628	0.2245519
85	0	0.3151377	-0.776208	0.2024817	0.2158259
86	1	0.0679183	-2.619116	0.2593801	0.0633054
87	1	0.2291689	-1.21301	0.2106423	0.1766505
88	0	0.5548028	0.2200954	0.1993964	0.2469967
89	0	0.8777808	1.9715812	0.2511567	0.1072816
90	0	0.658563	0.6568971	0.20868	0.2248578
91	1	0.2957477	-0.86763	0.1995458	0.208281

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Parameter Code=HBA_BL7 Parameter=HbA1c <7.0% Study Identifier=NN1218-4131

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Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
92	1	0.447092	-0.212427	0.1927806	0.2472007
93	1	0.3939286	-0.430828	0.193686	0.2387489
94	1	0.3431633	-0.649229	0.1959566	0.2254023
95	0	0.6304614	0.5341969	0.2090939	0.2329798
96	0	0.447092	-0.212427	0.1927806	0.2472007
97	1	0.6079007	0.4384962	0.2034348	0.2383574
98	1	0.2511629	-1.09242	0.2305628	0.1880801
99	1	0.4697855	-0.121006	0.1998822	0.2490871
100	1	0.2935306	-0.878298	0.2230405	0.2073704
101	0	0.9174643	2.4083829	0.2732772	0.0757235
102	1	0.4681943	-0.127395	0.2354678	0.2489884
103	1	0.1774821	-1.533501	0.2333347	0.1459822
104	0	0.7067346	0.879577	0.2084152	0.2072608
105	1	0.1781076	-1.529221	0.2399388	0.1463853
106	1	0.3417246	-0.655618	0.2255815	0.2249489
107	0	0.3939286	-0.430828	0.193686	0.2387489
108	0	0.1784167	-1.527111	0.2144704	0.1465842
109	0	0.658563	0.6568971	0.20868	0.2248578
110	0	0.3137604	-0.782597	0.2341762	0.2153148
111	0	0.7875114	1.3099894	0.2591046	0.1673372
112	0	0.7486807	1.0915886	0.2513774	0.1881579
113	0	0.6073976	0.4363861	0.233593	0.2384658
114	0	0.3417246	-0.655618	0.2255815	0.2249489
115	0	0.1097788	-2.093002	0.2608929	0.0977274
116	1	0.1774821	-1.533501	0.2333347	0.1459822

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Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
117	0	0.2511629	-1.09242	0.2305628	0.1880801
118	1	0.073795	-2.529804	0.2770424	0.0683493
119	0	0.5542815	0.2179852	0.2296962	0.2470535
120	0	0.678352	0.7462085	0.2524702	0.2181906
121	1	0.2123496	-1.310821	0.2347286	0.1672572
122	0	0.4144023	-0.345796	0.2338976	0.242673
123	1	0.3913845	-0.441496	0.2220115	0.2382027
124	1	0.0192344	-3.931631	0.3465147	0.0188645
125	0	0.1918863	-1.4378	0.2429921	0.1550659
126	1	0.0826326	-2.407104	0.2611445	0.0758044
127	0	0.2503589	-1.096699	0.2253403	0.1876793
128	1	0.2116347	-1.3151	0.2287887	0.1668455
129	1	0.0553302	-2.837516	0.2704414	0.0522688
130	1	0.1602727	-1.656201	0.2480262	0.1345853
131	1	0.0170867	-4.052221	0.3441334	0.0167947
132	1	0.2503589	-1.096699	0.2253403	0.1876793
133	1	0.0446891	-3.062306	0.290044	0.042692
134	1	0.3431633	-0.649229	0.1959566	0.2254023
135	1	0.4455131	-0.218816	0.2252866	0.2470312
136	1	0.3417246	-0.655618	0.2255815	0.2249489
137	0	0.7478747	1.0873095	0.2540328	0.1885581
138	1	0.3431633	-0.649229	0.1959566	0.2254023
139	1	0.362577	-0.564197	0.2334649	0.2311149
140	1	0.3924042	-0.437217	0.2248402	0.2384232
141	0	0.2935306	-0.878298	0.2230405	0.2073704

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
142	0	0.7478747	1.0873095	0.2540328	0.1885581
143	1	0.5558595	0.2243745	0.1951126	0.2468797
144	1	0.6304614	0.5341969	0.2090939	0.2329798
145	1	0.3151377	-0.776208	0.2024817	0.2158259
146	1	0.2957477	-0.86763	0.1995458	0.208281
147	1	0.7058469	0.8752979	0.2150436	0.2076271
148	1	0.1486141	-1.745512	0.2217748	0.126528
149	1	0.5558595	0.2243745	0.1951126	0.2468797
150	1	0.2700027	-0.994609	0.2059541	0.1971012
151	0	0.2948573	-0.871909	0.1991155	0.2079165
152	1	0.1491564	-1.741233	0.2254879	0.1269088
153	0	0.8777808	1.9715812	0.2511567	0.1072816
154	1	0.0449627	-3.055917	0.2820175	0.0429411
155	1	0.2523665	-1.086031	0.2043842	0.1886776
156	0	0.364055	-0.557807	0.2002882	0.2315189
157	1	0.5004236	0.0016946	0.196639	0.2499998
158	1	0.5004236	0.0016946	0.196639	0.2499998
159	0	0.4697855	-0.121006	0.1998822	0.2490871
160	1	0.3151377	-0.776208	0.2024817	0.2158259
161	0	0.4697855	-0.121006	0.1998822	0.2490871
162	0	0.7878643	1.3120996	0.2307402	0.1671342
163	0	0.3421995	-0.653508	0.1964682	0.225099
164	0	0.7058469	0.8752979	0.2150436	0.2076271
165	1	0.6089201	0.4427753	0.1983014	0.2381364
166	1	0.1784167	-1.527111	0.2144704	0.1465842

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
167	0	0.5558595	0.2243745	0.1951126	0.2468797
168	1	0.2523665	-1.086031	0.2043842	0.1886776
169	1	0.1790448	-1.522832	0.2174535	0.1469878
170	1	0.364055	-0.557807	0.2002882	0.2315189
171	1	0.658563	0.6568971	0.20868	0.2248578
172	0	0.5782994	0.3157961	0.2047673	0.2438692
173	1	0.0907086	-2.305014	0.2493144	0.0824805
174	1	0.0681897	-2.614836	0.2653827	0.0635398
175	1	0.3431633	-0.649229	0.1959566	0.2254023
176	1	0.2957477	-0.86763	0.1995458	0.208281
177	1	0.1784167	-1.527111	0.2144704	0.1465842
178	1	0.0492559	-2.960217	0.28151	0.0468297
179	1	0.2127027	-1.30871	0.2081968	0.1674603
180	0	0.5014934	0.0059736	0.1932595	0.2499978
181	1	0.4159537	-0.339406	0.199416	0.2429362
182	1	0.5558595	0.2243745	0.1951126	0.2468797
183	1	0.5004236	0.0016946	0.196639	0.2499998
184	1	0.0449627	-3.055917	0.2820175	0.0429411
185	1	0.2127027	-1.30871	0.2081968	0.1674603
186	1	0.3431633	-0.649229	0.1959566	0.2254023
187	1	0.1104048	-2.086613	0.2398553	0.0982156
188	0	0.5243296	0.0973952	0.2016776	0.2494081
189	1	0.10135	-2.182314	0.2390846	0.0910782
190	1	0.192879	-1.431411	0.2164672	0.1556767
191	1	0.6073976	0.4363861	0.233593	0.2384658

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
192	1	0.5558595	0.2243745	0.1951126	0.2468797
193	1	0.0492559	-2.960217	0.28151	0.0468297
194	1	0.8523535	1.7531804	0.241001	0.125847
195	0	0.1230442	-1.963913	0.2300116	0.1079043
196	1	0.5542815	0.2179852	0.2296962	0.2470535
197	1	0.0451468	-3.051638	0.2888399	0.0431086
198	0	0.2957477	-0.86763	0.1995458	0.208281
199	0	0.4697855	-0.121006	0.1998822	0.2490871
200	1	0.0555543	-2.833237	0.2768769	0.052468
201	1	0.1104048	-2.086613	0.2398553	0.0982156
202	0	0.3431633	-0.649229	0.1959566	0.2254023
203	1	0.6079007	0.4384962	0.2034348	0.2383574
204	1	0.5243296	0.0973952	0.2016776	0.2494081
205	1	0.5004236	0.0016946	0.196639	0.2499998
206	1	0.0605505	-2.741816	0.2702153	0.0568842
207	1	0.1104048	-2.086613	0.2398553	0.0982156
208	1	0.10135	-2.182314	0.2390846	0.0910782
209	1	0.364055	-0.557807	0.2002882	0.2315189
210	1	0.1017404	-2.178035	0.2440631	0.0913893
211	1	0.0052393	-5.246315	0.4147106	0.0052118
212	1	0.0553302	-2.837516	0.2704414	0.0522688
213	1	0.2948573	-0.871909	0.1991155	0.2079165
214	1	0.1223564	-1.970302	0.2454611	0.1073853
215	1	0.5548028	0.2200954	0.1993964	0.2469967
216	1	0.362577	-0.564197	0.2334649	0.2311149

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Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
217	0	0.4455131	-0.218816	0.2252866	0.2470312
218	1	0.1330102	-1.874602	0.2540151	0.1153185
219	1	0.05522	-2.839627	0.2892065	0.0521708
220	1	0.3417246	-0.655618	0.2255815	0.2249489
221	0	0.8777808	1.9715812	0.2511567	0.1072816
222	0	0.6304614	0.5341969	0.2090939	0.2329798
223	1	0.7490776	1.0936988	0.2224298	0.1879604
224	0	0.3929075	-0.435107	0.1951598	0.2385312
225	0	0.6304614	0.5341969	0.2090939	0.2329798
226	0	0.6304614	0.5341969	0.2090939	0.2329798
227	1	0.5004236	0.0016946	0.196639	0.2499998
228	1	0.1017404	-2.178035	0.2440631	0.0913893
229	1	0.0296429	-3.48844	0.3139557	0.0287642
230	0	0.3421995	-0.653508	0.1964682	0.225099
231	0	0.0449627	-3.055917	0.2820175	0.0429411
232	1	0.2957477	-0.86763	0.1995458	0.208281
233	1	0.0042426	-5.458326	0.4303254	0.0042246
234	1	0.2291689	-1.21301	0.2106423	0.1766505
235	1	0.1486141	-1.745512	0.2217748	0.126528
236	1	0.8518142	1.7489013	0.249755	0.1262268
237	1	0.1784167	-1.527111	0.2144704	0.1465842
238	1	0.5558595	0.2243745	0.1951126	0.2468797
239	1	0.25156	-1.09031	0.2030494	0.1882776
240	1	0.0605505	-2.741816	0.2702153	0.0568842
241	1	0.5782994	0.3157961	0.2047673	0.2438692

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=HBA_BL7 Parameter=HbA1c <7.0% Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
242	1	0.0492559	-2.960217	0.28151	0.0468297
243	0	0.447092	-0.212427	0.1927806	0.2472007
244	1	0.0555543	-2.833237	0.2768769	0.052468
245	0	0.3421995	-0.653508	0.1964682	0.225099
246	0	0.1330012	-1.87468	0.2674233	0.1153119
247	0	0.1602622	-1.656279	0.2615013	0.1345782
248	0	0.0734978	-2.534161	0.2897869	0.0680959
249	1	0.2687299	-1.001076	0.2493891	0.1965141
250	1	0.1093537	-2.097359	0.2752861	0.0973955
251	0	0.0737897	-2.529882	0.290036	0.0683448
252	1	0.1190289	-2.001659	0.2747423	0.104861
253	0	0.4671096	-0.131752	0.2557001	0.2489182
254	0	0.6279543	0.5234506	0.2674742	0.2336277
255	0	0.6500255	0.6191513	0.2705711	0.2274924
256	1	0.1325085	-1.878959	0.2692353	0.11495
257	1	0.0284577	-3.530465	0.3352238	0.0276479
258	1	0.1596871	-1.660558	0.26406	0.1341872
259	1	0.1093537	-2.097359	0.2752861	0.0973955
260	1	0.0209475	-3.844566	0.3484162	0.0205087
261	1	0.0601837	-2.748283	0.2989856	0.0565616
262	1	0.1596871	-1.660558	0.26406	0.1341872
263	0	0.0802865	-2.43846	0.2887036	0.0738406
264	1	0.1097712	-2.09308	0.2741939	0.0977215
265	1	0.0901765	-2.311481	0.281752	0.0820447
266	1	0.0071584	-4.932291	0.4141523	0.0071071

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=HBA_BL7 Parameter=HbA1c <7.0% Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
267	1	0.0169784	-4.058688	0.3636654	0.0166902
268	1	0.1097712	-2.09308	0.2741939	0.0977215
269	0	0.1439013	-1.783258	0.2689839	0.1231937
270	1	0.4133454	-0.350153	0.2537692	0.242491
271	1	0.8732003	1.9295563	0.3177281	0.1107215
272	1	0.1325085	-1.878959	0.2692353	0.11495
273	1	0.1912116	-1.442157	0.2598125	0.1546497
274	1	0.0655674	-2.656861	0.2967915	0.0612683
275	1	0.1330012	-1.87468	0.2674233	0.1153119
276	0	0.5216487	0.0866489	0.2586523	0.2495313
277	1	0.6279543	0.5234506	0.2674742	0.2336277
278	0	0.6279543	0.5234506	0.2674742	0.2336277
279	0	0.3337542	-0.691254	0.2544002	0.2223623
280	1	0.0655674	-2.656861	0.2967915	0.0612683
281	1	0.048755	-2.970963	0.3070988	0.046378
282	0	0.8954777	2.1479572	0.3277907	0.0935974
283	1	0.9298742	2.5847589	0.3493455	0.0652082
284	0	0.8164914	1.4927546	0.2992732	0.1498332
285	1	0.0599421	-2.752562	0.2981202	0.0563491
286	1	0.0489539	-2.966684	0.3085429	0.0465574
287	0	0.678335	0.7461305	0.263107	0.2181966
288	1	0.0489539	-2.966684	0.3085429	0.0465574
289	1	0.005762	-5.150692	0.4274067	0.0057288
290	1	2.2731E-8	-17.59954	1.304806	2.2731E-8
291	0	0.678335	0.7461305	0.263107	0.2181966

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=HBA_BL7 Parameter=HbA1c <7.0% Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
292	1	0.1093537	-2.097359	0.2752861	0.0973955
293	0	0.3839412	-0.472853	0.2545532	0.2365304
294	1	0.1097712	-2.09308	0.2741939	0.0977215
295	1	0.1325085	-1.878959	0.2692353	0.11495
296	1	0.0601837	-2.748283	0.2989856	0.0565616
297	0	0.5227163	0.090928	0.2501556	0.249484
298	0	0.7231723	0.9602523	0.2798627	0.2001941
299	1	0.2064503	-1.346456	0.2601821	0.1638286
300	1	0.3337542	-0.691254	0.2544002	0.2223623
301	1	0.7240281	0.9645314	0.2692782	0.1998114
302	1	0.0169071	-4.062967	0.3598638	0.0166213
303	1	0.2678898	-1.005355	0.2542766	0.1961249
304	1	0.1602622	-1.656279	0.2615013	0.1345782
305	1	0.1729508	-1.564857	0.2641138	0.1430388
306	1	0.1729508	-1.564857	0.2641138	0.1430388
307	1	0.362559	-0.564275	0.2464623	0.23111
308	1	0.0351596	-3.312064	0.3248081	0.0339234
309	1	0.0979635	-2.22006	0.2813345	0.0883667
310	1	0.5454615	0.1823496	0.2612274	0.2479333
311	0	0.5216487	0.0866489	0.2586523	0.2495313
312	1	0.1602622	-1.656279	0.2615013	0.1345782
313	1	0.2280285	-1.219477	0.2524337	0.1760315
314	1	0.0320537	-3.407765	0.3267754	0.0310262
315	1	0.3337542	-0.691254	0.2544002	0.2223623
316	1	0.362559	-0.564275	0.2464623	0.23111

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=HBA_BL7 Parameter=HbA1c <7.0% Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
317	1	0.1912116	-1.442157	0.2598125	0.1546497
318	1	0.2445201	-1.128055	0.2572317	0.18473
319	1	0.1325085	-1.878959	0.2692353	0.11495
320	1	0.0351596	-3.312064	0.3248081	0.0339234
321	0	0.2280285	-1.219477	0.2524337	0.1760315
322	1	0.2678898	-1.005355	0.2542766	0.1961249
323	1	0.2064503	-1.346456	0.2601821	0.1638286
324	0	0.5767214	0.3093288	0.2534933	0.2441138
325	1	0.2445201	-1.128055	0.2572317	0.18473
326	1	0.1729508	-1.564857	0.2641138	0.1430388
327	0	0.0210354	-3.840287	0.3518126	0.0205929
328	1	0.1330012	-1.87468	0.2674233	0.1153119
329	1	0.1918742	-1.437878	0.2564867	0.1550585
330	1	0.0599421	-2.752562	0.2981202	0.0563491
331	0	0.3137436	-0.782675	0.2473902	0.2153085
332	0	0.5988679	0.4007504	0.2654371	0.2402251
333	1	0.2272761	-1.223756	0.2565388	0.1756217
334	1	0.2064503	-1.346456	0.2601821	0.1638286
335	1	0.0050784	-5.277671	0.4320017	0.0050526
336	1	0.1602622	-1.656279	0.2615013	0.1345782
337	0	0.1602622	-1.656279	0.2615013	0.1345782
338	0	0.5988679	0.4007504	0.2654371	0.2402251
339	0	0.1918742	-1.437878	0.2564867	0.1550585
340	0	0.6774006	0.7418514	0.2732497	0.218529
341	0	0.2445201	-1.128055	0.2572317	0.18473

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=HBA_BL7 Parameter=HbA1c <7.0% Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
342	0	0.678335	0.7461305	0.263107	0.2181966
343	0	0.8954777	2.1479572	0.3277907	0.0935974
344	1	0.0737897	-2.529882	0.290036	0.0683448
345	1	0.0284577	-3.530465	0.3352238	0.0276479
346	1	0.6774006	0.7418514	0.2732497	0.218529
347	1	0.7654746	1.1829322	0.2762806	0.1795232
348	0	0.6979494	0.8375521	0.2765781	0.210816
349	1	0.0178701	-4.006594	0.3103676	0.0175508
350	0	0.4506414	-0.198079	0.202398	0.2475637
351	1	0.1030591	-2.163687	0.2213857	0.0924379
352	0	0.5050802	0.0203214	0.2067485	0.2499742
353	0	0.3464046	-0.634881	0.1975081	0.2264084
354	0	0.1811635	-1.508485	0.203755	0.1483433
355	0	0.5904199	0.3657015	0.2094785	0.2418242
356	0	0.2799512	-0.944704	0.1949932	0.2015785
357	1	0.503483	0.0139321	0.2286277	0.2499879
358	1	0.3731866	-0.51857	0.2134958	0.2339184
359	1	0.1997441	-1.387895	0.2113433	0.1598464
360	0	0.0686971	-2.606878	0.2441274	0.0639778
361	1	0.1143178	-2.047376	0.2216518	0.1012492
362	1	0.10247	-2.170076	0.2302799	0.0919699
363	1	0.5351697	0.1409114	0.2230287	0.2487631
364	1	0.297408	-0.859671	0.2148399	0.2089565
365	1	0.297408	-0.859671	0.2148399	0.2089565
366	0	0.1802176	-1.514874	0.2172231	0.1477392

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=HBA_BL7 Parameter=HbA1c <7.0% Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
367	0	0.3958303	-0.42287	0.2194169	0.2391487
368	1	0.2369465	-1.169494	0.2092527	0.1808029
369	1	0.1243708	-1.951675	0.2248252	0.1089027
370	1	0.0075225	-4.882308	0.3625867	0.0074659
371	1	0.10247	-2.170076	0.2302799	0.0919699
372	1	0.2778058	-0.955372	0.209572	0.2006297
373	1	0.0939972	-2.265777	0.2275429	0.0851618
374	1	0.534105	0.1366323	0.2282138	0.2488368
375	1	0.0686971	-2.606878	0.2441274	0.0639778
376	1	0.0628214	-2.702579	0.2422245	0.0588748
377	1	0.0336413	-3.357781	0.2702391	0.0325095
378	0	0.7735798	1.2286365	0.271317	0.1751541
379	0	0.1997441	-1.387895	0.2113433	0.1598464
380	0	0.2778058	-0.955372	0.209572	0.2006297
381	1	0.0511262	-2.920979	0.2508453	0.0485123
382	1	0.1383604	-1.828975	0.2168365	0.1192168
383	0	0.5888739	0.3593122	0.2293603	0.2421014
384	1	0.2550832	-1.071683	0.1979726	0.1900158
385	1	0.4806373	-0.077489	0.2177436	0.2496251
386	1	0.1143178	-2.047376	0.2216518	0.1012492
387	0	0.0082367	-4.790886	0.3528931	0.0081688
388	0	0.0143241	-4.231385	0.3156873	0.0141189
389	1	0.0939972	-2.265777	0.2275429	0.0851618
390	0	0.1665089	-1.610574	0.21317	0.1387837
391	1	0.0093415	-4.663907	0.349332	0.0092542

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=HBA_BL7 Parameter=HbA1c <7.0% Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
392	1	0.2000816	-1.385784	0.2047403	0.160049
393	0	0.7343147	1.0166249	0.2443291	0.1950966
394	1	0.1811635	-1.508485	0.203755	0.1483433
395	1	0.2987448	-0.853282	0.1970632	0.2094964
396	0	0.4270787	-0.29378	0.2048839	0.2446825
397	1	0.0686971	-2.606878	0.2441274	0.0639778
398	1	0.3973593	-0.41648	0.1992983	0.2394649
399	1	0.1811635	-1.508485	0.203755	0.1483433
400	1	0.3973593	-0.41648	0.1992983	0.2394649
401	0	0.0845488	-2.382088	0.2293027	0.0774003
402	1	0.3746824	-0.512181	0.2022277	0.2342955
403	1	0.1154024	-2.036708	0.21874	0.1020847
404	1	0.2373283	-1.167384	0.2021404	0.1810036
405	1	0.5050802	0.0203214	0.2067485	0.2499742
406	1	0.0945428	-2.259388	0.226932	0.0856044
407	0	0.6627389	0.6755239	0.2264812	0.223516
408	1	0.0243044	-3.692493	0.2919237	0.0237137
409	0	0.3731866	-0.51857	0.2134958	0.2339184
410	1	0.2147592	-1.296473	0.2151925	0.1686377
411	0	0.534105	0.1366323	0.2282138	0.2488368
412	1	0.297408	-0.859671	0.2148399	0.2089565
413	0	0.2361737	-1.173773	0.2095057	0.1803957
414	1	0.0772794	-2.479899	0.238924	0.0713073
415	1	0.0628214	-2.702579	0.2422245	0.0588748
416	0	0.4265624	-0.29589	0.2135826	0.2446069

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=HBA_BL7 Parameter=HbA1c <7.0% Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
417	0	0.8102009	1.4513164	0.2737701	0.1537754
418	1	0.6882252	0.7918348	0.2517855	0.2145713
419	1	0.2778058	-0.955372	0.209572	0.2006297
420	0	0.9409281	2.7681107	0.3234614	0.0555824
421	0	0.5356946	0.1430215	0.2138799	0.2487259
422	0	0.8423883	1.6761065	0.2626658	0.1327703
423	1	0.2007674	-1.381505	0.2008678	0.1604598
424	0	0.9643028	3.296334	0.365543	0.0344229
425	1	0.1811635	-1.508485	0.203755	0.1483433
426	0	0.2790895	-0.948983	0.2008425	0.2011985
427	0	0.7525624	1.1123256	0.2442682	0.1862122
428	0	0.069107	-2.600489	0.2380812	0.0643312
429	1	0.2790895	-0.948983	0.2008425	0.2011985
430	0	0.2381037	-1.163104	0.1972757	0.1814103
431	1	0.0631986	-2.696189	0.2439196	0.0592045
432	0	0.4822324	-0.0711	0.1994719	0.2496843
433	1	0.2987448	-0.853282	0.1970632	0.2094964
434	1	0.3756855	-0.507902	0.194515	0.2345459
435	0	0.7351486	1.020904	0.2324449	0.1947051
436	0	0.2799512	-0.944704	0.1949932	0.2015785
437	0	0.503483	0.0139321	0.2286277	0.2499879
438	1	0.2381037	-1.163104	0.1972757	0.1814103
439	1	0.1243708	-1.951675	0.2248252	0.1089027
440	0	0.1388713	-1.824696	0.2191553	0.1195861
441	0	0.3973593	-0.41648	0.1992983	0.2394649

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Parameter Code=HBA_BL7 Parameter=HbA1c <7.0% Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
442	1	0.0840556	-2.388477	0.2367406	0.0769903
443	0	0.428126	-0.289501	0.1963292	0.2448341
444	1	0.0634524	-2.69191	0.245275	0.0594262
445	1	0.0686971	-2.606878	0.2441274	0.0639778
446	1	0.297408	-0.859671	0.2148399	0.2089565
447	1	0.1673975	-1.604185	0.2085936	0.1393756
448	1	0.0415118	-3.13938	0.2602093	0.0397885
449	0	0.9607787	3.1985232	0.3721699	0.037683
450	1	0.0845488	-2.382088	0.2293027	0.0774003
451	1	0.0222282	-3.783915	0.3022864	0.0217341
452	1	0.0419383	-3.128712	0.2665376	0.0401795
453	1	0.0628214	-2.702579	0.2422245	0.0588748
454	1	0.1501692	-1.733275	0.2204512	0.1276184
455	1	0.0415118	-3.13938	0.2602093	0.0397885
456	0	0.1679947	-1.599906	0.2057008	0.1397725
457	1	0.0559733	-2.825279	0.252359	0.0528403
458	1	0.0272206	-3.576182	0.2808634	0.0264797
459	1	0.0939972	-2.265777	0.2275429	0.0851618
460	0	0.8111815	1.4577057	0.2519344	0.1531661
461	1	0.0777363	-2.473509	0.2356285	0.0716933
462	1	0.0298727	-3.480481	0.2813443	0.0289803
463	1	0.0416824	-3.135101	0.2663712	0.0399449
464	1	0.3464046	-0.634881	0.1975081	0.2264084
465	1	0.3741881	-0.514291	0.2106124	0.2341714
466	1	0.3250671	-0.730582	0.2008718	0.2193985

Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=HBA_BL7 Parameter=HbA1c <7.0% Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
467	1	0.3756855	-0.507902	0.194515	0.2345459
468	1	0.0631986	-2.696189	0.2439196	0.0592045
469	1	0.2790895	-0.948983	0.2008425	0.2011985
470	1	0.0628214	-2.702579	0.2422245	0.0588748
471	1	0.0300584	-3.474092	0.2800758	0.0291549
472	1	0.2000816	-1.385784	0.2047403	0.160049
473	1	0.10247	-2.170076	0.2302799	0.0919699
474	1	0.0221354	-3.788194	0.2980813	0.0216454
475	1	0.1673975	-1.604185	0.2085936	0.1393756
476	1	0.1811635	-1.508485	0.203755	0.1483433
477	1	0.428126	-0.289501	0.1963292	0.2448341
478	0	0.4270787	-0.29378	0.2048839	0.2446825
479	1	0.3464046	-0.634881	0.1975081	0.2264084
480	1	0.051437	-2.91459	0.253571	0.0487912
481	1	0.6420108	0.5841023	0.2161702	0.2298329
482	1	0.3746824	-0.512181	0.2022277	0.2342955
483	1	0.0417667	-3.132991	0.2638837	0.0400223
484	0	0.2373283	-1.167384	0.2021404	0.1810036
485	0	0.5904199	0.3657015	0.2094785	0.2418242
486	1	0.0457694	-3.03729	0.2578623	0.0436745
487	1	0.1673975	-1.604185	0.2085936	0.1393756
488	1	0.0243044	-3.692493	0.2919237	0.0237137
489	0	0.4506414	-0.198079	0.202398	0.2475637
490	1	0.051437	-2.91459	0.253571	0.0487912
491	0	0.5893847	0.3614224	0.2200691	0.2420104

Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=HBA_BL7 Parameter=HbA1c <7.0% Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
492	1	0.1154024	-2.036708	0.21874	0.1020847
493	1	0.428126	-0.289501	0.1963292	0.2448341
494	1	0.0371229	-3.255691	0.2687011	0.0357448
495	1	0.3464046	-0.634881	0.1975081	0.2264084
496	0	0.3756855	-0.507902	0.194515	0.2345459
497	1	0.1391239	-1.822586	0.2136323	0.1197684
498	1	0.3250671	-0.730582	0.2008718	0.2193985
499	1	0.5904199	0.3657015	0.2094785	0.2418242
500	0	0.6420108	0.5841023	0.2161702	0.2298329
501	1	0.4822324	-0.0711	0.1994719	0.2496843
502	1	0.0178701	-4.006594	0.3103676	0.0175508
503	1	0.7096994	0.8939247	0.2349743	0.2060261
504	1	0.1149663	-2.040987	0.219775	0.101749
505	0	0.3260066	-0.726303	0.1940665	0.2197263
506	0	0.8423883	1.6761065	0.2626658	0.1327703
507	1	0.1149663	-2.040987	0.219775	0.101749
508	1	0.5356946	0.1430215	0.2138799	0.2487259
509	1	0.0417667	-3.132991	0.2638837	0.0400223
510	1	0.0417667	-3.132991	0.2638837	0.0400223
511	0	0.4822324	-0.0711	0.1994719	0.2496843
512	0	0.774697	1.2350257	0.2540113	0.1745416
513	1	0.0777363	-2.473509	0.2356285	0.0716933
514	1	0.07743	-2.477789	0.2350107	0.0714346
515	0	0.1811635	-1.508485	0.203755	0.1483433
516	1	0.1030591	-2.163687	0.2213857	0.0924379

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=HBA_BL7 Parameter=HbA1c <7.0% Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
517	1	0.07743	-2.477789	0.2350107	0.0714346
518	1	0.0631986	-2.696189	0.2439196	0.0592045
519	0	0.6905097	0.8025031	0.2238587	0.2137061
520	1	0.2000816	-1.385784	0.2047403	0.160049
521	1	0.1509864	-1.726885	0.2085181	0.1281895
522	1	0.4822324	-0.0711	0.1994719	0.2496843
523	1	0.1154024	-2.036708	0.21874	0.1020847
524	0	0.051437	-2.91459	0.253571	0.0487912
525	0	0.1030591	-2.163687	0.2213857	0.0924379
526	1	0.069107	-2.600489	0.2380812	0.0643312
527	1	0.1391239	-1.822586	0.2136323	0.1197684
528	1	0.069107	-2.600489	0.2380812	0.0643312
529	0	0.7525624	1.1123256	0.2442682	0.1862122
530	0	0.3464046	-0.634881	0.1975081	0.2264084
531	1	0.7351486	1.020904	0.2324449	0.1947051
532	1	0.1811635	-1.508485	0.203755	0.1483433
533	1	0.2000816	-1.385784	0.2047403	0.160049
534	1	0.4811641	-0.075379	0.2087908	0.2496452
535	0	0.6627389	0.6755239	0.2264812	0.223516
536	1	0.1679947	-1.599906	0.2057008	0.1397725
537	1	0.5904199	0.3657015	0.2094785	0.2418242
538	1	0.1679947	-1.599906	0.2057008	0.1397725
539	1	0.2987448	-0.853282	0.1970632	0.2094964
540	1	0.0116686	-4.439117	0.3413577	0.0115324
541	1	0.1250683	-1.945286	0.2144255	0.1094262

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Parameter Code=HBA_BL7 Parameter=HbA1c <7.0% Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
542	1	0.1154024	-2.036708	0.21874	0.1020847
543	1	0.2381037	-1.163104	0.1972757	0.1814103
544	0	0.2158386	-1.290084	0.2002179	0.1692523
545	1	0.069107	-2.600489	0.2380812	0.0643312
546	1	0.1030591	-2.163687	0.2213857	0.0924379
547	1	0.5050802	0.0203214	0.2067485	0.2499742
548	1	0.07743	-2.477789	0.2350107	0.0714346
549	1	0.069107	-2.600489	0.2380812	0.0643312
550	1	0.0634524	-2.69191	0.245275	0.0594262
551	1	0.2799512	-0.944704	0.1949932	0.2015785
552	1	0.0563119	-2.81889	0.2476296	0.0531409
553	1	0.0845488	-2.382088	0.2293027	0.0774003
554	1	0.0339898	-3.347113	0.2780031	0.0328345
555	1	0.1030591	-2.163687	0.2213857	0.0924379
556	1	0.1811635	-1.508485	0.203755	0.1483433
557	1	0.0075703	-4.875919	0.3687336	0.007513
558	1	0.2987448	-0.853282	0.1970632	0.2094964
559	1	0.2987448	-0.853282	0.1970632	0.2094964
560	0	0.6905097	0.8025031	0.2238587	0.2137061
561	1	0.07743	-2.477789	0.2350107	0.0714346
562	1	0.0419383	-3.128712	0.2665376	0.0401795
563	1	0.2786651	-0.951093	0.2084279	0.2010109
564	1	0.3250671	-0.730582	0.2008718	0.2193985
565	0	0.5367587	0.1473006	0.2038817	0.2486488
566	1	0.0457694	-3.03729	0.2578623	0.0436745

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=HBA_BL7 Parameter=HbA1c <7.0% Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
567	0	0.1147517	-2.043097	0.2247505	0.1015838
568	1	0.1149663	-2.040987	0.219775	0.101749
569	1	0.5904199	0.3657015	0.2094785	0.2418242
570	1	0.1673975	-1.604185	0.2085936	0.1393756
571	1	0.0158393	-4.129295	0.3168246	0.0155884
572	0	0.4811641	-0.075379	0.2087908	0.2496452
573	1	0.1811635	-1.508485	0.203755	0.1483433
574	1	0.1391239	-1.822586	0.2136323	0.1197684
575	1	0.1391239	-1.822586	0.2136323	0.1197684
576	1	0.1250683	-1.945286	0.2144255	0.1094262
577	1	0.1396371	-1.818307	0.2116899	0.1201386
578	1	0.1154024	-2.036708	0.21874	0.1020847
579	1	0.5356946	0.1430215	0.2138799	0.2487259
580	1	0.4811641	-0.075379	0.2087908	0.2496452
581	1	0.1679947	-1.599906	0.2057008	0.1397725
582	1	0.3260066	-0.726303	0.1940665	0.2197263
583	1	0.2987448	-0.853282	0.1970632	0.2094964
584	0	0.4255161	-0.300169	0.2172848	0.2444521
585	1	0.1147517	-2.043097	0.2247505	0.1015838
586	1	0.1147517	-2.043097	0.2247505	0.1015838
587	1	0.0060555	-5.100709	0.3760853	0.0060189
588	0	0.6613094	0.6691347	0.2499439	0.2239793
589	1	0.0686971	-2.606878	0.2441274	0.0639778
590	0	0.1665089	-1.610574	0.21317	0.1387837
591	1	0.1997441	-1.387895	0.2113433	0.1598464

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=HBA_BL7 Parameter=HbA1c <7.0% Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
592	0	0.3246043	-0.732692	0.2088839	0.2192363
593	1	0.0272206	-3.576182	0.2808634	0.0264797
594	1	0.0559733	-2.825279	0.252359	0.0528403
595	1	0.0769748	-2.484178	0.2344287	0.0710497
596	1	0.0686971	-2.606878	0.2441274	0.0639778
597	1	0.1501692	-1.733275	0.2204512	0.1276184
598	0	0.3958303	-0.42287	0.2194169	0.2391487
599	1	0.019507	-3.917283	0.3035485	0.0191265
600	1	0.1147517	-2.043097	0.2247505	0.1015838
601	1	0.0415118	-3.13938	0.2602093	0.0397885
602	1	0.253871	-1.078072	0.2143936	0.1894205
603	0	0.5893847	0.3614224	0.2200691	0.2420104
604	1	0.0686971	-2.606878	0.2441274	0.0639778
605	1	0.0273342	-3.571903	0.2878778	0.026587
606	1	0.0772794	-2.479899	0.238924	0.0713073
607	1	0.0272206	-3.576182	0.2808634	0.0264797
608	1	0.1149663	-2.040987	0.219775	0.101749
609	1	0.297408	-0.859671	0.2148399	0.2089565
610	0	0.4255161	-0.300169	0.2172848	0.2444521
611	1	0.0416824	-3.135101	0.2663712	0.0399449
612	0	0.3236668	-0.736971	0.21091	0.2189066
613	1	0.2369465	-1.169494	0.2092527	0.1808029
614	0	0.6108137	0.4507338	0.2419436	0.2377203
615	1	0.5578234	0.232333	0.2348111	0.2466565
616	1	0.1501692	-1.733275	0.2204512	0.1276184

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=HBA_BL7 Parameter=HbA1c <7.0% Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
617	0	0.3731866	-0.51857	0.2134958	0.2339184
618	0	0.2369465	-1.169494	0.2092527	0.1808029
619	1	0.1665089	-1.610574	0.21317	0.1387837
620	1	0.3958303	-0.42287	0.2194169	0.2391487
621	1	0.0939972	-2.265777	0.2275429	0.0851618
622	1	0.0686971	-2.606878	0.2441274	0.0639778
623	1	0.0939972	-2.265777	0.2275429	0.0851618
624	1	0.0943623	-2.261498	0.2313684	0.085458
625	1	0.4265624	-0.29589	0.2135826	0.2446069
626	1	0.1501692	-1.733275	0.2204512	0.1276184
627	1	0.199061	-1.392174	0.2107122	0.1594357
628	0	0.1671036	-1.606295	0.2146628	0.13918
629	1	0.0082367	-4.790886	0.3528931	0.0081688
630	0	0.5888739	0.3593122	0.2293603	0.2421014
631	1	0.4795692	-0.081769	0.2222155	0.2495826
632	1	0.0840556	-2.388477	0.2367406	0.0769903
633	1	0.2369465	-1.169494	0.2092527	0.1808029
634	1	0.1143178	-2.047376	0.2216518	0.1012492
635	1	0.3741881	-0.514291	0.2106124	0.2341714
636	1	0.0454911	-3.04368	0.2613557	0.0434217
637	1	0.0840556	-2.388477	0.2367406	0.0769903
638	1	0.4265624	-0.29589	0.2135826	0.2446069
639	0	0.1143178	-2.047376	0.2216518	0.1012492
640	1	0.297408	-0.859671	0.2148399	0.2089565
641	0	0.4255161	-0.300169	0.2172848	0.2444521

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Parameter Code=HBA_BL7 Parameter=HbA1c <7.0% Study Identifier=NN1218-4131

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Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
642	1	0.0949097	-2.255109	0.2267523	0.0859019
643	1	0.3449594	-0.64127	0.2165239	0.2259624
644	1	0.2381037	-1.163104	0.1972757	0.1814103
645	1	0.1243708	-1.951675	0.2248252	0.1089027
646	1	0.1149663	-2.040987	0.219775	0.101749
647	1	0.253871	-1.078072	0.2143936	0.1894205
648	1	0.0039291	-5.5354	0.4045142	0.0039137
649	1	0.2381037	-1.163104	0.1972757	0.1814103
650	1	0.0945428	-2.259388	0.226932	0.0856044
651	1	0.0220898	-3.790304	0.2993925	0.0216018
652	1	0.3236668	-0.736971	0.21091	0.2189066
653	1	0.2361737	-1.173773	0.2095057	0.1803957
654	1	0.077743	-2.477789	0.2350107	0.0714346
655	1	0.2799512	-0.944704	0.1949932	0.2015785
656	1	0.0945428	-2.259388	0.226932	0.0856044
657	0	0.3260066	-0.726303	0.1940665	0.2197263
658	1	0.3260066	-0.726303	0.1940665	0.2197263
659	1	0.1391239	-1.822586	0.2136323	0.1197684
660	1	0.0102915	-4.566096	0.3430386	0.0101855
661	1	0.0454911	-3.04368	0.2613557	0.0434217
662	1	0.0178701	-4.006594	0.3103676	0.0175508
663	1	0.2799512	-0.944704	0.1949932	0.2015785
664	1	0.1679947	-1.599906	0.2057008	0.1397725
665	0	0.3260066	-0.726303	0.1940665	0.2197263
666	1	0.0158393	-4.129295	0.3168246	0.0155884

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
667	1	0.2987448	-0.853282	0.1970632	0.2094964
668	1	0.0949097	-2.255109	0.2267523	0.0859019
669	1	0.428126	-0.289501	0.1963292	0.2448341
670	1	0.002779	-5.882891	0.4207809	0.0027713
671	1	0.1143178	-2.047376	0.2216518	0.1012492
672	1	0.0053373	-5.227688	0.3793921	0.0053088
673	1	0.0017973	-6.319692	0.4492321	0.001794
674	1	0.0511262	-2.920979	0.2508453	0.0485123
675	1	0.2778058	-0.955372	0.209572	0.2006297
676	1	0.0513342	-2.9167	0.256507	0.048699
677	1	0.2786651	-0.951093	0.2084279	0.2010109
678	1	0.0368952	-3.26208	0.2710411	0.035534
679	1	0.0336413	-3.357781	0.2702391	0.0325095
680	1	0.2369465	-1.169494	0.2092527	0.1808029
681	1	0.2778058	-0.955372	0.209572	0.2006297
682	1	0.1665089	-1.610574	0.21317	0.1387837
683	1	0.0943623	-2.261498	0.2313684	0.085458
684	1	0.1388713	-1.824696	0.2191553	0.1195861
685	1	0.6108137	0.4507338	0.2419436	0.2377203
686	1	0.0769748	-2.484178	0.2344287	0.0710497
687	1	0.2147592	-1.296473	0.2151925	0.1686377
688	1	0.1388713	-1.824696	0.2191553	0.1195861
689	1	0.1671036	-1.606295	0.2146628	0.13918
690	1	0.2369465	-1.169494	0.2092527	0.1808029
691	1	0.1997441	-1.387895	0.2113433	0.1598464

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Parameter Code=HBA_BL7 Parameter=HbA1c <7.0% Study Identifier=NN1218-4131

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Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
692	1	0.1383604	-1.828975	0.2168365	0.1192168
693	0	0.0840556	-2.388477	0.2367406	0.0769903
694	1	0.362559	-0.564275	0.2464623	0.23111
695	1	0.5767214	0.3093288	0.2534933	0.2441138
696	1	0.2445201	-1.128055	0.2572317	0.18473
697	0	0.8023953	1.401333	0.2840529	0.1585571
698	1	0.0284577	-3.530465	0.3352238	0.0276479
699	1	0.2280285	-1.219477	0.2524337	0.1760315
700	0	0.436728	-0.254452	0.2557537	0.2459967
701	1	0.1325085	-1.878959	0.2692353	0.11495
702	1	0.0489539	-2.966684	0.3085429	0.0465574
703	1	0.5227163	0.090928	0.2501556	0.249484
704	1	0.1596871	-1.660558	0.26406	0.1341872
705	0	0.678335	0.7461305	0.263107	0.2181966
706	1	0.1918742	-1.437878	0.2564867	0.1550585
707	1	0.312823	-0.786954	0.2530531	0.2149648
708	1	0.6500255	0.6191513	0.2705711	0.2274924
709	0	0.678335	0.7461305	0.263107	0.2181966
710	1	0.0898261	-2.31576	0.282156	0.0817574
711	1	0.7419164	1.055953	0.2834025	0.1914765
712	1	0.436728	-0.254452	0.2557537	0.2459967
713	0	0.4681749	-0.127473	0.2478541	0.2489872
714	0	0.7240281	0.9645314	0.2692782	0.1998114
715	1	0.5227163	0.090928	0.2501556	0.249484
716	0	0.1439013	-1.783258	0.2689839	0.1231937

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Parameter Code=HBA_BL7 Parameter=HbA1c <7.0% Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
717	1	0.2678898	-1.005355	0.2542766	0.1961249
718	1	0.3137436	-0.782675	0.2473902	0.2153085
719	0	0.3615706	-0.568554	0.2528833	0.2308373
720	1	0.4681749	-0.127473	0.2478541	0.2489872
721	1	0.0489539	-2.966684	0.3085429	0.0465574
722	1	0.312823	-0.786954	0.2530531	0.2149648
723	1	0.6774006	0.7418514	0.2732497	0.218529
724	1	0.5756765	0.3050498	0.2625916	0.2442731
725	1	0.0540425	-2.862427	0.2506868	0.0511219
726	1	0.0748177	-2.514937	0.2667949	0.06922
727	1	0.1210596	-1.982435	0.2428051	0.1064041
728	1	0.0264179	-3.606941	0.3190192	0.02572
729	0	0.291021	-0.89043	0.2188557	0.2063278
730	1	0.0610346	-2.733338	0.2760953	0.0573094
731	1	0.0496544	-2.951739	0.286029	0.0471888
732	1	0.043905	-3.080828	0.2612432	0.0419774
733	1	0.3655305	-0.551439	0.1967732	0.231918
734	1	0.0746717	-2.517047	0.2418441	0.0690959
735	1	0.1203814	-1.988824	0.2158136	0.1058897
736	1	0.0072194	-4.923735	0.3644929	0.0071673
737	1	0.0098573	-4.609634	0.3479246	0.0097602
738	1	0.0289941	-3.51124	0.3112803	0.0281534
739	1	0.1938722	-1.425043	0.2053236	0.1562858
740	1	0.0402235	-3.17225	0.2733217	0.0386056
741	1	0.0812394	-2.425625	0.2316033	0.0746395

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Observation Statistics

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742	1	0.1210596	-1.982435	0.2428051	0.1064041
743	1	0.1210596	-1.982435	0.2428051	0.1064041
744	1	0.161997	-1.643444	0.2106046	0.135754
745	1	0.3655305	-0.551439	0.1967732	0.231918
746	1	0.0324543	-3.394929	0.2741558	0.031401
747	0	0.2096176	-1.327232	0.2252021	0.1656781
748	0	0.8365213	1.6325689	0.2599253	0.1367534
749	1	0.4180147	-0.330928	0.2238363	0.2432784
750	1	0.5248505	0.099484	0.2041938	0.2493825
751	1	0.0404709	-3.16586	0.3028866	0.038833
752	1	0.1210596	-1.982435	0.2428051	0.1064041
753	1	0.0400586	-3.176529	0.2627902	0.0384539
754	1	0.0152705	-4.166443	0.3481064	0.0150373
755	1	0.2295381	-1.210921	0.19545	0.1768504
756	1	0.0606695	-2.739727	0.2417803	0.0569887
757	1	0.5788087	0.3178848	0.2101174	0.2437892
758	1	0.0325889	-3.39065	0.2849207	0.0315269
759	0	0.1203814	-1.988824	0.2158136	0.1058897
760	1	0.0213014	-3.827452	0.3094095	0.0208476
761	0	0.3155887	-0.774119	0.1929411	0.2159925
762	0	0.3165136	-0.76984	0.1969188	0.2163328
763	1	0.2295381	-1.210921	0.19545	0.1768504
764	1	0.1106101	-2.084524	0.2157945	0.0983755
765	0	0.4713719	-0.114638	0.2005231	0.2491804
766	1	0.4729643	-0.108249	0.2225605	0.2492691

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Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
767	1	0.2302957	-1.206642	0.2012363	0.1772596
768	1	0.0288148	-3.51763	0.2840082	0.0279845
769	1	0.026254	-3.61333	0.2860051	0.0255648
770	1	0.1110317	-2.080245	0.2243921	0.0987037
771	1	0.1932044	-1.429322	0.1987212	0.1558764
772	0	0.2302957	-1.206642	0.2012363	0.1772596
773	1	0.1932044	-1.429322	0.1987212	0.1558764
774	1	0.0400586	-3.176529	0.2627902	0.0384539
775	1	0.1344882	-1.861845	0.2169923	0.1164011
776	0	0.8037484	1.409889	0.2538556	0.1577369
777	0	0.2468989	-1.11522	0.1971397	0.1859398
778	1	0.3645387	-0.555719	0.1937556	0.2316502
779	1	0.043905	-3.080828	0.2612432	0.0419774
780	1	0.0540425	-2.862427	0.2506868	0.0511219
781	1	0.1462859	-1.764034	0.2359521	0.1248863
782	0	0.5788087	0.3178848	0.2101174	0.2437892
783	1	0.0912351	-2.298646	0.2327075	0.0829113
784	0	0.8746146	1.9423914	0.2815316	0.1096639
785	1	0.1106101	-2.084524	0.2157945	0.0983755
786	1	0.2096176	-1.327232	0.2252021	0.1656781
787	1	0.1462859	-1.764034	0.2359521	0.1248863
788	1	0.090881	-2.302925	0.2235977	0.0826216
789	1	0.2096176	-1.327232	0.2252021	0.1656781
790	1	0.1344882	-1.861845	0.2169923	0.1164011
791	1	0.161417	-1.647723	0.2032593	0.1353615

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Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
792	1	0.0540425	-2.862427	0.2506868	0.0511219
793	1	0.1110317	-2.080245	0.2243921	0.0987037
794	1	0.1938722	-1.425043	0.2053236	0.1562858
795	0	0.1938722	-1.425043	0.2053236	0.1562858
796	0	0.4398879	-0.241617	0.1992726	0.2463865
797	0	0.3155887	-0.774119	0.1929411	0.2159925
798	0	0.4941962	-0.023216	0.2031206	0.2499663
799	0	0.2314303	-1.200253	0.2292901	0.1778703
800	1	0.4414627	-0.235228	0.2183612	0.2465734
801	0	0.7019867	0.8567764	0.2408682	0.2092014
802	1	0.3380426	-0.672029	0.2174648	0.2237698
803	0	0.6324344	0.5426749	0.2380055	0.2324611
804	0	0.9388291	2.7309624	0.3228002	0.057429
805	0	0.7689082	1.2021565	0.2520576	0.1776884
806	1	0.1622837	-1.641334	0.2373416	0.1359477
807	1	0.032791	-3.384261	0.3142708	0.0317157
808	1	0.0498567	-2.947459	0.2919747	0.047371
809	0	0.271677	-0.986131	0.2254112	0.1978686
810	1	0.271677	-0.986131	0.2254112	0.1978686
811	1	0.3178975	-0.763451	0.2230543	0.2168387
812	0	0.7443664	1.068788	0.2387931	0.1902851
813	0	0.5486418	0.1951846	0.2081855	0.247634
814	1	0.2295381	-1.210921	0.19545	0.1768504
815	1	0.208561	-1.333621	0.1999743	0.1650633
816	1	0.0122339	-4.391233	0.3345202	0.0120843

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Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
817	1	0.23067	-1.204532	0.2282886	0.1774614
818	1	0.0355977	-3.299229	0.2723728	0.0343305
819	1	0.1110317	-2.080245	0.2243921	0.0987037
820	1	0.1938722	-1.425043	0.2053236	0.1562858
821	1	0.1344882	-1.861845	0.2169923	0.1164011
822	0	0.4703058	-0.118917	0.1994384	0.2491183
823	0	0.5248505	0.099484	0.2041938	0.2493825
824	1	0.1454897	-1.770423	0.209393	0.1243225
825	1	0.0232931	-3.736031	0.2960899	0.0227505
826	1	0.0912351	-2.298646	0.2327075	0.0829113
827	1	0.1462859	-1.764034	0.2359521	0.1248863
828	0	0.6529397	0.6319863	0.2216124	0.2266094
829	0	0.3155887	-0.774119	0.1929411	0.2159925
830	1	0.0324543	-3.394929	0.2741558	0.031401
831	1	0.0912351	-2.298646	0.2327075	0.0829113
832	0	0.6811291	0.7589656	0.222726	0.2171922
833	1	0.2704146	-0.99252	0.1935099	0.1972905
834	0	0.4164612	-0.337318	0.1959364	0.2430213
835	0	0.3366143	-0.678419	0.1954922	0.2233051
836	1	0.2314303	-1.200253	0.2292901	0.1778703
837	0	0.3670136	-0.54505	0.2216869	0.2323146
838	1	0.0996755	-2.200835	0.2505395	0.0897403
839	1	0.05437	-2.856038	0.2782554	0.0514139
840	0	0.2314303	-1.200253	0.2292901	0.1778703
841	1	0.1112402	-2.078135	0.250371	0.0988658

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
842	0	0.4729643	-0.108249	0.2225605	0.2492691
843	1	0.0404709	-3.16586	0.3028866	0.038833
844	1	0.0996755	-2.200835	0.2505395	0.0897403
845	0	0.1948727	-1.418654	0.2340652	0.1568974
846	0	0.6034772	0.4199747	0.2286454	0.2392925
847	1	0.5814073	0.3285531	0.2281678	0.2433729
848	0	0.5803655	0.3242741	0.232827	0.2435414
849	0	0.8881002	2.0714808	0.2978065	0.0993782
850	1	0.1462859	-1.764034	0.2359521	0.1248863
851	1	0.3884984	-0.453629	0.217299	0.2375674
852	0	0.5803655	0.3242741	0.232827	0.2435414
853	1	0.271677	-0.986131	0.2254112	0.1978686
854	1	0.0746717	-2.517047	0.2418441	0.0690959
855	1	0.0912351	-2.298646	0.2327075	0.0829113
856	1	0.1339909	-1.866124	0.2089818	0.1160373
857	1	0.4164612	-0.337318	0.1959364	0.2430213
858	1	0.0812394	-2.425625	0.2316033	0.0746395
859	1	0.043905	-3.080828	0.2612432	0.0419774
860	1	0.0748177	-2.514937	0.2667949	0.06922
861	0	0.7019867	0.8567764	0.2408682	0.2092014
862	1	0.1352337	-1.855455	0.2466092	0.1169455
863	0	0.3645387	-0.555719	0.1937556	0.2316502
864	0	0.36602	-0.549329	0.2231675	0.2320494
865	1	0.680199	0.7546865	0.2250828	0.2175283
866	1	0.2704146	-0.99252	0.1935099	0.1972905

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Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
867	0	0.8044225	1.4141681	0.2495404	0.1573269
868	0	0.6529397	0.6319863	0.2216124	0.2266094
869	1	0.3155887	-0.7741119	0.1929411	0.2159925
870	1	0.161997	-1.643444	0.2106046	0.135754
871	1	0.2480889	-1.108831	0.2214486	0.1865408
872	0	0.1747944	-1.552022	0.2040837	0.1442413
873	1	0.3165136	-0.76984	0.1969188	0.2163328
874	1	0.3165136	-0.76984	0.1969188	0.2163328
875	1	0.3366143	-0.678419	0.1954922	0.2233051
876	1	0.208561	-1.333621	0.1999743	0.1650633
877	0	0.5259175	0.103763	0.2043444	0.2493283
878	0	0.3645387	-0.555719	0.1937556	0.2316502
879	1	0.2897045	-0.89682	0.1956354	0.2057758
880	0	0.7257344	0.9730873	0.233925	0.199044
881	0	0.7006484	0.8503872	0.2297818	0.2097402
882	1	0.2897045	-0.89682	0.1956354	0.2057758
883	1	0.1747944	-1.552022	0.2040837	0.1442413
884	0	0.2712596	-0.988241	0.1984165	0.1976778
885	1	0.0402235	-3.17225	0.2733217	0.0386056
886	1	0.2295381	-1.210921	0.19545	0.1768504
887	1	0.0402235	-3.17225	0.2733217	0.0386056
888	0	0.6019473	0.4135855	0.214381	0.2396067
889	1	0.3655305	-0.551439	0.1967732	0.231918
890	1	0.4164612	-0.337318	0.1959364	0.2430213
891	0	0.4703058	-0.118917	0.1994384	0.2491183

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Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
892	1	0.1938722	-1.425043	0.2053236	0.1562858
893	0	0.5248505	0.099484	0.2041938	0.2493825
894	0	0.1339909	-1.866124	0.2089818	0.1160373
895	1	0.161997	-1.643444	0.2106046	0.135754
896	1	0.6319438	0.5405647	0.215535	0.2325908
897	1	0.0326555	-3.38854	0.3075466	0.0315892
898	1	0.3366143	-0.678419	0.1954922	0.2233051
899	0	0.3155887	-0.774119	0.1929411	0.2159925
900	1	0.5788087	0.3178848	0.2101174	0.2437892
901	1	0.208561	-1.333621	0.1999743	0.1650633
902	1	0.2897045	-0.89682	0.1956354	0.2057758
903	0	0.6529397	0.6319863	0.2216124	0.2266094
904	1	0.090881	-2.302925	0.2235977	0.0826216
905	0	0.7278528	0.9837556	0.2446685	0.1980831
906	0	0.2725245	-0.981852	0.2256018	0.1982549
907	1	0.4703058	-0.118917	0.1994384	0.2491183
908	1	0.1757179	-1.545633	0.2300593	0.1448411
909	1	0.0914103	-2.296536	0.258196	0.0830544
910	1	0.0751144	-2.510658	0.2717932	0.0694722
911	0	0.3155887	-0.774119	0.1929411	0.2159925
912	0	0.5275103	0.1101523	0.2247876	0.2492432
913	1	0.1112402	-2.078135	0.250371	0.0988658
914	1	0.8047543	1.4162783	0.2678573	0.1571248
915	0	0.6543862	0.6383756	0.2342663	0.2261649
916	1	0.0917663	-2.292257	0.2626498	0.0833452

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=HBA_BL7 Parameter=HbA1c <7.0% Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
917	0	0.8054258	1.4205573	0.2602655	0.1567151
918	1	0.2897045	-0.89682	0.1956354	0.2057758
919	1	0.1203814	-1.988824	0.2158136	0.1058897
920	0	0.8193543	1.5119789	0.2657757	0.1480128
921	1	0.2712596	-0.988241	0.1984165	0.1976778
922	1	0.1462859	-1.764034	0.2359521	0.1248863
923	0	0.5486418	0.1951846	0.2081855	0.247634
924	0	0.1932044	-1.429322	0.1987212	0.1558764
925	0	0.8193543	1.5119789	0.2657757	0.1480128
926	1	0.1106101	-2.084524	0.2157945	0.0983755
927	1	0.1110317	-2.080245	0.2243921	0.0987037
928	1	0.36602	-0.549329	0.2231675	0.2320494
929	1	0.0991036	-2.207225	0.2232496	0.0892821
930	0	0.6543862	0.6383756	0.2342663	0.2261649
931	1	0.5264436	0.1058732	0.2287029	0.2493007
932	1	0.3645387	-0.555719	0.1937556	0.2316502
933	1	0.0265282	-3.602662	0.3260779	0.0258244
934	1	0.044174	-3.074439	0.2887578	0.0422227
935	1	0.3884984	-0.453629	0.217299	0.2375674
936	1	0.1938722	-1.425043	0.2053236	0.1562858
937	1	0.2480889	-1.108831	0.2214486	0.1865408
938	1	0.5264436	0.1058732	0.2287029	0.2493007
939	1	0.0606695	-2.739727	0.2417803	0.0569887
940	1	0.0812394	-2.425625	0.2316033	0.0746395
941	0	0.2314303	-1.200253	0.2292901	0.1778703

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Parameter Code=HBA_BL7 Parameter=HbA1c <7.0% Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
942	0	0.0663582	-2.644026	0.2407791	0.0619547
943	1	0.090881	-2.302925	0.2235977	0.0826216
944	1	0.208561	-1.333621	0.1999743	0.1650633
945	1	0.7006484	0.8503872	0.2297818	0.2097402
946	1	0.0817176	-2.419236	0.2590764	0.0750398
947	1	0.1106101	-2.084524	0.2157945	0.0983755
948	1	0.3155887	-0.774119	0.1929411	0.2159925
949	1	0.5248505	0.099484	0.2041938	0.2493825
950	0	0.1948727	-1.418654	0.2340652	0.1568974
951	1	0.1203814	-1.988824	0.2158136	0.1058897
952	1	0.0996755	-2.200835	0.2505395	0.0897403
953	1	0.3165136	-0.76984	0.1969188	0.2163328
954	0	0.6319438	0.5405647	0.215535	0.2325908
955	1	0.090881	-2.302925	0.2235977	0.0826216
956	0	0.2897045	-0.89682	0.1956354	0.2057758
957	1	0.6034772	0.4199747	0.2286454	0.2392925
958	1	0.0663582	-2.644026	0.2407791	0.0619547
959	0	0.5248505	0.099484	0.2041938	0.2493825
960	0	0.1106101	-2.084524	0.2157945	0.0983755
961	0	0.2468989	-1.11522	0.1971397	0.1859398
962	1	0.4957934	-0.016827	0.2206336	0.2499823
963	1	0.0663582	-2.644026	0.2407791	0.0619547
964	1	0.3165136	-0.76984	0.1969188	0.2163328
965	1	0.1757179	-1.545633	0.2300593	0.1448411
966	0	0.6811291	0.7589656	0.222726	0.2171922

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=HBA_BL7 Parameter=HbA1c <7.0% Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
967	1	0.043905	-3.080828	0.2612432	0.0419774
968	1	0.0991036	-2.207225	0.2232496	0.0892821
969	1	0.043905	-3.080828	0.2612432	0.0419774
970	1	0.0263637	-3.609051	0.2969673	0.0256686
971	0	0.6825152	0.7653548	0.2381747	0.2166882
972	1	0.090881	-2.302925	0.2235977	0.0826216
973	1	0.0748177	-2.514937	0.2667949	0.06922
974	1	0.0404709	-3.16586	0.3028866	0.038833
975	0	0.4180147	-0.330928	0.2238363	0.2432784
976	1	0.044174	-3.074439	0.2887578	0.0422227
977	0	0.9078592	2.2877715	0.2943508	0.0836509
978	0	0.4190561	-0.326649	0.2215214	0.2434481
979	1	0.0151747	-4.172832	0.3213888	0.0149445
980	1	0.1352337	-1.855455	0.2466092	0.1169455
981	1	0.3380426	-0.672029	0.2174648	0.2237698
982	0	0.8193543	1.5119789	0.2657757	0.1480128
983	1	0.2302957	-1.206642	0.2012363	0.1772596
984	1	0.5486418	0.1951846	0.2081855	0.247634
985	1	0.3655305	-0.551439	0.1967732	0.231918
986	0	0.3169703	-0.76773	0.2236953	0.2165001
987	1	0.3645387	-0.555719	0.1937556	0.2316502
988	1	0.5259175	0.103763	0.2043444	0.2493283
989	1	0.161997	-1.643444	0.2106046	0.135754
990	1	0.1454897	-1.770423	0.209393	0.1243225
991	1	0.161997	-1.643444	0.2106046	0.135754

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=HBA_BL7 Parameter=HbA1c <7.0% Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
992	0	0.6319438	0.5405647	0.215535	0.2325908
993	1	0.5248505	0.099484	0.2041938	0.2493825
994	1	0.017194	-4.045853	0.3222013	0.0168983
995	1	0.2704146	-0.99252	0.1935099	0.1972905
996	1	0.0493538	-2.958128	0.2519738	0.046918
997	1	0.1110317	-2.080245	0.2243921	0.0987037
998	1	0.6543862	0.6383756	0.2342663	0.2261649
999	1	0.0912351	-2.298646	0.2327075	0.0829113
1000	1	0.7443664	1.068788	0.2387931	0.1902851
1001	0	0.4957934	-0.016827	0.2206336	0.2499823
1002	1	0.0748177	-2.514937	0.2667949	0.06922
1003	1	0.5259175	0.103763	0.2043444	0.2493283
1004	1	0.2295381	-1.210921	0.19545	0.1768504
1005	0	0.7677709	1.1957672	0.2398216	0.1782987
1006	1	0.3366143	-0.678419	0.1954922	0.2233051
1007	1	0.043905	-3.080828	0.2612432	0.0419774
1008	1	0.1938722	-1.425043	0.2053236	0.1562858
1009	1	0.5259175	0.103763	0.2043444	0.2493283
1010	1	0.0400586	-3.176529	0.2627902	0.0384539
1011	1	0.208561	-1.333621	0.1999743	0.1650633
1012	1	0.5486418	0.1951846	0.2081855	0.247634
1013	1	0.1203814	-1.988824	0.2158136	0.1058897
1014	1	0.5248505	0.099484	0.2041938	0.2493825
1015	1	0.6019473	0.4135855	0.214381	0.2396067
1016	1	0.1932044	-1.429322	0.1987212	0.1558764

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=HBA_BL7 Parameter=HbA1c <7.0% Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
1017	1	0.3645387	-0.555719	0.1937556	0.2316502
1018	1	0.4175015	-0.333039	0.1979828	0.243194
1019	0	0.7455802	1.0751773	0.2483729	0.1896903
1020	1	0.3869816	-0.460018	0.1967129	0.2372268
1021	1	0.1339909	-1.866124	0.2089818	0.1160373
1022	1	0.6019473	0.4135855	0.214381	0.2396067
1023	0	0.6319438	0.5405647	0.215535	0.2325908
1024	0	0.3655305	-0.551439	0.1967732	0.231918
1025	1	0.0609138	-2.735448	0.2517124	0.0572033

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Parameter Code=HBA70 Parameter=HbA1c <7.0% without severe hypo and with minimal weight gain Study Identifier=NN1218-4131

The GENMOD Procedure

```

Model Information

Data Set          WORK.ENDPOINT
Distribution       Binomial
Link Function     Logit
Dependent Variable      aval

Number of Observations Read      1025
Number of Observations Used      1025
Number of Events                  183
Number of Trials                  1025

```

```

Class Level Information

Class      Levels  Values
TRTPN      3       2 3 4
REGION1    4       ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1     2       BOLUS INSULIN ALGORITHM (SLIDING SCALE)
                        CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN
                        THERAPY

```

```

Response Profile

Ordered      Total
Value      aval  Frequency
1          0       183
2          1       842

```

PROC GENMOD is modeling the probability that aval='0'. One way to change this to model the probability that aval='1' is to

```

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=HBA70 Parameter=HbA1c <7.0% without severe hypo and with minimal weight gain Study Identifier=NN1218-4131

The GENMOD Procedure

specify the DESCENDING option in the PROC statement.

Parameter Information

Parameter	Effect	TRTPN	REGION1	BOLAD1
Prm1	Intercept			
Prm2	TRTPN	2		
Prm3	TRTPN	3		
Prm4	TRTPN	4		
Prm5	REGION1		ASIA (EXCLUDING JAPAN)	
Prm6	REGION1		EUROPE	
Prm7	REGION1		JAPAN	
Prm8	REGION1		NORTH AMERICA	
Prm9	BOLAD1			BOLUS INSULIN ALGORITHM (SLIDING SCALE)
Prm10	BOLAD1			CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY
Prm11	HBA1CBL			

Criteria For Assessing Goodness Of Fit

Criterion	DF	Value	Value/DF
Log Likelihood		-402.1974	
Full Log Likelihood		-402.1974	
AIC (smaller is better)		820.3948	
AICC (smaller is better)		820.5365	
BIC (smaller is better)		859.8544	

Algorithm converged.

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=HBA70 Parameter=HbA1c <7.0% without severe hypo and with minimal weight gain Study Identifier=NN1218-4131

The GENMOD Procedure

Analysis Of Maximum Likelihood Parameter Estimates

Parameter		DF	Estimate	Standard Error	Wald 95% Confidence Limits		Wald Chi-Square
Intercept		1	11.9030	1.2441	9.4646	14.3414	91.54
TRTPN	2	1	-0.1403	0.2202	-0.5720	0.2913	0.41
TRTPN	3	1	-0.0523	0.2149	-0.4735	0.3688	0.06
TRTPN	4	0	0.0000	0.0000	0.0000	0.0000	.
REGION1	ASIA (EXCLUDING JAPAN)	1	-0.4537	0.3588	-1.1569	0.2495	1.60
REGION1	EUROPE	1	-0.2426	0.2312	-0.6958	0.2106	1.10
REGION1	JAPAN	1	0.0871	0.2459	-0.3949	0.5691	0.13
REGION1	NORTH AMERICA	0	0.0000	0.0000	0.0000	0.0000	.
BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	1	-0.2004	0.1976	-0.5877	0.1869	1.03
BOLAD1	CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY	0	0.0000	0.0000	0.0000	0.0000	.
HBA1CBL Scale		1	-1.8245	0.1719	-2.1613	-1.4877	112.70
		0	1.0000	0.0000	1.0000	1.0000	

Analysis Of Maximum Likelihood Parameter Estimates

Parameter		Pr > ChiSq
Intercept		<.0001
TRTPN	2	0.5240
TRTPN	3	0.8076
TRTPN	4	.
REGION1	ASIA (EXCLUDING JAPAN)	0.2060
REGION1	EUROPE	0.2941
REGION1	JAPAN	0.7232
REGION1	NORTH AMERICA	.
BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.3105
BOLAD1	CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY	.
HBA1CBL		<.0001

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Parameter Code=HBA70 Parameter=HbA1c <7.0% without severe hypo and with minimal weight gain Study Identifier=NN1218-4131
The GENMOD Procedure

Analysis Of Maximum Likelihood Parameter Estimates

Parameter Pr > ChiSq

Scale

NOTE: The scale parameter was held fixed.

Coefficients for TRTPN Least Squares Means Using WORK.ENDPOINT Margins

Parameter	Geographic Region Grouping Method 1
Intercept	
Planned Treatment (N) 2	
Planned Treatment (N) 3	
Planned Treatment (N) 4	
Geographic Region Grouping Method 1 ASIA (EXCLUDING JAPAN)	ASIA (EXCLUDING JAPAN)

Coefficients for TRTPN Least Squares Means Using WORK.ENDPOINT Margins

Bolus Adjustment Method at Timepoint 1	Planned Treatment (N)	Row		
		Row1	Row2	Row3
		1	1	1
	2	1		
	3		1	
	4			1
		0.1307	0.1307	0.1307

Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=HBA70 Parameter=HbA1c <7.0% without severe hypo and with minimal weight gain Study Identifier=NN1218-4131

The GENMOD Procedure

Coefficients for TRTPN Least Squares Means Using WORK.ENDPOINT Margins

Parameter	Geographic Region Grouping Method 1
Geographic Region Grouping Method 1 EUROPE	EUROPE
Geographic Region Grouping Method 1 JAPAN	JAPAN
Geographic Region Grouping Method 1 NORTH AMERICA	NORTH AMERICA
Bolus Adjustment Method at Timepoint 1 BOLUS INSULIN ALGORITHM (SLIDING SCALE)	
Bolus Adjustment Method at Timepoint 1 CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY	
HbA1c at Baseline	

Coefficients for TRTPN Least Squares Means Using WORK.ENDPOINT Margins

	Planned Treatment (N)	Row1	Row2	Row3
Bolus Adjustment Method at Timepoint 1		0.3366	0.3366	0.3366
		0.239	0.239	0.239
		0.2937	0.2937	0.2937
BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.5824	0.5824	0.5824
CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0.4176	0.4176	0.4176
		7.4245	7.4245	7.4245

Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=HBA70 Parameter=HbA1c <7.0% without severe hypo and with minimal weight gain Study Identifier=NN1218-4131

The GENMOD Procedure

TRTPN Least Squares Means

Planned Treatment (N)	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
2	WORK.ENDPOINT	-2.0202	0.1736	-11.64	<.0001	0.05	-2.3604	-1.6800
3	WORK.ENDPOINT	-1.9322	0.1657	-11.66	<.0001	0.05	-2.2570	-1.6073
4	WORK.ENDPOINT	-1.8798	0.1660	-11.32	<.0001	0.05	-2.2052	-1.5545

Differences of TRTPN Least Squares Means

Planned Treatment (N)	Planned Treatment (N)	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
2	4	WORK.ENDPOINT	-0.1403	0.2202	-0.64	0.5240	0.05	-0.5720	0.2913
3	4	WORK.ENDPOINT	-0.05234	0.2149	-0.24	0.8076	0.05	-0.4735	0.3688

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) / NovoRapid (meal)	WORK.ENDPOINT	-0.1403	0.2202	-0.64	0.5240	0.05	-0.5720	0.2913

Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=HBA70 Parameter=HbA1c <7.0% without severe hypo and with minimal weight gain Study Identifier=NN1218-4131

The GENMOD Procedure

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
TRTPN	Faster aspart (post) / NovoRapid (meal)	WORK.ENDPOINT	-0.05234	0.2149	-0.24	0.8076	0.05	-0.4735	0.3688

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
1	1	0.4074833	-0.374379	0.2683126	0.2414407
2	0	0.4074833	-0.374379	0.2683126	0.2414407
3	1	0.2164243	-1.286627	0.2600044	0.1695848
4	1	0.187083	-1.469076	0.2617185	0.152083
5	1	0.187083	-1.469076	0.2617185	0.152083
6	1	0.1843661	-1.487042	0.2285833	0.1503752
7	1	0.2657724	-1.016179	0.2425458	0.1951374
8	1	0.1269248	-1.928427	0.2558144	0.1108149
9	1	0.0603003	-2.746223	0.3021542	0.0566642
10	1	0.3504855	-0.616906	0.2171098	0.2276454
11	0	0.4521644	-0.19193	0.2732063	0.2477118
12	1	0.5648742	0.2609679	0.2727297	0.2457913
13	0	0.3848931	-0.46883	0.248897	0.2367504
14	0	0.5326679	0.130858	0.2681454	0.2489328
15	1	0.0998516	-2.198875	0.279251	0.0898812
16	1	0.1552981	-1.693638	0.2572212	0.1311806

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=HBA70 Parameter=HbA1c <7.0% without severe hypo and with minimal weight gain Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
17	1	0.158492	-1.669492	0.2317708	0.1333723
18	1	0.106325	-2.128842	0.2375146	0.09502
19	1	0.2064097	-1.346704	0.2171021	0.1638048
20	1	0.081403	-2.423436	0.2835621	0.0747765
21	1	0.0172705	-4.041336	0.355739	0.0169722
22	1	0.081403	-2.423436	0.2835621	0.0747765
23	1	0.3427012	-0.65128	0.2455984	0.2252571
24	1	0.1249473	-1.946392	0.2309461	0.1093354
25	1	0.0654839	-2.658225	0.285244	0.0611957
26	1	0.1269248	-1.928427	0.2558144	0.1108149
27	1	0.077574	-2.475775	0.2765814	0.0715562
28	1	0.2622814	-1.034145	0.2163603	0.1934899
29	1	0.0603003	-2.746223	0.3021542	0.0566642
30	1	0.1529559	-1.711603	0.2251134	0.1295604
31	1	0.4244953	-0.304346	0.2285288	0.244299
32	1	0.0603003	-2.746223	0.3021542	0.0566642
33	1	0.1269248	-1.928427	0.2558144	0.1108149
34	0	0.1529559	-1.711603	0.2251134	0.1295604
35	1	0.2317193	-1.198629	0.2428364	0.1780255
36	0	0.4417553	-0.234041	0.2569597	0.2466076
37	1	0.2411676	-1.146289	0.2483584	0.1830058
38	1	0.1485553	-1.745977	0.2508726	0.1264866
39	0	0.3848931	-0.46883	0.248897	0.2367504
40	1	0.1080442	-2.110876	0.2617932	0.0963706
41	0	0.3427012	-0.65128	0.2455984	0.2252571

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=HBA70 Parameter=HbA1c <7.0% without severe hypo and with minimal weight gain Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
42	0	0.3386658	-0.669246	0.2198571	0.2239713
43	1	0.4244953	-0.304346	0.2285288	0.244299
44	0	0.3101634	-0.799355	0.2150575	0.2139621
45	1	0.2133931	-1.304593	0.2266575	0.1678565
46	1	0.0982484	-2.21684	0.2483229	0.0885956
47	0	0.5835718	0.3374535	0.2647005	0.2430158
48	0	0.2622814	-1.034145	0.2163603	0.1934899
49	1	0.0800696	-2.441401	0.254657	0.0736585
50	0	0.5386736	0.1550039	0.2561766	0.2485044
51	0	0.5835718	0.3374535	0.2647005	0.2430158
52	1	0.2622814	-1.034145	0.2163603	0.1934899
53	0	0.3806486	-0.486796	0.2235753	0.2357553
54	1	0.1781175	-1.529154	0.2204752	0.1463917
55	1	0.106325	-2.128842	0.2375146	0.09502
56	0	0.1843661	-1.487042	0.2285833	0.1503752
57	1	0.0901921	-2.311292	0.2451142	0.0820575
58	1	0.0592903	-2.764189	0.2737287	0.055775
59	1	0.1307831	-1.894053	0.2309404	0.1136789
60	0	0.0382894	-3.223539	0.2954332	0.0368234
61	0	0.5733034	0.2953419	0.2458296	0.2446266
62	1	0.0832269	-2.39929	0.2559191	0.0763002
63	1	0.1249473	-1.946392	0.2309461	0.1093354
64	1	0.5281932	0.1128923	0.23789	0.2492051
65	0	0.4244953	-0.304346	0.2285288	0.244299
66	1	0.4244953	-0.304346	0.2285288	0.244299

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
67	1	0.1705841	-1.581493	0.2212559	0.1414852
68	1	0.4244953	-0.304346	0.2285288	0.244299
69	1	0.2809623	-0.939693	0.2266991	0.2020225
70	1	0.0144318	-4.223785	0.3691718	0.0142235
71	1	0.319245	-0.757244	0.2286657	0.2173276
72	1	0.2725338	-0.981805	0.2143678	0.1982591
73	0	0.2990774	-0.851695	0.2174376	0.2096301
74	1	0.3101634	-0.799355	0.2150575	0.2139621
75	0	0.1843661	-1.487042	0.2285833	0.1503752
76	0	0.2064097	-1.346704	0.2171021	0.1638048
77	1	0.2990774	-0.851695	0.2174376	0.2096301
78	1	0.4373296	-0.252007	0.2251281	0.2460724
79	1	0.0351775	-3.311538	0.3057893	0.03394
80	0	0.493139	-0.027446	0.2485504	0.2499529
81	1	0.0337759	-3.353649	0.3096115	0.0326351
82	1	0.1356451	-1.851941	0.2361691	0.1172455
83	1	0.4373296	-0.252007	0.2251281	0.2460724
84	1	0.3504855	-0.616906	0.2171098	0.2276454
85	0	0.1356451	-1.851941	0.2361691	0.1172455
86	1	0.0382894	-3.223539	0.2954332	0.0368234
87	1	0.0982484	-2.21684	0.2483229	0.0885956
88	1	0.2990774	-0.851695	0.2174376	0.2096301
89	0	0.6172262	0.4777915	0.2546831	0.236258
90	0	0.3806486	-0.486796	0.2235753	0.2357553
91	1	0.1307831	-1.894053	0.2309404	0.1136789

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
92	1	0.2064097	-1.346704	0.2171021	0.1638048
93	1	0.1781175	-1.529154	0.2204752	0.1463917
94	1	0.1529559	-1.711603	0.2251134	0.1295604
95	0	0.319245	-0.757244	0.2286657	0.2173276
96	0	0.2064097	-1.346704	0.2171021	0.1638048
97	1	0.3386658	-0.669246	0.2198571	0.2239713
98	1	0.1552981	-1.693638	0.2572212	0.1311806
99	1	0.2133931	-1.304593	0.2266575	0.1678565
100	1	0.2008359	-1.381078	0.2443385	0.1605008
101	1	0.6990316	0.8426906	0.2747695	0.2103864
102	1	0.284606	-0.921728	0.2599728	0.2036054
103	1	0.1269248	-1.928427	0.2558144	0.1108149
104	0	0.3930627	-0.434456	0.2204865	0.2385644
105	1	0.1131926	-2.058537	0.2685213	0.1003801
106	1	0.2093681	-1.328738	0.2501695	0.1655331
107	1	0.1781175	-1.529154	0.2204752	0.1463917
108	1	0.0901921	-2.311292	0.2451142	0.0820575
109	1	0.3806486	-0.486796	0.2235753	0.2357553
110	0	0.187083	-1.469076	0.2617185	0.152083
111	0	0.5776924	0.3133075	0.2751816	0.2439639
112	0	0.5326679	0.130858	0.2681454	0.2489328
113	1	0.3973568	-0.416491	0.2529379	0.2394644
114	0	0.2093681	-1.328738	0.2501695	0.1655331
115	1	0.0715066	-2.563774	0.2937137	0.0663934
116	1	0.1269248	-1.928427	0.2558144	0.1108149

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
117	1	0.1552981	-1.693638	0.2572212	0.1311806
118	1	0.0507542	-2.928673	0.3113155	0.0481782
119	1	0.3545862	-0.59894	0.2500351	0.2288548
120	0	0.4521644	-0.19193	0.2732063	0.2477118
121	1	0.132839	-1.876087	0.2623697	0.1151928
122	0	0.248958	-1.104177	0.2594199	0.1869779
123	1	0.2657724	-1.016179	0.2425458	0.1951374
124	1	0.0168654	-4.065482	0.3834263	0.016581
125	0	0.1174891	-2.016425	0.2733567	0.1036854
126	1	0.0654839	-2.658225	0.285244	0.0611957
127	1	0.173141	-1.563528	0.24703	0.1431632
128	1	0.1485553	-1.745977	0.2508726	0.1264866
129	1	0.0321088	-3.405989	0.307397	0.0310778
130	1	0.0998516	-2.198875	0.279251	0.0898812
131	1	0.0100639	-4.588685	0.396907	0.0099626
132	1	0.173141	-1.563528	0.24703	0.1431632
133	1	0.0389565	-3.205574	0.3154507	0.0374389
134	1	0.1529559	-1.711603	0.2251134	0.1295604
135	1	0.2761102	-0.963839	0.2477291	0.1998733
136	1	0.2093681	-1.328738	0.2501695	0.1655331
137	1	0.5648742	0.2609679	0.2727297	0.2457913
138	1	0.1529559	-1.711603	0.2251134	0.1295604
139	1	0.2164243	-1.286627	0.2600044	0.1695848
140	1	0.2411676	-1.146289	0.2483584	0.1830058
141	0	0.2008359	-1.381078	0.2443385	0.1605008

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
142	0	0.5648742	0.2609679	0.2727297	0.2457913
143	1	0.2725338	-0.981805	0.2143678	0.1982591
144	1	0.319245	-0.757244	0.2286657	0.2173276
145	1	0.1356451	-1.851941	0.2361691	0.1172455
146	1	0.1307831	-1.894053	0.2309404	0.1136789
147	1	0.4244953	-0.304346	0.2285288	0.244299
148	1	0.0762981	-2.493741	0.2536522	0.0704767
149	1	0.2725338	-0.981805	0.2143678	0.1982591
150	1	0.1156391	-2.034391	0.241712	0.1022667
151	0	0.1462972	-1.763943	0.225499	0.1248943
152	1	0.0676191	-2.623851	0.2643304	0.0630468
153	0	0.6172262	0.4777915	0.2546831	0.236258
154	1	0.026898	-3.588438	0.3198372	0.0261745
155	1	0.1114017	-2.076502	0.237869	0.0989914
156	1	0.158492	-1.669492	0.2317708	0.1333723
157	1	0.2622814	-1.034145	0.2163603	0.1934899
158	1	0.2622814	-1.034145	0.2163603	0.1934899
159	0	0.2133931	-1.304593	0.2266575	0.1678565
160	1	0.1356451	-1.851941	0.2361691	0.1172455
161	1	0.2133931	-1.304593	0.2266575	0.1678565
162	0	0.5151336	0.0605527	0.2418194	0.249771
163	1	0.1705841	-1.581493	0.2212559	0.1414852
164	0	0.4244953	-0.304346	0.2285288	0.244299
165	1	0.3101634	-0.799355	0.2150575	0.2139621
166	1	0.0901921	-2.311292	0.2451142	0.0820575

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
167	1	0.2725338	-0.981805	0.2143678	0.1982591
168	1	0.1114017	-2.076502	0.237869	0.0989914
169	1	0.0800696	-2.441401	0.254657	0.0736585
170	1	0.158492	-1.669492	0.2317708	0.1333723
171	1	0.3806486	-0.486796	0.2235753	0.2357553
172	0	0.2809623	-0.939693	0.2266991	0.2020225
173	1	0.0419232	-3.129088	0.2944879	0.0401657
174	1	0.0337759	-3.353649	0.3096115	0.0326351
175	1	0.1529559	-1.711603	0.2251134	0.1295604
176	1	0.1307831	-1.894053	0.2309404	0.1136789
177	1	0.0901921	-2.311292	0.2451142	0.0820575
178	1	0.0246881	-3.676437	0.32992	0.0240786
179	1	0.106325	-2.128842	0.2375146	0.09502
180	1	0.2378951	-1.164255	0.2150536	0.181301
181	1	0.1843661	-1.487042	0.2285833	0.1503752
182	1	0.2725338	-0.981805	0.2143678	0.1982591
183	1	0.2622814	-1.034145	0.2163603	0.1934899
184	1	0.026898	-3.588438	0.3198372	0.0261745
185	1	0.106325	-2.128842	0.2375146	0.09502
186	1	0.1529559	-1.711603	0.2251134	0.1295604
187	1	0.0498956	-2.946639	0.2837779	0.0474061
188	1	0.245614	-1.122143	0.2260259	0.1852878
189	1	0.0542364	-2.85864	0.2731825	0.0512948
190	1	0.0832269	-2.39929	0.2559191	0.0763002
191	1	0.3973568	-0.416491	0.2529379	0.2394644

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
192	1	0.2725338	-0.981805	0.2143678	0.1982591
193	1	0.0246881	-3.676437	0.32992	0.0240786
194	1	0.5733034	0.2953419	0.2458296	0.2446266
195	1	0.064393	-2.676191	0.2630375	0.0602465
196	1	0.3545862	-0.59894	0.2500351	0.2288548
197	1	0.0236941	-3.718548	0.3352581	0.0231327
198	0	0.1307831	-1.894053	0.2309404	0.1136789
199	0	0.2133931	-1.304593	0.2266575	0.1678565
200	1	0.0283024	-3.536099	0.3222317	0.0275014
201	1	0.0498956	-2.946639	0.2837779	0.0474061
202	1	0.1529559	-1.711603	0.2251134	0.1295604
203	1	0.3386658	-0.669246	0.2198571	0.2239713
204	1	0.245614	-1.122143	0.2260259	0.1852878
205	1	0.2622814	-1.034145	0.2163603	0.1934899
206	1	0.0294838	-3.493987	0.3176189	0.0286145
207	1	0.0498956	-2.946639	0.2837779	0.0474061
208	1	0.0542364	-2.85864	0.2731825	0.0512948
209	1	0.158492	-1.669492	0.2317708	0.1333723
210	1	0.0479367	-2.98875	0.2858032	0.0456388
211	1	0.0064959	-5.030069	0.4454098	0.0064537
212	1	0.0321088	-3.405989	0.307397	0.0310778
213	1	0.1462972	-1.763943	0.225499	0.1248943
214	1	0.0916772	-2.293326	0.2687399	0.0832725
215	1	0.2990774	-0.851695	0.2174376	0.2096301
216	1	0.2164243	-1.286627	0.2600044	0.1695848

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
217	1	0.2761102	-0.963839	0.2477291	0.1998733
218	1	0.0846079	-2.381324	0.2860578	0.0774494
219	1	0.040964	-3.153234	0.3226513	0.039286
220	1	0.2093681	-1.328738	0.2501695	0.1655331
221	0	0.6172262	0.4777915	0.2546831	0.236258
222	0	0.319245	-0.757244	0.2286657	0.2173276
223	1	0.4695635	-0.121897	0.2346394	0.2490736
224	0	0.1979679	-1.399044	0.2182873	0.1587766
225	1	0.319245	-0.757244	0.2286657	0.2173276
226	0	0.319245	-0.757244	0.2286657	0.2173276
227	1	0.2622814	-1.034145	0.2163603	0.1934899
228	1	0.0479367	-2.98875	0.2858032	0.0456388
229	1	0.0165701	-4.083447	0.362353	0.0162955
230	0	0.1705841	-1.581493	0.2212559	0.1414852
231	0	0.026898	-3.588438	0.3198372	0.0261745
232	1	0.1307831	-1.894053	0.2309404	0.1136789
233	1	0.0037012	-5.595384	0.4765665	0.0036875
234	1	0.0982484	-2.21684	0.2483229	0.0885956
235	1	0.0762981	-2.493741	0.2536522	0.0704767
236	1	0.6047871	0.4254518	0.2590187	0.2390197
237	1	0.0901921	-2.311292	0.2451142	0.0820575
238	1	0.2725338	-0.981805	0.2143678	0.1982591
239	1	0.1249473	-1.946392	0.2309461	0.1093354
240	1	0.0294838	-3.493987	0.3176189	0.0286145
241	1	0.2809623	-0.939693	0.2266991	0.2020225

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
242	1	0.0246881	-3.676437	0.32992	0.0240786
243	1	0.2064097	-1.346704	0.2171021	0.1638048
244	1	0.0283024	-3.536099	0.3222317	0.0275014
245	0	0.1705841	-1.581493	0.2212559	0.1414852
246	1	0.0405173	-3.164666	0.3501693	0.0388756
247	1	0.0482358	-2.982216	0.3427027	0.0459091
248	1	0.0270695	-3.581905	0.3692996	0.0263368
249	1	0.0805522	-2.434868	0.3247607	0.0740636
250	1	0.0385308	-3.217005	0.3529951	0.0370461
251	1	0.0238458	-3.712014	0.3764079	0.0232771
252	1	0.0353999	-3.305004	0.3541905	0.0341468
253	1	0.1715105	-1.574959	0.3175716	0.1420947
254	1	0.2635476	-1.027611	0.3218182	0.1940902
255	1	0.2468267	-1.115609	0.3200967	0.1859033
256	1	0.0458889	-3.034556	0.3458371	0.0437831
257	1	0.0101292	-4.582151	0.4220718	0.0100266
258	1	0.0545725	-2.852106	0.3393992	0.0515944
259	1	0.0385308	-3.217005	0.3529951	0.0370461
260	1	0.0092247	-4.676602	0.4311491	0.0091396
261	1	0.0199482	-3.894464	0.386289	0.0195503
262	1	0.0545725	-2.852106	0.3393992	0.0515944
263	1	0.0248459	-3.669903	0.3708808	0.0242286
264	1	0.0339898	-3.347115	0.3583052	0.0328344
265	1	0.0284826	-3.529565	0.3670659	0.0276714
266	1	0.0032724	-5.71896	0.5070225	0.0032617

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
267	1	0.0067653	-4.989161	0.4547989	0.0067195
268	1	0.0339898	-3.347115	0.3583052	0.0328344
269	0	0.0421864	-3.122554	0.3468229	0.0404067
270	1	0.1471151	-1.757409	0.3180065	0.1254723
271	1	0.4947722	-0.020912	0.3505235	0.2499727
272	1	0.0458889	-3.034556	0.3458371	0.0437831
273	1	0.0647878	-2.669657	0.333723	0.0605903
274	1	0.0207884	-3.852352	0.3801178	0.0203562
275	1	0.0405173	-3.164666	0.3501693	0.0388756
276	1	0.1990074	-1.39251	0.3180662	0.1594034
277	1	0.2635476	-1.027611	0.3218182	0.1940902
278	1	0.2635476	-1.027611	0.3218182	0.1940902
279	1	0.0988288	-2.210306	0.3214394	0.0890616
280	1	0.0207884	-3.852352	0.3801178	0.0203562
281	1	0.0189503	-3.946804	0.3879713	0.0185912
282	1	0.5402969	0.1615378	0.3582388	0.2483762
283	1	0.6286517	0.5264369	0.3755582	0.2334487
284	1	0.4047261	-0.385811	0.3371975	0.2409229
285	1	0.0226573	-3.764354	0.3783604	0.022144
286	1	0.0166769	-4.076914	0.3966688	0.0163988
287	0	0.2738311	-0.975271	0.3154781	0.1988476
288	1	0.0166769	-4.076914	0.3966688	0.0163988
289	1	0.0027281	-5.901409	0.5206785	0.0027207
290	1	8.3282E-8	-16.30103	1.4309206	8.3282E-8
291	0	0.2738311	-0.975271	0.3154781	0.1988476

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
292	1	0.0385308	-3.217005	0.3529951	0.0370461
293	1	0.116309	-2.027857	0.3189089	0.1027812
294	1	0.0339898	-3.347115	0.3583052	0.0328344
295	1	0.0458889	-3.034556	0.3458371	0.0437831
296	1	0.0199482	-3.894464	0.386289	0.0195503
297	0	0.1790761	-1.52262	0.3119689	0.1470078
298	0	0.3401307	-0.662712	0.3291363	0.2244418
299	1	0.0596558	-2.757655	0.3342586	0.056097
300	1	0.0988288	-2.210306	0.3214394	0.0890616
301	1	0.3115631	-0.792822	0.3184993	0.2144916
302	1	0.0076981	-4.859051	0.4429541	0.0076389
303	1	0.0907297	-2.304758	0.3248103	0.0824978
304	1	0.0482358	-2.982216	0.3427027	0.0459091
305	1	0.0502063	-2.940105	0.3401648	0.0476856
306	1	0.0502063	-2.940105	0.3401648	0.0476856
307	1	0.1120502	-2.069968	0.3169217	0.0994949
308	1	0.012132	-4.399701	0.4109072	0.0119848
309	1	0.0296713	-3.487453	0.3622242	0.0287909
310	1	0.1853507	-1.480508	0.3168377	0.1509958
311	0	0.1990074	-1.39251	0.3180662	0.1594034
312	1	0.0482358	-2.982216	0.3427027	0.0459091
313	1	0.0680322	-2.617317	0.3299555	0.0634038
314	1	0.0132332	-4.311703	0.4086859	0.0130581
315	1	0.0988288	-2.210306	0.3214394	0.0890616
316	1	0.1120502	-2.069968	0.3169217	0.0994949

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
317	1	0.0647878	-2.669657	0.333723	0.0605903
318	1	0.0707513	-2.575206	0.3291447	0.0657455
319	1	0.0458889	-3.034556	0.3458371	0.0437831
320	1	0.012132	-4.399701	0.4109072	0.0119848
321	0	0.0680322	-2.617317	0.3299555	0.0634038
322	1	0.0907297	-2.304758	0.3248103	0.0824978
323	1	0.0596558	-2.757655	0.3342586	0.056097
324	1	0.2074821	-1.34017	0.3121984	0.1644333
325	1	0.0707513	-2.575206	0.3291447	0.0657455
326	1	0.0502063	-2.940105	0.3401648	0.0476856
327	0	0.0081084	-4.806712	0.4424493	0.0080427
328	1	0.0405173	-3.164666	0.3501693	0.0388756
329	1	0.0573368	-2.799767	0.3359502	0.0540493
330	1	0.0226573	-3.764354	0.3783604	0.022144
331	1	0.0951411	-2.252418	0.3204045	0.0860893
332	1	0.2144919	-1.298059	0.3180073	0.1684851
333	1	0.0767599	-2.487207	0.328848	0.0708678
334	1	0.0596558	-2.757655	0.3342586	0.056097
335	1	0.0023718	-6.041747	0.5232683	0.0023661
336	1	0.0482358	-2.982216	0.3427027	0.0459091
337	1	0.0482358	-2.982216	0.3427027	0.0459091
338	1	0.2144919	-1.298059	0.3180073	0.1684851
339	0	0.0573368	-2.799767	0.3359502	0.0540493
340	0	0.3004489	-0.845161	0.3250438	0.2101794
341	1	0.0707513	-2.575206	0.3291447	0.0657455

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
342	1	0.2738311	-0.975271	0.3154781	0.1988476
343	1	0.5402969	0.1615378	0.3582388	0.2483762
344	1	0.0238458	-3.712014	0.3764079	0.0232771
345	1	0.0101292	-4.582151	0.4220718	0.0100266
346	1	0.3004489	-0.845161	0.3250438	0.2101794
347	1	0.3519743	-0.610372	0.3224096	0.2280884
348	1	0.2822841	-0.93316	0.323088	0.2025998
349	1	0.0162934	-4.100569	0.3420102	0.0160279
350	0	0.2521978	-1.086925	0.2236293	0.1885941
351	1	0.0612854	-2.728971	0.2558842	0.0575295
352	0	0.2881317	-0.904475	0.226374	0.2051118
353	0	0.189721	-1.451824	0.2220631	0.153727
354	0	0.101413	-2.181622	0.2345306	0.0911284
355	1	0.3585444	-0.581688	0.2235917	0.2299903
356	0	0.1575748	-1.676385	0.2189762	0.132745
357	1	0.3724758	-0.52161	0.246621	0.2337376
358	1	0.3103441	-0.798511	0.2300492	0.2140306
359	1	0.1599743	-1.658419	0.2293763	0.1343825
360	0	0.0623271	-2.711005	0.2665008	0.0584424
361	1	0.1114853	-2.075658	0.2359403	0.0990564
362	1	0.0873758	-2.346106	0.2518239	0.0797413
363	1	0.4058201	-0.381272	0.2386225	0.2411301
364	1	0.2224564	-1.251409	0.234031	0.1729696
365	1	0.2224564	-1.251409	0.234031	0.1729696
366	1	0.1420024	-1.798757	0.2375597	0.1218377

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
367	1	0.2918307	-0.886509	0.2379386	0.2066655
368	1	0.1860369	-1.47597	0.2268468	0.1514272
369	1	0.103062	-2.163656	0.2459627	0.0924402
370	1	0.0101748	-4.577612	0.3891232	0.0100713
371	1	0.0873758	-2.346106	0.2518239	0.0797413
372	1	0.2380482	-1.16341	0.225285	0.1813812
373	1	0.0946524	-2.258108	0.2417083	0.0856933
374	1	0.4375374	-0.251162	0.246185	0.2460984
375	1	0.0623271	-2.711005	0.2665008	0.0584424
376	1	0.0676723	-2.623007	0.2563303	0.0630928
377	1	0.0402967	-3.170355	0.284709	0.0386729
378	1	0.6595042	0.6610854	0.2919401	0.2245584
379	1	0.1599743	-1.658419	0.2293763	0.1343825
380	0	0.2380482	-1.16341	0.225285	0.1813812
381	1	0.05703	-2.805456	0.2650142	0.0537776
382	1	0.1308791	-1.893208	0.2313081	0.1137497
383	0	0.4504574	-0.198823	0.2447892	0.2475455
384	1	0.1398276	-1.816723	0.2257805	0.1202758
385	1	0.3626867	-0.563722	0.2335601	0.2311451
386	1	0.1114853	-2.075658	0.2359403	0.0990564
387	0	0.0106078	-4.535501	0.3801361	0.0104953
388	0	0.0198373	-3.900154	0.3313629	0.0194438
389	1	0.0946524	-2.258108	0.2417083	0.0856933
390	0	0.1530653	-1.710759	0.2278812	0.1296363
391	1	0.0121865	-4.395163	0.3752481	0.012038

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
392	1	0.128849	-1.911174	0.2285222	0.1122469
393	0	0.5239245	0.0957711	0.2599935	0.2494276
394	1	0.101413	-2.181622	0.2345306	0.0911284
395	1	0.1632458	-1.634273	0.223269	0.1365966
396	0	0.2691526	-0.998926	0.2243875	0.1967095
397	1	0.0623271	-2.711005	0.2665008	0.0584424
398	1	0.2193644	-1.269374	0.2221839	0.1712437
399	1	0.101413	-2.181622	0.2345306	0.0911284
400	1	0.2193644	-1.269374	0.2221839	0.1712437
401	0	0.0515919	-2.91142	0.2648563	0.0489302
402	1	0.2348049	-1.181376	0.2225821	0.1796716
403	1	0.0698736	-2.588633	0.2499868	0.0649913
404	1	0.1507508	-1.728725	0.225092	0.128025
405	1	0.2881317	-0.904475	0.226374	0.2051118
406	1	0.0665476	-2.640972	0.2536801	0.062119
407	1	0.4116554	-0.357126	0.2418573	0.2421952
408	1	0.0178785	-4.006118	0.3325464	0.0175588
409	0	0.3103441	-0.798511	0.2300492	0.2140306
410	1	0.1657147	-1.616308	0.2351365	0.1382534
411	0	0.4375374	-0.251162	0.246185	0.2460984
412	1	0.2224564	-1.251409	0.234031	0.1729696
413	0	0.2065481	-1.34586	0.2248439	0.163886
414	1	0.0710503	-2.570667	0.2593155	0.0660021
415	1	0.0676723	-2.623007	0.2563303	0.0630928
416	0	0.3216561	-0.746171	0.2296752	0.2181935

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
417	0	0.6711575	0.713425	0.289289	0.2207051
418	1	0.57351	0.2961863	0.271308	0.2445963
419	1	0.2380482	-1.16341	0.225285	0.1813812
420	0	0.8061613	1.4252576	0.3301079	0.1562652
421	1	0.346598	-0.634027	0.2318098	0.2264678
422	0	0.6255118	0.5130098	0.2707437	0.2342468
423	1	0.1149361	-2.041284	0.2280253	0.1017258
424	0	0.8620317	1.8322683	0.375046	0.118933
425	1	0.101413	-2.181622	0.2345306	0.0911284
426	0	0.1756249	-1.546275	0.2229375	0.1447808
427	0	0.5019432	0.0077727	0.2574524	0.2499962
428	1	0.0433608	-3.09387	0.274612	0.0414807
429	1	0.1756249	-1.546275	0.2229375	0.1447808
430	1	0.134839	-1.858834	0.2228849	0.1166574
431	1	0.0471613	-3.005871	0.2719624	0.0449371
432	0	0.2795718	-0.946587	0.2166782	0.2014114
433	1	0.1632458	-1.634273	0.223269	0.1365966
434	1	0.2122383	-1.311486	0.2151013	0.1671932
435	0	0.4914161	-0.034339	0.2428774	0.2499263
436	0	0.1575748	-1.676385	0.2189762	0.132745
437	0	0.3724758	-0.52161	0.246621	0.2337376
438	1	0.134839	-1.858834	0.2228849	0.1166574
439	1	0.103062	-2.163656	0.2459627	0.0924402
440	0	0.1167763	-2.023318	0.2381044	0.1031396
441	1	0.2193644	-1.269374	0.2221839	0.1712437

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
442	1	0.0738804	-2.528555	0.258696	0.0684221
443	1	0.244339	-1.129036	0.215206	0.1846375
444	1	0.0416472	-3.135981	0.2798354	0.0399127
445	1	0.0623271	-2.711005	0.2665008	0.0584424
446	1	0.2224564	-1.251409	0.234031	0.1729696
447	1	0.1097181	-2.093624	0.2331718	0.0976801
448	1	0.0479753	-2.987906	0.2745004	0.0456736
449	0	0.8978005	2.1730214	0.3904256	0.0917547
450	1	0.0515919	-2.91142	0.2648563	0.0489302
451	1	0.0171539	-4.048229	0.3412913	0.0168596
452	1	0.0292872	-3.50088	0.3029924	0.0284295
453	1	0.0676723	-2.623007	0.2563303	0.0630928
454	1	0.1211903	-1.981207	0.2411862	0.1065032
455	1	0.0479753	-2.987906	0.2745004	0.0456736
456	1	0.0976394	-2.223734	0.2343162	0.0881059
457	1	0.0524781	-2.893455	0.275159	0.0497241
458	1	0.0338034	-3.352805	0.295565	0.0326608
459	1	0.0946524	-2.258108	0.2417083	0.0856933
460	1	0.5818957	0.3305602	0.260654	0.2432931
461	1	0.0495699	-2.953532	0.2691572	0.0471127
462	1	0.0310443	-3.440803	0.3054934	0.0300806
463	1	0.0423702	-3.118016	0.2882913	0.040575
464	1	0.189721	-1.451824	0.2220631	0.153727
465	1	0.2832046	-0.928621	0.2270282	0.2029997
466	1	0.2036193	-1.363825	0.2220959	0.1621585

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
467	1	0.2122383	-1.311486	0.2151013	0.1671932
468	1	0.0471613	-3.005871	0.2719624	0.0449371
469	1	0.1756249	-1.546275	0.2229375	0.1447808
470	1	0.0676723	-2.623007	0.2563303	0.0630928
471	1	0.0213804	-3.823668	0.3199541	0.0209233
472	1	0.128849	-1.911174	0.2285222	0.1122469
473	1	0.0873758	-2.346106	0.2518239	0.0797413
474	1	0.019491	-3.918119	0.3291296	0.0191111
475	1	0.1097181	-2.093624	0.2331718	0.0976801
476	1	0.101413	-2.181622	0.2345306	0.0911284
477	1	0.244339	-1.129036	0.215206	0.1846375
478	1	0.2691526	-0.998926	0.2243875	0.1967095
479	1	0.189721	-1.451824	0.2220631	0.153727
480	1	0.0396076	-3.188321	0.2822316	0.0380388
481	1	0.4014954	-0.399238	0.2289132	0.2402969
482	1	0.2348049	-1.181376	0.2225821	0.1796716
483	1	0.0332216	-3.370771	0.2931492	0.0321179
484	0	0.1507508	-1.728725	0.225092	0.128025
485	0	0.3585444	-0.581688	0.2235917	0.2299903
486	1	0.0305084	-3.458769	0.2961583	0.0295777
487	1	0.1097181	-2.093624	0.2331718	0.0976801
488	1	0.0178785	-4.006118	0.3325464	0.0175588
489	0	0.2521978	-1.086925	0.2236293	0.1885941
490	1	0.0396076	-3.188321	0.2822316	0.0380388
491	1	0.3889857	-0.451578	0.2373076	0.2376758

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
492	1	0.0698736	-2.588633	0.2499868	0.0649913
493	1	0.244339	-1.129036	0.215206	0.1846375
494	1	0.0255504	-3.641218	0.3078064	0.0248976
495	1	0.189721	-1.451824	0.2220631	0.153727
496	0	0.2122383	-1.311486	0.2151013	0.1671932
497	1	0.0931241	-2.276073	0.2389697	0.084452
498	1	0.2036193	-1.363825	0.2220959	0.1621585
499	1	0.3585444	-0.581688	0.2235917	0.2299903
500	0	0.4014954	-0.399238	0.2289132	0.2402969
501	1	0.2795718	-0.946587	0.2166782	0.2014114
502	1	0.0162934	-4.100569	0.3420102	0.0160279
503	1	0.4564415	-0.174677	0.2491846	0.2481027
504	1	0.0788175	-2.458523	0.2458347	0.0726053
505	1	0.1833318	-1.493935	0.2163659	0.1497212
506	1	0.6255118	0.5130098	0.2707437	0.2342468
507	1	0.0788175	-2.458523	0.2458347	0.0726053
508	1	0.346598	-0.634027	0.2318098	0.2264678
509	1	0.0332216	-3.370771	0.2931492	0.0321179
510	1	0.0332216	-3.370771	0.2931492	0.0321179
511	0	0.2795718	-0.946587	0.2166782	0.2014114
512	0	0.5691099	0.2782206	0.26933	0.2452238
513	1	0.0495699	-2.953532	0.2691572	0.0471127
514	1	0.0560715	-2.823422	0.262418	0.0529275
515	1	0.101413	-2.181622	0.2345306	0.0911284
516	1	0.0612854	-2.728971	0.2558842	0.0575295

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
517	1	0.0560715	-2.823422	0.262418	0.0529275
518	1	0.0471613	-3.005871	0.2719624	0.0449371
519	0	0.4460142	-0.216788	0.235372	0.2470855
520	1	0.128849	-1.911174	0.2285222	0.1122469
521	1	0.0859538	-2.364072	0.2406337	0.0785657
522	1	0.2795718	-0.946587	0.2166782	0.2014114
523	1	0.0698736	-2.588633	0.2499868	0.0649913
524	1	0.0396076	-3.188321	0.2822316	0.0380388
525	0	0.0612854	-2.728971	0.2558842	0.0575295
526	1	0.0433608	-3.09387	0.274612	0.0414807
527	1	0.0931241	-2.276073	0.2389697	0.084452
528	1	0.0433608	-3.09387	0.274612	0.0414807
529	1	0.5019432	0.0077727	0.2574524	0.2499962
530	1	0.189721	-1.451824	0.2220631	0.153727
531	1	0.4914161	-0.034339	0.2428774	0.2499263
532	1	0.101413	-2.181622	0.2345306	0.0911284
533	1	0.128849	-1.911174	0.2285222	0.1122469
534	1	0.3065121	-0.816477	0.2274805	0.2125624
535	1	0.4116554	-0.357126	0.2418573	0.2421952
536	1	0.0976394	-2.223734	0.2343162	0.0881059
537	1	0.3585444	-0.581688	0.2235917	0.2299903
538	1	0.0976394	-2.223734	0.2343162	0.0881059
539	1	0.1632458	-1.634273	0.223269	0.1365966
540	1	0.0099955	-4.595578	0.3827162	0.0098956
541	1	0.0726605	-2.546521	0.2477807	0.067381

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
542	1	0.0698736	-2.588633	0.2499868	0.0649913
543	1	0.134839	-1.858834	0.2228849	0.1166574
544	0	0.1192898	-1.999172	0.2295547	0.1050598
545	1	0.0433608	-3.09387	0.274612	0.0414807
546	1	0.0612854	-2.728971	0.2558842	0.0575295
547	1	0.2881317	-0.904475	0.226374	0.2051118
548	1	0.0560715	-2.823422	0.262418	0.0529275
549	1	0.0433608	-3.09387	0.274612	0.0414807
550	1	0.0416472	-3.135981	0.2798354	0.0399127
551	1	0.1575748	-1.676385	0.2189762	0.132745
552	1	0.0363926	-3.276319	0.2850708	0.0350682
553	1	0.0515919	-2.91142	0.2648563	0.0489302
554	1	0.0245226	-3.68333	0.3153392	0.0239213
555	1	0.0612854	-2.728971	0.2558842	0.0575295
556	1	0.101413	-2.181622	0.2345306	0.0911284
557	1	0.0069608	-4.960477	0.4116065	0.0069123
558	1	0.1632458	-1.634273	0.223269	0.1365966
559	1	0.1632458	-1.634273	0.223269	0.1365966
560	0	0.4460142	-0.216788	0.235372	0.2470855
561	1	0.0560715	-2.823422	0.262418	0.0529275
562	1	0.0292872	-3.50088	0.3029924	0.0284295
563	1	0.2152576	-1.29352	0.2256019	0.1689218
564	1	0.2036193	-1.363825	0.2220959	0.1621585
565	0	0.3177487	-0.764137	0.2194903	0.2167845
566	1	0.0305084	-3.458769	0.2961583	0.0295777

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
567	0	0.0992337	-2.205768	0.2441719	0.0893864
568	1	0.0788175	-2.458523	0.2458347	0.0726053
569	1	0.3585444	-0.581688	0.2235917	0.2299903
570	1	0.1097181	-2.093624	0.2331718	0.0976801
571	1	0.0124807	-4.371017	0.3588765	0.0123249
572	1	0.3065121	-0.816477	0.2274805	0.2125624
573	1	0.101413	-2.181622	0.2345306	0.0911284
574	1	0.0931241	-2.276073	0.2389697	0.084452
575	1	0.0931241	-2.276073	0.2389697	0.084452
576	1	0.0726605	-2.546521	0.2477807	0.067381
577	1	0.0827024	-2.406183	0.2416679	0.0758627
578	1	0.0698736	-2.588633	0.2499868	0.0649913
579	1	0.346598	-0.634027	0.2318098	0.2264678
580	1	0.3065121	-0.816477	0.2274805	0.2125624
581	1	0.0976394	-2.223734	0.2343162	0.0881059
582	1	0.1833318	-1.493935	0.2163659	0.1497212
583	1	0.1632458	-1.634273	0.223269	0.1365966
584	0	0.3506777	-0.616062	0.2342934	0.2277029
585	1	0.0992337	-2.205768	0.2441719	0.0893864
586	1	0.0992337	-2.205768	0.2441719	0.0893864
587	1	0.0084923	-4.760062	0.4032533	0.0084202
588	0	0.5064342	0.0257383	0.2675128	0.2499586
589	1	0.0623271	-2.711005	0.2665008	0.0584424
590	0	0.1530653	-1.710759	0.2278812	0.1296363
591	1	0.1599743	-1.658419	0.2293763	0.1343825

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
592	1	0.2476714	-1.111071	0.2256627	0.1863303
593	1	0.0338034	-3.352805	0.295565	0.0326608
594	1	0.0524781	-2.893455	0.275159	0.0497241
595	1	0.0801318	-2.440557	0.2485331	0.0737107
596	1	0.0623271	-2.711005	0.2665008	0.0584424
597	1	0.1211903	-1.981207	0.2411862	0.1065032
598	0	0.2918307	-0.886509	0.2379386	0.2066655
599	1	0.0217596	-3.805702	0.3286676	0.0212861
600	1	0.0992337	-2.205768	0.2441719	0.0893864
601	1	0.0479753	-2.987906	0.2745004	0.0456736
602	1	0.1924983	-1.433858	0.233954	0.1554427
603	0	0.3889857	-0.451578	0.2373076	0.2376758
604	1	0.0623271	-2.711005	0.2665008	0.0584424
605	1	0.0298023	-3.482915	0.3108758	0.0289141
606	1	0.0710503	-2.570667	0.2593155	0.0660021
607	1	0.0338034	-3.352805	0.295565	0.0326608
608	1	0.0788175	-2.458523	0.2458347	0.0726053
609	1	0.2224564	-1.251409	0.234031	0.1729696
610	0	0.3506777	-0.616062	0.2342934	0.2277029
611	1	0.0423702	-3.118016	0.2882913	0.040575
612	1	0.2727012	-0.980961	0.22703	0.1983353
613	1	0.1860369	-1.47597	0.2268468	0.1514272
614	0	0.4609022	-0.156711	0.2595997	0.2484714
615	1	0.4160133	-0.339161	0.2526095	0.2429462
616	1	0.1211903	-1.981207	0.2411862	0.1065032

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
617	0	0.3103441	-0.798511	0.2300492	0.2140306
618	0	0.1860369	-1.47597	0.2268468	0.1514272
619	1	0.1530653	-1.710759	0.2278812	0.1296363
620	1	0.2918307	-0.886509	0.2379386	0.2066655
621	1	0.0946524	-2.258108	0.2417083	0.0856933
622	1	0.0623271	-2.711005	0.2665008	0.0584424
623	1	0.0946524	-2.258108	0.2417083	0.0856933
624	1	0.0840756	-2.388217	0.2512705	0.0770069
625	1	0.3216561	-0.746171	0.2296752	0.2181935
626	1	0.1211903	-1.981207	0.2411862	0.1065032
627	1	0.1782412	-1.528309	0.2257143	0.1464713
628	0	0.1369486	-1.840869	0.2331486	0.1181937
629	1	0.0106078	-4.535501	0.3801361	0.0104953
630	0	0.4504574	-0.198823	0.2447892	0.2475455
631	1	0.3932642	-0.433612	0.2396975	0.2386075
632	1	0.0738804	-2.528555	0.258696	0.0684221
633	1	0.1860369	-1.47597	0.2268468	0.1514272
634	1	0.1114853	-2.075658	0.2359403	0.0990564
635	1	0.2832046	-0.928621	0.2270282	0.2029997
636	1	0.0441122	-3.075904	0.2845927	0.0421663
637	1	0.0738804	-2.528555	0.258696	0.0684221
638	1	0.3216561	-0.746171	0.2296752	0.2181935
639	0	0.1114853	-2.075658	0.2359403	0.0990564
640	1	0.2224564	-1.251409	0.234031	0.1729696
641	0	0.3506777	-0.616062	0.2342934	0.2277029

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
642	1	0.058907	-2.771082	0.2591798	0.055437
643	1	0.2556011	-1.068959	0.2353662	0.1902692
644	1	0.134839	-1.858834	0.2228849	0.1166574
645	1	0.103062	-2.163656	0.2459627	0.0924402
646	1	0.0788175	-2.458523	0.2458347	0.0726053
647	1	0.1924983	-1.433858	0.233954	0.1554427
648	1	0.0045971	-5.377716	0.4404821	0.004576
649	1	0.134839	-1.858834	0.2228849	0.1166574
650	1	0.0665476	-2.640972	0.2536801	0.062119
651	1	0.0249561	-3.665364	0.3229485	0.0243333
652	1	0.2727012	-0.980961	0.22703	0.1983353
653	1	0.2065481	-1.34586	0.2248439	0.163886
654	1	0.0560715	-2.823422	0.262418	0.0529275
655	1	0.1575748	-1.676385	0.2189762	0.132745
656	1	0.0665476	-2.640972	0.2536801	0.062119
657	0	0.1833318	-1.493935	0.2163659	0.1497212
658	1	0.1833318	-1.493935	0.2163659	0.1497212
659	1	0.0931241	-2.276073	0.2389697	0.084452
660	1	0.0086981	-4.735916	0.3864719	0.0086224
661	1	0.0441122	-3.075904	0.2845927	0.0421663
662	1	0.0162934	-4.100569	0.3420102	0.0160279
663	1	0.1575748	-1.676385	0.2189762	0.132745
664	1	0.0976394	-2.223734	0.2343162	0.0881059
665	0	0.1833318	-1.493935	0.2163659	0.1497212
666	1	0.0124807	-4.371017	0.3588765	0.0123249

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=HBA70 Parameter=HbA1c <7.0% without severe hypo and with minimal weight gain Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
667	1	0.1632458	-1.634273	0.223269	0.1365966
668	1	0.058907	-2.771082	0.2591798	0.055437
669	1	0.244339	-1.129036	0.215206	0.1846375
670	1	0.0042875	-5.447748	0.4509946	0.0042691
671	1	0.1114853	-2.075658	0.2359403	0.0990564
672	1	0.0073886	-4.9004	0.4077847	0.007334
673	1	0.0029806	-5.812647	0.4807165	0.0029717
674	1	0.05703	-2.805456	0.2650142	0.0537776
675	1	0.2380482	-1.16341	0.225285	0.1813812
676	1	0.0504231	-2.935566	0.2779065	0.0478807
677	1	0.2152576	-1.29352	0.2256019	0.1689218
678	1	0.0370279	-3.258354	0.2947274	0.0356568
679	1	0.0402967	-3.170355	0.284709	0.0386729
680	1	0.1860369	-1.47597	0.2268468	0.1514272
681	1	0.2380482	-1.16341	0.225285	0.1813812
682	1	0.1530653	-1.710759	0.2278812	0.1296363
683	1	0.0840756	-2.388217	0.2512705	0.0770069
684	1	0.1167763	-2.023318	0.2381044	0.1031396
685	1	0.4609022	-0.156711	0.2595997	0.2484714
686	1	0.0801318	-2.440557	0.2485331	0.0737107
687	1	0.1657147	-1.616308	0.2351365	0.1382534
688	1	0.1167763	-2.023318	0.2381044	0.1031396
689	1	0.1369486	-1.840869	0.2331486	0.1181937
690	1	0.1860369	-1.47597	0.2268468	0.1514272
691	1	0.1599743	-1.658419	0.2293763	0.1343825

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=HBA70 Parameter=HbA1c <7.0% without severe hypo and with minimal weight gain Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
692	1	0.1308791	-1.893208	0.2313081	0.1137497
693	0	0.0738804	-2.528555	0.258696	0.0684221
694	1	0.1120502	-2.069968	0.3169217	0.0994949
695	1	0.2074821	-1.34017	0.3121984	0.1644333
696	1	0.0707513	-2.575206	0.3291447	0.0657455
697	1	0.3946225	-0.427922	0.327177	0.2388956
698	1	0.0101292	-4.582151	0.4220718	0.0100266
699	1	0.0680322	-2.617317	0.3299555	0.0634038
700	0	0.136413	-1.845407	0.3172904	0.1178045
701	1	0.0458889	-3.034556	0.3458371	0.0437831
702	1	0.0166769	-4.076914	0.3966688	0.0163988
703	1	0.1790761	-1.52262	0.3119689	0.1470078
704	1	0.0545725	-2.852106	0.3393992	0.0515944
705	0	0.2738311	-0.975271	0.3154781	0.1988476
706	1	0.0573368	-2.799767	0.3359502	0.0540493
707	1	0.1069474	-2.122308	0.3216413	0.0955097
708	1	0.2468267	-1.115609	0.3200967	0.1859033
709	0	0.2738311	-0.975271	0.3154781	0.1988476
710	1	0.0323125	-3.399455	0.3608303	0.0312684
711	1	0.3206666	-0.75071	0.3269565	0.2178395
712	1	0.136413	-1.845407	0.3172904	0.1178045
713	0	0.1538043	-1.705069	0.3126854	0.1301486
714	0	0.3115631	-0.792822	0.3184993	0.2144916
715	1	0.1790761	-1.52262	0.3119689	0.1470078
716	1	0.0421864	-3.122554	0.3468229	0.0404067

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Parameter Code=HBA70 Parameter=HbA1c <7.0% without severe hypo and with minimal weight gain Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
717	1	0.0907297	-2.304758	0.3248103	0.0824978
718	1	0.0951411	-2.252418	0.3204045	0.0860893
719	0	0.1256634	-1.939859	0.319367	0.1098721
720	1	0.1538043	-1.705069	0.3126854	0.1301486
721	1	0.0166769	-4.076914	0.3966688	0.0163988
722	1	0.1069474	-2.122308	0.3216413	0.0955097
723	1	0.3004489	-0.845161	0.3250438	0.2101794
724	1	0.2296904	-1.21006	0.3194857	0.1769327
725	1	0.0392329	-3.198217	0.2841018	0.0376937
726	1	0.0419596	-3.128184	0.3067272	0.0401989
727	1	0.054615	-2.851283	0.2867215	0.0516322
728	1	0.0172858	-4.040432	0.3635863	0.016987
729	1	0.1257539	-1.939035	0.2529005	0.1099398
730	1	0.0352082	-3.310633	0.3170533	0.0339686
731	1	0.0295097	-3.493083	0.3279554	0.0286389
732	1	0.0329052	-3.380666	0.2955253	0.0318224
733	1	0.2255899	-1.233383	0.2177849	0.1746991
734	1	0.0533816	-2.875429	0.2742276	0.050532
735	1	0.078102	-2.468418	0.2452255	0.0720021
736	1	0.0085583	-4.752264	0.3954144	0.008485
737	1	0.009398	-4.657813	0.3875892	0.0093097
738	1	0.0158528	-4.12843	0.3641025	0.0156015
739	1	0.1231232	-1.963181	0.2320893	0.1079639
740	1	0.0315911	-3.422778	0.3083678	0.0305931
741	1	0.0555501	-2.833318	0.2631411	0.0524643

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
742	1	0.054615	-2.851283	0.2867215	0.0516322
743	1	0.054615	-2.851283	0.2867215	0.0516322
744	1	0.1047402	-2.145631	0.2386442	0.0937697
745	1	0.2255899	-1.233383	0.2177849	0.1746991
746	1	0.0300286	-3.475117	0.300774	0.0291269
747	0	0.0907976	-2.303934	0.2636033	0.0825534
748	1	0.6436204	0.5911125	0.269617	0.2293732
749	1	0.2135449	-1.303688	0.2493179	0.1679435
750	1	0.364491	-0.555924	0.220361	0.2316373
751	1	0.0217608	-3.805643	0.3534959	0.0212873
752	1	0.054615	-2.851283	0.2867215	0.0516322
753	1	0.0358236	-3.292668	0.2888173	0.0345403
754	1	0.0092322	-4.675779	0.4037511	0.009147
755	1	0.1610249	-1.650622	0.2157589	0.1350959
756	1	0.0507978	-2.927769	0.2666241	0.0482174
757	1	0.4077016	-0.373475	0.2257455	0.241481
758	1	0.026462	-3.605227	0.3207837	0.0257618
759	1	0.078102	-2.468418	0.2452255	0.0720021
760	1	0.0185215	-3.970126	0.3468389	0.0181785
761	0	0.2165777	-1.285723	0.2117971	0.1696718
762	0	0.1953157	-1.415833	0.2194378	0.1571675
763	1	0.1610249	-1.650622	0.2157589	0.1350959
764	1	0.084678	-2.38042	0.2388062	0.0775076
765	0	0.2955699	-0.868484	0.2185339	0.2082083
766	1	0.2224668	-1.251349	0.2476534	0.1729753

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=HBA70 Parameter=HbA1c <7.0% without severe hypo and with minimal weight gain Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
767	1	0.1442128	-1.780732	0.2266507	0.1234155
768	1	0.0230771	-3.745565	0.3199222	0.0225446
769	1	0.0251465	-3.657567	0.3132177	0.0245142
770	1	0.0751233	-2.51053	0.2547439	0.0694798
771	1	0.1378728	-1.833071	0.2197383	0.1188639
772	0	0.1442128	-1.780732	0.2266507	0.1234155
773	1	0.1378728	-1.833071	0.2197383	0.1188639
774	1	0.0358236	-3.292668	0.2888173	0.0345403
775	1	0.0888239	-2.32808	0.2462263	0.0809342
776	0	0.6315269	0.5387729	0.2680155	0.2327007
777	0	0.1494883	-1.73862	0.2213795	0.1271415
778	1	0.2491271	-1.103273	0.2118895	0.1870628
779	1	0.0329052	-3.380666	0.2955253	0.0318224
780	1	0.0392329	-3.198217	0.2841018	0.0376937
781	1	0.0648377	-2.668834	0.2781684	0.0606337
782	0	0.4077016	-0.373475	0.2257455	0.241481
783	1	0.0633889	-2.69298	0.2641065	0.0593707
784	1	0.6933172	0.8156736	0.2906844	0.2126285
785	1	0.084678	-2.38042	0.2388062	0.0775076
786	1	0.0907976	-2.303934	0.2636033	0.0825534
787	1	0.0648377	-2.668834	0.2781684	0.0606337
788	1	0.0715666	-2.56287	0.2472334	0.0664449
789	1	0.0907976	-2.303934	0.2636033	0.0825534
790	1	0.0888239	-2.32808	0.2462263	0.0809342
791	1	0.1175829	-2.015521	0.2249638	0.1037572

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
792	1	0.0392329	-3.198217	0.2841018	0.0376937
793	1	0.0751233	-2.51053	0.2547439	0.0694798
794	1	0.1231232	-1.963181	0.2320893	0.1079639
795	1	0.1231232	-1.963181	0.2320893	0.1079639
796	1	0.2672105	-1.008822	0.2175636	0.195809
797	1	0.2165777	-1.285723	0.2117971	0.1696718
798	0	0.3044127	-0.826372	0.2199818	0.2117456
799	0	0.1030675	-2.163596	0.2660165	0.0924446
800	1	0.1991386	-1.391687	0.245147	0.1594824
801	0	0.3823846	-0.479439	0.2558821	0.2361666
802	1	0.1472185	-1.756586	0.2491601	0.1255452
803	0	0.3603397	-0.57389	0.2567703	0.230495
804	0	0.7540806	1.1204955	0.3254577	0.185443
805	0	0.460917	-0.156651	0.2636421	0.2484725
806	1	0.0832959	-2.398386	0.2724408	0.0763577
807	1	0.0181977	-3.988092	0.3659707	0.0178666
808	1	0.0260031	-3.623193	0.3414305	0.0253269
809	0	0.1357512	-1.851037	0.255995	0.1173228
810	1	0.1357512	-1.851037	0.255995	0.1173228
811	1	0.1420097	-1.798697	0.2553812	0.1218429
812	0	0.5214557	0.0858754	0.2500866	0.2495397
813	0	0.3443603	-0.643923	0.223698	0.2257763
814	1	0.1610249	-1.650622	0.2157589	0.1350959
815	1	0.1277423	-1.92107	0.2256202	0.1114242
816	1	0.0112579	-4.475364	0.3734553	0.0111312

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=HBA70 Parameter=HbA1c <7.0% without severe hypo and with minimal weight gain Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
817	1	0.1157316	-2.033487	0.2604603	0.1023378
818	1	0.0275688	-3.563116	0.3074855	0.0268087
819	1	0.0751233	-2.51053	0.2547439	0.0694798
820	1	0.1231232	-1.963181	0.2320893	0.1079639
821	1	0.0888239	-2.32808	0.2462263	0.0809342
822	0	0.3233598	-0.738374	0.2162121	0.2187982
823	0	0.364491	-0.555924	0.220361	0.2316373
824	1	0.0922917	-2.285969	0.2376295	0.0837739
825	1	0.0193028	-3.928015	0.3327819	0.0189302
826	1	0.0633889	-2.69298	0.2641065	0.0593707
827	1	0.0648377	-2.668834	0.2781684	0.0606337
828	0	0.4306931	-0.279024	0.2347564	0.2451966
829	0	0.2165777	-1.285723	0.2117971	0.1696718
830	1	0.0300286	-3.475117	0.300774	0.0291269
831	1	0.0633889	-2.69298	0.2641065	0.0593707
832	0	0.465384	-0.138686	0.235583	0.2488017
833	1	0.1872206	-1.468172	0.2130953	0.152169
834	0	0.2847901	-0.920824	0.2133707	0.2036847
835	0	0.2020193	-1.373721	0.2167717	0.1612075
836	1	0.1030675	-2.163596	0.2660165	0.0924446
837	1	0.165723	-1.616248	0.2516606	0.1382589
838	1	0.045925	-3.033733	0.2960262	0.0438159
839	1	0.0270912	-3.581081	0.3277847	0.0263573
840	1	0.1030675	-2.163596	0.2660165	0.0924446
841	1	0.0593407	-2.763285	0.2880474	0.0558194

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Parameter Code=HBA70 Parameter=HbA1c <7.0% without severe hypo and with minimal weight gain Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
842	0	0.2224668	-1.251349	0.2476534	0.1729753
843	1	0.0217608	-3.805643	0.3534959	0.0212873
844	1	0.045925	-3.033733	0.2960262	0.0438159
845	0	0.0873806	-2.346046	0.2728067	0.0797452
846	0	0.3006219	-0.844338	0.2480968	0.2102484
847	1	0.291843	-0.88645	0.2483833	0.2066707
848	0	0.3194415	-0.75634	0.2531837	0.2173986
849	1	0.6689094	0.7032568	0.3086652	0.2214696
850	1	0.0648377	-2.668834	0.2781684	0.0606337
851	1	0.1716275	-1.574136	0.2465635	0.1421715
852	1	0.3194415	-0.75634	0.2531837	0.2173986
853	1	0.1357512	-1.851037	0.255995	0.1173228
854	1	0.0533816	-2.875429	0.2742276	0.050532
855	1	0.0633889	-2.69298	0.2641065	0.0593707
856	1	0.0999329	-2.19797	0.2313508	0.0899463
857	1	0.2847901	-0.920824	0.2133707	0.2036847
858	1	0.0555501	-2.833318	0.2631411	0.0524643
859	1	0.0329052	-3.380666	0.2955253	0.0318224
860	1	0.0419596	-3.128184	0.3067272	0.0401989
861	1	0.3823846	-0.479439	0.2558821	0.2361666
862	1	0.0623306	-2.710945	0.2889863	0.0584455
863	0	0.2491271	-1.103273	0.2118895	0.1870628
864	1	0.1845021	-1.486138	0.2503864	0.1504611
865	1	0.4978561	-0.008576	0.2398695	0.2499954
866	1	0.1872206	-1.468172	0.2130953	0.152169

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Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
867	0	0.6007672	0.4086629	0.2598245	0.239846
868	0	0.4306931	-0.279024	0.2347564	0.2451966
869	1	0.2165777	-1.285723	0.2117971	0.1696718
870	1	0.1047402	-2.145631	0.2386442	0.0937697
871	1	0.1070261	-2.121485	0.257735	0.0955715
872	0	0.1087552	-2.103519	0.2310644	0.0969275
873	1	0.1953157	-1.415833	0.2194378	0.1571675
874	1	0.1953157	-1.415833	0.2194378	0.1571675
875	1	0.2020193	-1.373721	0.2167717	0.1612075
876	1	0.1277423	-1.92107	0.2256202	0.1114242
877	1	0.3349158	-0.686034	0.220922	0.2227472
878	0	0.2491271	-1.103273	0.2118895	0.1870628
879	1	0.1741968	-1.556171	0.2184126	0.1438523
880	0	0.5433593	0.1738737	0.2484182	0.24812
881	0	0.4758752	-0.096574	0.241933	0.249418
882	1	0.1741968	-1.556171	0.2184126	0.1438523
883	1	0.1087552	-2.103519	0.2310644	0.0969275
884	1	0.1682218	-1.598282	0.2224104	0.1399233
885	1	0.0315911	-3.422778	0.3083678	0.0305931
886	1	0.1610249	-1.650622	0.2157589	0.1350959
887	1	0.0315911	-3.422778	0.3083678	0.0305931
888	0	0.3866364	-0.461473	0.2286489	0.2371487
889	1	0.2255899	-1.233383	0.2177849	0.1746991
890	1	0.2847901	-0.920824	0.2133707	0.2036847
891	0	0.3233598	-0.738374	0.2162121	0.2187982

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=HBA70 Parameter=HbA1c <7.0% without severe hypo and with minimal weight gain Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
892	1	0.1231232	-1.963181	0.2320893	0.1079639
893	0	0.364491	-0.555924	0.220361	0.2316373
894	1	0.0999329	-2.19797	0.2313508	0.0899463
895	1	0.1047402	-2.145631	0.2386442	0.0937697
896	1	0.4203991	-0.321135	0.2295162	0.2436637
897	1	0.0206741	-3.857982	0.3512703	0.0202467
898	1	0.2020193	-1.373721	0.2167717	0.1612075
899	1	0.2165777	-1.285723	0.2117971	0.1696718
900	1	0.4077016	-0.373475	0.2257455	0.241481
901	1	0.1277423	-1.92107	0.2256202	0.1114242
902	1	0.1741968	-1.556171	0.2184126	0.1438523
903	1	0.4306931	-0.279024	0.2347564	0.2451966
904	1	0.0715666	-2.56287	0.2472334	0.0664449
905	0	0.4160279	-0.339101	0.2582012	0.2429487
906	1	0.1211966	-1.981147	0.2601861	0.106508
907	1	0.3233598	-0.738374	0.2162121	0.2187982
908	1	0.0768182	-2.486384	0.2704382	0.0709172
909	1	0.0499385	-2.945734	0.2970372	0.0474447
910	1	0.03703	-3.258294	0.3187129	0.0356588
911	0	0.2165777	-1.285723	0.2117971	0.1696718
912	1	0.2556125	-1.068899	0.2474225	0.1902747
913	1	0.0593407	-2.763285	0.2880474	0.0558194
914	1	0.5388983	0.1559081	0.2813435	0.2484869
915	1	0.3403155	-0.661888	0.2514328	0.2245009
916	1	0.0441147	-3.075844	0.3081649	0.0421686

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=HBA70 Parameter=HbA1c <7.0% without severe hypo and with minimal weight gain Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
917	1	0.5064492	0.0257982	0.2700689	0.2499584
918	1	0.1741968	-1.556171	0.2184126	0.1438523
919	1	0.078102	-2.468418	0.2452255	0.0720021
920	0	0.5169709	0.0679097	0.2753026	0.249712
921	1	0.1682218	-1.598282	0.2224104	0.1399233
922	1	0.0648377	-2.668834	0.2781684	0.0606337
923	0	0.3443603	-0.643923	0.223698	0.2257763
924	0	0.1378728	-1.833071	0.2197383	0.1188639
925	0	0.5169709	0.0679097	0.2753026	0.249712
926	1	0.084678	-2.38042	0.2388062	0.0775076
927	1	0.0751233	-2.51053	0.2547439	0.0694798
928	1	0.1845021	-1.486138	0.2503864	0.1504611
929	1	0.0659355	-2.650868	0.2537598	0.061588
930	1	0.3403155	-0.661888	0.2514328	0.2245009
931	1	0.281145	-0.938789	0.2507264	0.2021025
932	1	0.2491271	-1.103273	0.2118895	0.1870628
933	1	0.015209	-4.170542	0.3788147	0.0149777
934	1	0.0226756	-3.763531	0.3394525	0.0221614
935	1	0.1716275	-1.574136	0.2465635	0.1421715
936	1	0.1231232	-1.963181	0.2320893	0.1079639
937	1	0.1070261	-2.121485	0.257735	0.0955715
938	1	0.281145	-0.938789	0.2507264	0.2021025
939	1	0.0507978	-2.927769	0.2666241	0.0482174
940	1	0.0555501	-2.833318	0.2631411	0.0524643
941	0	0.1030675	-2.163596	0.2660165	0.0924446

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=HBA70 Parameter=HbA1c <7.0% without severe hypo and with minimal weight gain Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
942	1	0.0467186	-3.015767	0.2732822	0.044536
943	1	0.0715666	-2.56287	0.2472334	0.0664449
944	1	0.1277423	-1.92107	0.2256202	0.1114242
945	1	0.4758752	-0.096574	0.241933	0.249418
946	1	0.0385613	-3.216182	0.306014	0.0370743
947	1	0.084678	-2.38042	0.2388062	0.0775076
948	1	0.2165777	-1.285723	0.2117971	0.1696718
949	1	0.364491	-0.555924	0.220361	0.2316373
950	0	0.0873806	-2.346046	0.2728067	0.0797452
951	1	0.078102	-2.468418	0.2452255	0.0720021
952	1	0.045925	-3.033733	0.2960262	0.0438159
953	1	0.1953157	-1.415833	0.2194378	0.1571675
954	0	0.4203991	-0.321135	0.2295162	0.2436637
955	1	0.0715666	-2.56287	0.2472334	0.0664449
956	0	0.1741968	-1.556171	0.2184126	0.1438523
957	1	0.3006219	-0.844338	0.2480968	0.2102484
958	1	0.0467186	-3.015767	0.2732822	0.044536
959	0	0.364491	-0.555924	0.220361	0.2316373
960	0	0.084678	-2.38042	0.2388062	0.0775076
961	1	0.1494883	-1.73862	0.2213795	0.1271415
962	1	0.2298361	-1.209237	0.2449313	0.1770114
963	1	0.0467186	-3.015767	0.2732822	0.044536
964	1	0.1953157	-1.415833	0.2194378	0.1571675
965	1	0.0768182	-2.486384	0.2704382	0.0709172
966	1	0.465384	-0.138686	0.235583	0.2488017

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=HBA70 Parameter=HbA1c <7.0% without severe hypo and with minimal weight gain Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
967	1	0.0329052	-3.380666	0.2955253	0.0318224
968	1	0.0659355	-2.650868	0.2537598	0.061588
969	1	0.0329052	-3.380666	0.2955253	0.0318224
970	1	0.0221466	-3.787677	0.333623	0.0216561
971	1	0.3724897	-0.52155	0.2538095	0.2337411
972	1	0.0715666	-2.56287	0.2472334	0.0664449
973	1	0.0419596	-3.128184	0.3067272	0.0401989
974	1	0.0217608	-3.805643	0.3534959	0.0212873
975	0	0.2135449	-1.303688	0.2493179	0.1679435
976	1	0.0226756	-3.763531	0.3394525	0.0221614
977	1	0.757397	1.1384611	0.3029711	0.1837468
978	1	0.1925076	-1.433798	0.2490728	0.1554484
979	1	0.0134808	-4.292914	0.3595874	0.0132991
980	1	0.0623306	-2.710945	0.2889863	0.0584455
981	1	0.1472185	-1.756586	0.2491601	0.1255452
982	0	0.5169709	0.0679097	0.2753026	0.249712
983	1	0.1442128	-1.780732	0.2266507	0.1234155
984	1	0.3443603	-0.643923	0.223698	0.2257763
985	1	0.2255899	-1.233383	0.2177849	0.1746991
986	1	0.1586126	-1.668587	0.2526223	0.1334546
987	1	0.2491271	-1.103273	0.2118895	0.1870628
988	1	0.3349158	-0.686034	0.220922	0.2227472
989	1	0.1047402	-2.145631	0.2386442	0.0937697
990	1	0.0922917	-2.285969	0.2376295	0.0837739
991	1	0.1047402	-2.145631	0.2386442	0.0937697

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=HBA70 Parameter=HbA1c <7.0% without severe hypo and with minimal weight gain Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
992	0	0.4203991	-0.321135	0.2295162	0.2436637
993	1	0.364491	-0.555924	0.220361	0.2316373
994	1	0.0154804	-4.152576	0.3603899	0.0152408
995	1	0.1872206	-1.468172	0.2130953	0.152169
996	1	0.0426877	-3.110218	0.2774105	0.0408655
997	1	0.0751233	-2.51053	0.2547439	0.0694798
998	1	0.3403155	-0.661888	0.2514328	0.2245009
999	1	0.0633889	-2.69298	0.2641065	0.0593707
1000	1	0.5214557	0.0858754	0.2500866	0.2495397
1001	1	0.2298361	-1.209237	0.2449313	0.1770114
1002	1	0.0419596	-3.128184	0.3067272	0.0401989
1003	1	0.3349158	-0.686034	0.220922	0.2227472
1004	1	0.1610249	-1.650622	0.2157589	0.1350959
1005	1	0.5563134	0.2262134	0.2508284	0.2468288
1006	1	0.2020193	-1.373721	0.2167717	0.1612075
1007	1	0.0329052	-3.380666	0.2955253	0.0318224
1008	1	0.1231232	-1.963181	0.2320893	0.1079639
1009	1	0.3349158	-0.686034	0.220922	0.2227472
1010	1	0.0358236	-3.292668	0.2888173	0.0345403
1011	1	0.1277423	-1.92107	0.2256202	0.1114242
1012	1	0.3443603	-0.643923	0.223698	0.2257763
1013	1	0.078102	-2.468418	0.2452255	0.0720021
1014	1	0.364491	-0.555924	0.220361	0.2316373
1015	1	0.3866364	-0.461473	0.2286489	0.2371487
1016	1	0.1378728	-1.833071	0.2197383	0.1188639

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=HBA70 Parameter=HbA1c <7.0% without severe hypo and with minimal weight gain Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
1017	1	0.2491271	-1.103273	0.2118895	0.1870628
1018	1	0.2590459	-1.050934	0.2174817	0.1919411
1019	1	0.4262936	-0.296989	0.2613877	0.2445674
1020	1	0.2330316	-1.191272	0.2164869	0.1787279
1021	1	0.0999329	-2.19797	0.2313508	0.0899463
1022	1	0.3866364	-0.461473	0.2286489	0.2371487
1023	0	0.4203991	-0.321135	0.2295162	0.2436637
1024	0	0.2255899	-1.233383	0.2177849	0.1746991
1025	1	0.0448785	-3.057879	0.2850264	0.0428645

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Parameter Code=HBAB7SHY Parameter=HbA1c <7.0% without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Model Information

Data Set	WORK.ENDPOINT
Distribution	Binomial
Link Function	Logit
Dependent Variable	aval

Number of Observations Read	1025
Number of Observations Used	1025
Number of Events	279
Number of Trials	1025

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Response Profile

Ordered Value	aval	Total Frequency
1	0	279
2	1	746

PROC GENMOD is modeling the probability that aval='0'. One way to change this to model the probability that aval='1' is to

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Parameter Code=HBAB7SHY Parameter=HbA1c <7.0% without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

specify the DESCENDING option in the PROC statement.

Parameter Information

Parameter	Effect	TRTPN	REGION1	BOLAD1
Prm1	Intercept			
Prm2	TRTPN	2		
Prm3	TRTPN	3		
Prm4	TRTPN	4		
Prm5	REGION1		ASIA (EXCLUDING JAPAN)	
Prm6	REGION1		EUROPE	
Prm7	REGION1		JAPAN	
Prm8	REGION1		NORTH AMERICA	
Prm9	BOLAD1			BOLUS INSULIN ALGORITHM (SLIDING SCALE)
Prm10	BOLAD1			CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY
Prm11	HBA1CBL			

Criteria For Assessing Goodness Of Fit

Criterion	DF	Value	Value/DF
Log Likelihood		-474.5816	
Full Log Likelihood		-474.5816	
AIC (smaller is better)		965.1633	
AICC (smaller is better)		965.3050	
BIC (smaller is better)		1004.6229	

Algorithm converged.

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Parameter Code=HBAB7SHY Parameter=HbA1c <7.0% without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Analysis Of Maximum Likelihood Parameter Estimates

Parameter		DF	Estimate	Standard Error	Wald 95% Confidence Limits		Wald Chi-Square
Intercept		1	14.3098	1.1898	11.9779	16.6416	144.66
TRTPN	2	1	-0.1539	0.1975	-0.5409	0.2331	0.61
TRTPN	3	1	-0.1806	0.1947	-0.5621	0.2010	0.86
TRTPN	4	0	0.0000	0.0000	0.0000	0.0000	.
REGION1	ASIA (EXCLUDING JAPAN)	1	-0.3926	0.3049	-0.9903	0.2050	1.66
REGION1	EUROPE	1	-0.5384	0.2124	-0.9546	-0.1221	6.43
REGION1	JAPAN	1	0.0464	0.2228	-0.3902	0.4831	0.04
REGION1	NORTH AMERICA	0	0.0000	0.0000	0.0000	0.0000	.
BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	1	0.1567	0.1800	-0.1961	0.5094	0.76
BOLAD1	CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY	0	0.0000	0.0000	0.0000	0.0000	.
HBA1CBL	Scale	1	-2.0770	0.1624	-2.3952	-1.7587	163.63
		0	1.0000	0.0000	1.0000	1.0000	

Analysis Of Maximum Likelihood Parameter Estimates

Parameter		Pr > ChiSq
Intercept		<.0001
TRTPN	2	0.4358
TRTPN	3	0.3537
TRTPN	4	.
REGION1	ASIA (EXCLUDING JAPAN)	0.1979
REGION1	EUROPE	0.0112
REGION1	JAPAN	0.8350
REGION1	NORTH AMERICA	.
BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.3841
BOLAD1	CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY	.
HBA1CBL		<.0001

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The GENMOD Procedure

Analysis Of Maximum Likelihood Parameter Estimates

Parameter Pr > ChiSq

Scale

NOTE: The scale parameter was held fixed.

Coefficients for TRTPN Least Squares Means Using WORK.ENDPOINT Margins

Parameter	Geographic Region Grouping Method 1
Intercept	
Planned Treatment (N) 2	
Planned Treatment (N) 3	
Planned Treatment (N) 4	
Geographic Region Grouping Method 1 ASIA (EXCLUDING JAPAN)	ASIA (EXCLUDING JAPAN)

Coefficients for TRTPN Least Squares Means Using WORK.ENDPOINT Margins

Bolus Adjustment Method at Timepoint 1	Planned Treatment (N)	Row		
		Row1	Row2	Row3
	2	1	1	1
	3	1	1	
	4			1
		0.1307	0.1307	0.1307

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Parameter Code=HBAB7SHY Parameter=HbA1c <7.0% without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Coefficients for TRTPN Least Squares Means Using WORK.ENDPOINT Margins

Parameter	Geographic Region Grouping Method 1
Geographic Region Grouping Method 1 EUROPE	EUROPE
Geographic Region Grouping Method 1 JAPAN	JAPAN
Geographic Region Grouping Method 1 NORTH AMERICA	NORTH AMERICA
Bolus Adjustment Method at Timepoint 1 BOLUS INSULIN ALGORITHM (SLIDING SCALE)	
Bolus Adjustment Method at Timepoint 1 CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY	
HbA1c at Baseline	

Coefficients for TRTPN Least Squares Means Using WORK.ENDPOINT Margins

	Planned Treatment (N)	Row1	Row2	Row3
Bolus Adjustment Method at Timepoint 1				
		0.3366	0.3366	0.3366
		0.239	0.239	0.239
		0.2937	0.2937	0.2937
BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.5824	0.5824	0.5824
CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0.4176	0.4176	0.4176
		7.4245	7.4245	7.4245

Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=HBAB7SHY Parameter=HbA1c <7.0% without severe hypoglycaemic episodes Study Identifier=NN1218-4131

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TRTPN Least Squares Means

Planned Treatment (N)	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
2	WORK.ENDPOINT	-1.3949	0.1501	-9.29	<.0001	0.05	-1.6891	-1.1006
3	WORK.ENDPOINT	-1.4215	0.1473	-9.65	<.0001	0.05	-1.7103	-1.1327
4	WORK.ENDPOINT	-1.2410	0.1438	-8.63	<.0001	0.05	-1.5228	-0.9591

Differences of TRTPN Least Squares Means

Planned Treatment (N)	Planned Treatment (N)	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
2	4	WORK.ENDPOINT	-0.1539	0.1975	-0.78	0.4358	0.05	-0.5409	0.2331
3	4	WORK.ENDPOINT	-0.1806	0.1947	-0.93	0.3537	0.05	-0.5621	0.2010

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) / NovoRapid (meal)	WORK.ENDPOINT	-0.1539	0.1975	-0.78	0.4358	0.05	-0.5409	0.2331

Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=HBAB7SHY Parameter=HbA1c <7.0% without severe hypoglycaemic episodes Study Identifier=NN1218-4131

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Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
TRTPN	Faster aspart (post) / NovoRapid (meal)	WORK.ENDPOINT	-0.1806	0.1947	-0.93	0.3537	0.05	-0.5621	0.2010

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
1	1	0.5711405	0.2865059	0.2472647	0.244939
2	0	0.5711405	0.2865059	0.2472647	0.244939
3	1	0.3203891	-0.751984	0.235819	0.2177399
4	1	0.2769418	-0.959682	0.2368261	0.200245
5	1	0.2769418	-0.959682	0.2368261	0.200245
6	1	0.3554125	-0.595331	0.2017481	0.2290945
7	0	0.3610205	-0.570938	0.2232604	0.2306847
8	1	0.1666681	-1.609428	0.2348948	0.1388898
9	1	0.0821439	-2.413569	0.2723638	0.0753962
10	1	0.596129	0.3893615	0.2019352	0.2407592
11	0	0.6210963	0.4942039	0.2526411	0.2353357
12	0	0.7074329	0.8829487	0.2540239	0.2069716
13	0	0.5130362	0.0521565	0.2301614	0.2498301
14	0	0.701783	0.8558027	0.2508531	0.2092836
15	1	0.1430146	-1.790474	0.2515218	0.1225614
16	1	0.2277293	-1.221178	0.2328146	0.1758687

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
17	1	0.3093779	-0.803029	0.2031754	0.2136632
18	1	0.1895749	-1.452775	0.2105406	0.1536362
19	1	0.3914001	-0.441431	0.1941544	0.2382061
20	1	0.1138535	-2.05197	0.2558836	0.1008909
21	1	0.029224	-3.503104	0.3110879	0.02837
22	1	0.1138535	-2.05197	0.2558836	0.1008909
23	1	0.4611928	-0.155542	0.2267244	0.248494
24	1	0.2235535	-1.245077	0.2051944	0.1735773
25	1	0.0801567	-2.44022	0.2625467	0.0737316
26	1	0.1666681	-1.609428	0.2348948	0.1388898
27	1	0.0968678	-2.232522	0.254364	0.0874844
28	1	0.4485362	-0.206587	0.1972328	0.2473515
29	1	0.0821439	-2.413569	0.2723638	0.0753962
30	0	0.2980028	-0.856827	0.1982893	0.2091971
31	0	0.6511744	0.6242055	0.2140759	0.2271463
32	1	0.0821439	-2.413569	0.2723638	0.0753962
33	1	0.1666681	-1.609428	0.2348948	0.1388898
34	0	0.2980028	-0.856827	0.1982893	0.2091971
35	1	0.314614	-0.778636	0.2232862	0.215632
36	0	0.6083559	0.4404066	0.2386717	0.238259
37	1	0.3547823	-0.598084	0.226459	0.2289118
38	1	0.1975418	-1.40173	0.2303366	0.158519
39	0	0.5130362	0.0521565	0.2301614	0.2498301
40	1	0.1397791	-1.817126	0.2404651	0.1202409
41	0	0.4611928	-0.155542	0.2267244	0.248494

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=HBAB7SHY Parameter=HbA1c <7.0% without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
42	0	0.5520135	0.2088094	0.2032488	0.2472946
43	1	0.6511744	0.6242055	0.2140759	0.2271463
44	0	0.5452914	0.1816634	0.1980314	0.2479487
45	0	0.4042871	-0.387633	0.2016224	0.240839
46	1	0.1937034	-1.426124	0.2148902	0.1561824
47	0	0.8148215	1.4816489	0.2528292	0.1508874
48	0	0.4485362	-0.206587	0.1972328	0.2473515
49	1	0.1560892	-1.687619	0.2211138	0.1317254
50	0	0.7814183	1.2739509	0.2433678	0.1708037
51	0	0.8148215	1.4816489	0.2528292	0.1508874
52	1	0.4485362	-0.206587	0.1972328	0.2473515
53	0	0.6026472	0.4165074	0.2081001	0.2394636
54	1	0.3431859	-0.649129	0.1955598	0.2254093
55	0	0.1895749	-1.452775	0.2105406	0.1536362
56	0	0.3554125	-0.595331	0.2017481	0.2290945
57	1	0.1596985	-1.660473	0.2169729	0.1341949
58	1	0.1141315	-2.049218	0.2362642	0.1011055
59	1	0.2564457	-1.064525	0.2022891	0.1906813
60	0	0.0630346	-2.698963	0.262175	0.0590612
61	0	0.8065664	1.4278516	0.2376843	0.1560171
62	1	0.1633075	-1.633822	0.221054	0.1366382
63	1	0.2235535	-1.245077	0.2051944	0.1735773
64	0	0.7720906	1.2201536	0.2286833	0.1759667
65	0	0.6511744	0.6242055	0.2140759	0.2271463
66	1	0.6511744	0.6242055	0.2140759	0.2271463

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Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
67	1	0.3037126	-0.829681	0.1980942	0.2114712
68	0	0.6511744	0.6242055	0.2140759	0.2271463
69	0	0.5069402	0.0277627	0.2052609	0.2499518
70	1	0.023874	-3.710802	0.3236285	0.023304
71	0	0.5585947	0.2354607	0.2089573	0.2465667
72	0	0.4934917	-0.026035	0.195403	0.2499576
73	0	0.5002778	0.0011114	0.1996041	0.2499999
74	1	0.5452914	0.1816634	0.1980314	0.2479487
75	0	0.3554125	-0.595331	0.2017481	0.2290945
76	0	0.3914001	-0.441431	0.1941544	0.2382061
77	0	0.5002778	0.0011114	0.1996041	0.2499999
78	1	0.6909912	0.8047575	0.213266	0.2135223
79	1	0.0646271	-2.672312	0.2649703	0.0604504
80	0	0.7438837	1.0662529	0.2346495	0.1905208
81	1	0.0614502	-2.726109	0.2696679	0.0576741
82	1	0.2668375	-1.010727	0.2058774	0.1956353
83	0	0.6909912	0.8047575	0.213266	0.2135223
84	1	0.596129	0.3893615	0.2019352	0.2407592
85	0	0.2668375	-1.010727	0.2058774	0.1956353
86	1	0.0630346	-2.698963	0.262175	0.0590612
87	1	0.1937034	-1.426124	0.2148902	0.1561824
88	0	0.5002778	0.0011114	0.1996041	0.2499999
89	0	0.8369285	1.6355497	0.2474244	0.1364792
90	0	0.6026472	0.4165074	0.2081001	0.2394636
91	1	0.2564457	-1.064525	0.2022891	0.1906813

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
92	1	0.3914001	-0.441431	0.1941544	0.2382061
93	1	0.3431859	-0.649129	0.1955598	0.2254093
94	1	0.2980028	-0.856827	0.1982893	0.2091971
95	0	0.5585947	0.2354607	0.2089573	0.2465667
96	0	0.3914001	-0.441431	0.1941544	0.2382061
97	1	0.5520135	0.2088094	0.2032488	0.2472946
98	1	0.2277293	-1.221178	0.2328146	0.1758687
99	1	0.4042871	-0.387633	0.2016224	0.240839
100	1	0.2716369	-0.986334	0.2244895	0.1978503
101	0	0.8860431	2.0509457	0.2687949	0.1009707
102	1	0.4166385	-0.336588	0.2371508	0.2430509
103	1	0.1666681	-1.609428	0.2348948	0.1388898
104	0	0.6449833	0.5970595	0.2070422	0.2289798
105	1	0.1629318	-1.636574	0.2424561	0.136385
106	1	0.3087901	-0.805782	0.227441	0.2134388
107	0	0.3431859	-0.649129	0.1955598	0.2254093
108	0	0.1596985	-1.660473	0.2169729	0.1341949
109	0	0.6026472	0.4165074	0.2081001	0.2394636
110	0	0.2769418	-0.959682	0.2368261	0.200245
111	0	0.743359	1.0635007	0.258263	0.1907764
112	0	0.701783	0.8558027	0.2508531	0.2092836
113	0	0.557916	0.2327086	0.2340375	0.2466457
114	0	0.3087901	-0.805782	0.227441	0.2134388
115	0	0.0992246	-2.205871	0.2646037	0.089379
116	1	0.1666681	-1.609428	0.2348948	0.1388898

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
117	0	0.2277293	-1.221178	0.2328146	0.1758687
118	1	0.0677822	-2.621267	0.280849	0.0631878
119	0	0.5062523	0.0250106	0.2304564	0.2499609
120	0	0.6210963	0.4942039	0.2526411	0.2353357
121	1	0.1932739	-1.428876	0.237129	0.1559191
122	0	0.3671911	-0.544286	0.2359278	0.2323618
123	1	0.3610205	-0.570938	0.2232604	0.2306847
124	1	0.0194312	-3.921252	0.3488378	0.0190536
125	0	0.1704026	-1.582776	0.2463293	0.1413656
126	1	0.0801567	-2.44022	0.2625467	0.0737316
127	0	0.2325386	-1.194032	0.2268515	0.1784644
128	1	0.1975418	-1.40173	0.2303366	0.158519
129	1	0.0518253	-2.906661	0.2732202	0.0491394
130	1	0.1430146	-1.790474	0.2515218	0.1225614
131	1	0.0158877	-4.126198	0.3496238	0.0156352
132	1	0.2325386	-1.194032	0.2268515	0.1784644
133	1	0.0446461	-3.063314	0.2911761	0.0426529
134	1	0.2980028	-0.856827	0.1982893	0.2091971
135	1	0.4036245	-0.390385	0.226639	0.2407118
136	1	0.3087901	-0.805782	0.227441	0.2134388
137	1	0.7074329	0.8829487	0.2540239	0.2069716
138	1	0.2980028	-0.856827	0.1982893	0.2091971
139	1	0.3203891	-0.751984	0.235819	0.2177399
140	1	0.3547823	-0.598084	0.226459	0.2289118
141	0	0.2716369	-0.986334	0.2244895	0.1978503

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
142	0	0.7074329	0.8829487	0.2540239	0.2069716
143	1	0.4934917	-0.026035	0.195403	0.2499576
144	1	0.5585947	0.2354607	0.2089573	0.2465667
145	1	0.2668375	-1.010727	0.2058774	0.1956353
146	1	0.2564457	-1.064525	0.2022891	0.1906813
147	1	0.6511744	0.6242055	0.2140759	0.2271463
148	1	0.1337535	-1.868171	0.2243978	0.1158635
149	1	0.4934917	-0.026035	0.195403	0.2499576
150	1	0.2282136	-1.218426	0.2098047	0.1761322
151	0	0.2616561	-1.037379	0.2010209	0.1931922
152	1	0.1306394	-1.895317	0.2293526	0.1135728
153	0	0.8369285	1.6355497	0.2474244	0.1364792
154	1	0.0425188	-3.114359	0.2847632	0.040711
155	1	0.218877	-1.272223	0.2074859	0.1709699
156	1	0.3093779	-0.803029	0.2031754	0.2136632
157	1	0.4485362	-0.206587	0.1972328	0.2473515
158	1	0.4485362	-0.206587	0.1972328	0.2473515
159	0	0.4042871	-0.387633	0.2016224	0.240839
160	1	0.2668375	-1.010727	0.2058774	0.1956353
161	0	0.4042871	-0.387633	0.2016224	0.240839
162	0	0.7387731	1.0396015	0.2290327	0.1929874
163	0	0.3037126	-0.829681	0.1980942	0.2114712
164	0	0.6511744	0.6242055	0.2140759	0.2271463
165	1	0.5452914	0.1816634	0.1980314	0.2479487
166	1	0.1596985	-1.660473	0.2169729	0.1341949

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Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
167	0	0.4934917	-0.026035	0.195403	0.2499576
168	1	0.218877	-1.272223	0.2074859	0.1709699
169	1	0.1560892	-1.687619	0.2211138	0.1317254
170	1	0.3093779	-0.803029	0.2031754	0.2136632
171	1	0.6026472	0.4165074	0.2081001	0.2394636
172	0	0.5069402	0.0277627	0.2052609	0.2499518
173	1	0.0783764	-2.464614	0.2547269	0.0722336
174	1	0.0614502	-2.726109	0.2696679	0.0576741
175	1	0.2980028	-0.856827	0.1982893	0.2091971
176	1	0.2564457	-1.064525	0.2022891	0.1906813
177	1	0.1596985	-1.660473	0.2169729	0.1341949
178	1	0.0436172	-3.087708	0.28712	0.0417147
179	1	0.1895749	-1.452775	0.2105406	0.1536362
180	0	0.4418314	-0.233733	0.1941018	0.2466164
181	1	0.3554125	-0.595331	0.2017481	0.2290945
182	1	0.4934917	-0.026035	0.195403	0.2499576
183	1	0.4485362	-0.206587	0.1972328	0.2473515
184	1	0.0425188	-3.114359	0.2847632	0.040711
185	1	0.1895749	-1.452775	0.2105406	0.1536362
186	1	0.2980028	-0.856827	0.1982893	0.2091971
187	1	0.0947546	-2.256916	0.2451319	0.0857762
188	0	0.4551371	-0.179935	0.2028008	0.2479873
189	1	0.0924931	-2.283567	0.2418481	0.0839381
190	1	0.1633075	-1.633822	0.221054	0.1366382
191	1	0.557916	0.2327086	0.2340375	0.2466457

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
192	1	0.4934917	-0.026035	0.195403	0.2499576
193	1	0.0436172	-3.087708	0.28712	0.0417147
194	1	0.8065664	1.4278516	0.2376843	0.1560171
195	0	0.1114644	-2.075869	0.2327205	0.0990401
196	1	0.5062523	0.0250106	0.2304564	0.2499609
197	1	0.0414273	-3.141505	0.2931611	0.0397111
198	0	0.2564457	-1.064525	0.2022891	0.1906813
199	0	0.4042871	-0.387633	0.2016224	0.240839
200	1	0.0505074	-2.933807	0.2811912	0.0479564
201	1	0.0947546	-2.256916	0.2451319	0.0857762
202	1	0.2980028	-0.856827	0.1982893	0.2091971
203	1	0.5520135	0.2088094	0.2032488	0.2472946
204	1	0.4551371	-0.179935	0.2028008	0.2479873
205	1	0.4485362	-0.206587	0.1972328	0.2473515
206	1	0.0531506	-2.88001	0.2757897	0.0503257
207	1	0.0947546	-2.256916	0.2451319	0.0857762
208	1	0.0924931	-2.283567	0.2418481	0.0839381
209	1	0.3093779	-0.803029	0.2031754	0.2136632
210	1	0.0902396	-2.310713	0.2482079	0.0820964
211	1	0.0058219	-5.140294	0.4146068	0.005788
212	1	0.0518253	-2.906661	0.2732202	0.0491394
213	1	0.2616561	-1.037379	0.2010209	0.1931922
214	1	0.1166211	-2.024824	0.246979	0.1030206
215	1	0.5002778	0.0011114	0.1996041	0.2499999
216	1	0.3203891	-0.751984	0.235819	0.2177399

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=HBAB7SHY Parameter=HbA1c <7.0% without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
217	0	0.4036245	-0.390385	0.226639	0.2407118
218	1	0.1193949	-1.998172	0.2576345	0.1051398
219	1	0.0530123	-2.882762	0.2918673	0.050202
220	1	0.3087901	-0.805782	0.227441	0.2134388
221	0	0.8369285	1.6355497	0.2474244	0.1364792
222	0	0.5585947	0.2354607	0.2089573	0.2465667
223	1	0.6967573	0.8319035	0.2210851	0.2112866
224	0	0.3493306	-0.621983	0.1964702	0.2272987
225	0	0.5585947	0.2354607	0.2089573	0.2465667
226	0	0.5585947	0.2354607	0.2089573	0.2465667
227	1	0.4485362	-0.206587	0.1972328	0.2473515
228	1	0.0902396	-2.310713	0.2482079	0.0820964
229	1	0.0277359	-3.556901	0.3182377	0.0269666
230	0	0.3037126	-0.829681	0.1980942	0.2114712
231	0	0.0425188	-3.114359	0.2847632	0.040711
232	1	0.2564457	-1.064525	0.2022891	0.1906813
233	1	0.0045006	-5.399038	0.4321328	0.0044803
234	1	0.1937034	-1.426124	0.2148902	0.1561824
235	1	0.1337535	-1.868171	0.2243978	0.1158635
236	1	0.8107664	1.4549976	0.2473714	0.1534243
237	1	0.1596985	-1.660473	0.2169729	0.1341949
238	1	0.4934917	-0.026035	0.195403	0.2499576
239	1	0.2235535	-1.245077	0.2051944	0.1735773
240	1	0.0531506	-2.88001	0.2757897	0.0503257
241	1	0.5069402	0.0277627	0.2052609	0.2499518

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Parameter Code=HBAB7SHY Parameter=HbA1c <7.0% without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
242	1	0.0436172	-3.087708	0.28712	0.0417147
243	1	0.3914001	-0.441431	0.1941544	0.2382061
244	1	0.0505074	-2.933807	0.2811912	0.0479564
245	0	0.3037126	-0.829681	0.1980942	0.2114712
246	0	0.0883167	-2.334363	0.2863822	0.0805169
247	1	0.106532	-2.126665	0.2798351	0.0951829
248	0	0.0506753	-2.930311	0.3087299	0.0481074
249	1	0.1818935	-1.503571	0.265236	0.1488083
250	1	0.0748192	-2.514915	0.2934826	0.0692212
251	0	0.0493852	-2.957457	0.3103217	0.0469463
252	1	0.076685	-2.488264	0.2935273	0.0708044
253	0	0.3439743	-0.645633	0.266294	0.225656
254	0	0.4943655	-0.022539	0.2744636	0.2499683
255	1	0.5010281	0.0041124	0.2758812	0.2499989
256	1	0.090527	-2.307217	0.2869353	0.0823319
257	1	0.019037	-3.94215	0.3564873	0.0186746
258	1	0.1091436	-2.099519	0.2811743	0.0972312
259	1	0.0748192	-2.514915	0.2934826	0.0692212
260	1	0.01512	-4.1765	0.3681236	0.0148914
261	1	0.0404982	-3.165155	0.3195555	0.0388581
262	1	0.1091436	-2.099519	0.2811743	0.0972312
263	1	0.0519729	-2.90366	0.3085689	0.0492717
264	1	0.0729616	-2.542061	0.293682	0.0676382
265	1	0.0601002	-2.749759	0.3016798	0.0564882
266	1	0.0052611	-5.242136	0.4350601	0.0052334

Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

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267	1	0.0119933	-4.411344	0.3848186	0.0118494
268	1	0.0729616	-2.542061	0.293682	0.0676382
269	0	0.0927453	-2.280566	0.2870905	0.0841436
270	1	0.2987346	-0.853331	0.265508	0.2094922
271	1	0.7773519	1.2503006	0.3155301	0.1730759
272	1	0.090527	-2.307217	0.2869353	0.0823319
273	1	0.131037	-1.891821	0.2762488	0.1138663
274	1	0.0426412	-3.111358	0.3170708	0.0408229
275	1	0.0883167	-2.334363	0.2863822	0.0805169
276	1	0.3922331	-0.437935	0.2680631	0.2383863
277	1	0.4943655	-0.022539	0.2744636	0.2499683
278	0	0.4943655	-0.022539	0.2744636	0.2499683
279	0	0.2240749	-1.242076	0.267663	0.1738653
280	1	0.0426412	-3.111358	0.3170708	0.0408229
281	1	0.034036	-3.345707	0.3265047	0.0328776
282	1	0.8112264	1.4579986	0.3245194	0.1531381
283	1	0.8668506	1.8733947	0.3440957	0.1154207
284	1	0.697391	0.8349045	0.2993892	0.2110368
285	1	0.0415663	-3.138009	0.3173265	0.0398386
286	1	0.0331547	-3.372853	0.3293314	0.0320555
287	0	0.5394213	0.1580131	0.2689423	0.248446
288	1	0.0331547	-3.372853	0.3293314	0.0320555
289	1	0.0042786	-5.449834	0.4482114	0.0042603
290	1	3.102E-8	-17.28862	1.3170406	3.102E-8
291	0	0.5394213	0.1580131	0.2689423	0.248446

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
292	1	0.0748192	-2.514915	0.2934826	0.0692212
293	1	0.2622363	-1.034378	0.2665892	0.1934684
294	1	0.0729616	-2.542061	0.293682	0.0676382
295	1	0.090527	-2.307217	0.2869353	0.0823319
296	1	0.0404982	-3.165155	0.3195555	0.0388581
297	0	0.3857812	-0.465081	0.2600634	0.2369541
298	0	0.5969703	0.3928571	0.2844499	0.2405968
299	1	0.1341016	-1.86517	0.2766372	0.1161184
300	1	0.2240749	-1.242076	0.267663	0.1738653
301	1	0.5904222	0.3657112	0.2737703	0.2418238
302	1	0.0123192	-4.384198	0.3795532	0.0121675
303	1	0.185968	-1.476425	0.2690799	0.1513839
304	1	0.106532	-2.126665	0.2798351	0.0951829
305	1	0.111762	-2.072868	0.2814444	0.0992713
306	1	0.111762	-2.072868	0.2814444	0.0992713
307	1	0.2519621	-1.088175	0.2601566	0.1884772
308	1	0.023329	-3.734452	0.3459118	0.0227848
309	1	0.063212	-2.695962	0.300704	0.0592163
310	1	0.3986044	-0.411284	0.2692812	0.2397189
311	0	0.3922331	-0.437935	0.2680631	0.2383863
312	1	0.106532	-2.126665	0.2798351	0.0951829
313	1	0.1529992	-1.711269	0.2692125	0.1295904
314	1	0.0227294	-3.761104	0.3464183	0.0222128
315	1	0.2240749	-1.242076	0.267663	0.1738653
316	1	0.2519621	-1.088175	0.2601566	0.1884772

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
317	1	0.131037	-1.891821	0.2762488	0.1138663
318	1	0.1601017	-1.657472	0.2727135	0.1344691
319	1	0.090527	-2.307217	0.2869353	0.0823319
320	1	0.023329	-3.734452	0.3459118	0.0227848
321	0	0.1529992	-1.711269	0.2692125	0.1295904
322	1	0.185968	-1.476425	0.2690799	0.1513839
323	1	0.1341016	-1.86517	0.2766372	0.1161184
324	0	0.4360071	-0.257383	0.2620523	0.2459049
325	1	0.1601017	-1.657472	0.2727135	0.1344691
326	1	0.111762	-2.072868	0.2814444	0.0992713
327	0	0.0147211	-4.203646	0.3729686	0.0145044
328	1	0.0883167	-2.334363	0.2863822	0.0805169
329	1	0.1279768	-1.918967	0.2740947	0.1115987
330	1	0.0415663	-3.138009	0.3173265	0.0398386
331	1	0.2148604	-1.295873	0.2622063	0.1686954
332	0	0.4492787	-0.203586	0.2721172	0.2474273
333	1	0.1565503	-1.684123	0.2722041	0.1320423
334	1	0.1341016	-1.86517	0.2766372	0.1161184
335	1	0.0036706	-5.603735	0.453311	0.0036571
336	1	0.106532	-2.126665	0.2798351	0.0951829
337	0	0.106532	-2.126665	0.2798351	0.0951829
338	1	0.4492787	-0.203586	0.2721172	0.2474273
339	0	0.1279768	-1.918967	0.2740947	0.1115987
340	0	0.546158	0.1851591	0.2790293	0.2478694
341	0	0.1601017	-1.657472	0.2727135	0.1344691

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
342	0	0.5394213	0.1580131	0.2689423	0.248446
343	0	0.8112264	1.4579986	0.3245194	0.1531381
344	1	0.0493852	-2.957457	0.3103217	0.0469463
345	1	0.019037	-3.94215	0.3564873	0.0186746
346	1	0.546158	0.1851591	0.2790293	0.2478694
347	1	0.6395495	0.5734092	0.2794596	0.2305259
348	0	0.5527555	0.2118104	0.2805359	0.2472169
349	1	0.0197075	-3.906852	0.3095742	0.0193191
350	0	0.413544	-0.349334	0.2032753	0.2425254
351	1	0.0980912	-2.218616	0.2239524	0.0884693
352	0	0.4646501	-0.141636	0.2073057	0.2487504
353	0	0.3176202	-0.76473	0.1989799	0.2167376
354	0	0.1686084	-1.595522	0.2060694	0.1401796
355	1	0.5547701	0.2199629	0.2093004	0.2470002
356	0	0.2638166	-1.026225	0.1960654	0.1942174
357	1	0.4773678	-0.090591	0.2292735	0.2494878
358	1	0.3699018	-0.532638	0.2139624	0.2330745
359	1	0.1993158	-1.390576	0.2115819	0.159589
360	0	0.0702427	-2.582967	0.2448615	0.0653087
361	1	0.1206251	-1.986524	0.2206481	0.1060747
362	1	0.1027007	-2.167571	0.2311983	0.0921532
363	1	0.5158222	0.0633101	0.2233711	0.2497497
364	1	0.2846762	-0.921383	0.2158554	0.2036357
365	1	0.2846762	-0.921383	0.2158554	0.2036357
366	0	0.1758854	-1.544477	0.2182897	0.1449497

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
367	0	0.3761348	-0.505987	0.2202848	0.2346574
368	1	0.2345351	-1.182878	0.2095653	0.1795284
369	1	0.1234808	-1.959873	0.2258125	0.1082333
370	1	0.0088914	-4.713745	0.3606446	0.0088123
371	1	0.1027007	-2.167571	0.2311983	0.0921532
372	1	0.2792803	-0.948034	0.2096992	0.2012828
373	1	0.1002705	-2.194222	0.2262957	0.0902163
374	1	0.5225986	0.090456	0.2290059	0.2494893
375	1	0.0702427	-2.582967	0.2448615	0.0653087
376	1	0.068522	-2.609618	0.2404994	0.0638267
377	1	0.0379531	-3.232713	0.2678428	0.0365126
378	0	0.7556444	1.1289462	0.2722049	0.184646
379	0	0.1993158	-1.390576	0.2115819	0.159589
380	0	0.2792803	-0.948034	0.2096992	0.2012828
381	1	0.0563956	-2.817316	0.2488894	0.0532151
382	1	0.1444481	-1.778826	0.2160756	0.1235829
383	0	0.5673404	0.2710081	0.2296438	0.2454653
384	1	0.2350295	-1.180126	0.1999356	0.1797907
385	1	0.4639656	-0.144388	0.2181291	0.2487015
386	1	0.1206251	-1.986524	0.2206481	0.1060747
387	0	0.0093782	-4.659947	0.3523013	0.0092902
388	0	0.0168982	-4.063505	0.3124975	0.0166127
389	1	0.1002705	-2.194222	0.2262957	0.0902163
390	0	0.1720556	-1.571128	0.2126476	0.1424525
391	1	0.0109214	-4.506047	0.3475326	0.0108022

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
392	1	0.1955291	-1.414475	0.2053693	0.1572975
393	0	0.7047879	0.870203	0.2443124	0.2080619
394	1	0.1686084	-1.595522	0.2060694	0.1401796
395	1	0.2743968	-0.972428	0.1987964	0.1991032
396	0	0.4070956	-0.375985	0.2054932	0.2413688
397	1	0.0702427	-2.582967	0.2448615	0.0653087
398	1	0.3642345	-0.557032	0.2004826	0.2315677
399	1	0.1686084	-1.595522	0.2060694	0.1401796
400	1	0.3642345	-0.557032	0.2004826	0.2315677
401	0	0.081188	-2.426314	0.2318891	0.0745965
402	1	0.3580855	-0.583683	0.202886	0.2298603
403	1	0.1125739	-2.064715	0.2201607	0.099901
404	1	0.2302718	-1.206777	0.2028107	0.1772467
405	1	0.4646501	-0.141636	0.2073057	0.2487504
406	1	0.0957585	-2.245268	0.2272152	0.0865888
407	0	0.6180922	0.4814582	0.2260615	0.2360542
408	1	0.024783	-3.672502	0.2941984	0.0241688
409	0	0.3699018	-0.532638	0.2139624	0.2330745
410	1	0.2080403	-1.336779	0.2162657	0.1647595
411	0	0.5225986	0.090456	0.2290059	0.2494893
412	1	0.2846762	-0.921383	0.2158554	0.2036357
413	0	0.2394436	-1.155732	0.2094315	0.1821104
414	1	0.0809829	-2.429066	0.2385842	0.0744247
415	1	0.068522	-2.609618	0.2404994	0.0638267
416	0	0.4128767	-0.352086	0.2139935	0.2424095

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=HBAB7SHY Parameter=HbA1c <7.0% without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
417	0	0.7874292	1.3094983	0.2735937	0.1673845
418	1	0.6711851	0.7135501	0.2526915	0.2206957
419	1	0.2792803	-0.948034	0.2096992	0.2012828
420	0	0.9244666	2.5046413	0.3208467	0.0698281
421	1	0.5098514	0.0394108	0.2143333	0.2499029
422	0	0.8124717	1.4661511	0.2610623	0.1523615
423	1	0.1912944	-1.441621	0.2021669	0.1547009
424	0	0.951378	2.9738346	0.362037	0.0462579
425	1	0.1686084	-1.595522	0.2060694	0.1401796
426	0	0.2691225	-0.999079	0.2015319	0.1966956
427	0	0.7103026	0.8968543	0.243226	0.2057728
428	0	0.0669813	-2.634012	0.240661	0.0624948
429	1	0.2691225	-0.999079	0.2015319	0.1966956
430	0	0.2254955	-1.233923	0.1984765	0.1746473
431	1	0.0653348	-2.660664	0.2439579	0.0610662
432	0	0.4512966	-0.195433	0.199773	0.247628
433	1	0.2743968	-0.972428	0.1987964	0.1991032
434	1	0.3518701	-0.610829	0.1952457	0.2280575
435	0	0.6991087	0.843057	0.2315327	0.2103557
436	0	0.2638166	-1.026225	0.1960654	0.1942174
437	0	0.4773678	-0.090591	0.2292735	0.2494878
438	1	0.2254955	-1.233923	0.1984765	0.1746473
439	1	0.1234808	-1.959873	0.2258125	0.1082333
440	0	0.1411256	-1.805972	0.2191969	0.1212092
441	0	0.3642345	-0.557032	0.2004826	0.2315677

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=HBAB7SHY Parameter=HbA1c <7.0% without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
442	1	0.0850781	-2.375269	0.2375737	0.0778398
443	0	0.4005603	-0.403131	0.1968538	0.2401117
444	1	0.0636965	-2.68781	0.246608	0.0596393
445	1	0.0702427	-2.582967	0.2448615	0.0653087
446	1	0.2846762	-0.921383	0.2158554	0.2036357
447	1	0.1649053	-1.622173	0.2091607	0.1377116
448	1	0.0463085	-3.025014	0.2580295	0.044164
449	0	0.9512505	2.9710825	0.3710245	0.046373
450	1	0.081188	-2.426314	0.2318891	0.0745965
451	1	0.0235155	-3.7263	0.3032087	0.0229625
452	1	0.0429752	-3.103206	0.2677344	0.0411284
453	1	0.068522	-2.609618	0.2404994	0.0638267
454	1	0.1477731	-1.752175	0.2214886	0.1259362
455	1	0.0463085	-3.025014	0.2580295	0.044164
456	1	0.161201	-1.649319	0.2070683	0.1352152
457	1	0.0578307	-2.790665	0.2529829	0.0544863
458	1	0.0310561	-3.440411	0.2782581	0.0300916
459	1	0.1002705	-2.194222	0.2262957	0.0902163
460	0	0.7787597	1.2584531	0.2505545	0.172293
461	1	0.0772643	-2.480112	0.2370091	0.0712945
462	1	0.0318682	-3.413759	0.281591	0.0308526
463	1	0.0451243	-3.05216	0.2655993	0.0430881
464	1	0.3176202	-0.76473	0.1989799	0.2167376
465	1	0.3635974	-0.559784	0.2110294	0.2313943
466	1	0.3118722	-0.791381	0.2015572	0.2146079

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=HBAB7SHY Parameter=HbA1c <7.0% without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
467	1	0.3518701	-0.610829	0.1952457	0.2280575
468	1	0.0653348	-2.660664	0.2439579	0.0610662
469	1	0.2691225	-0.999079	0.2015319	0.1966956
470	1	0.068522	-2.609618	0.2404994	0.0638267
471	1	0.0303304	-3.464804	0.2824379	0.0294105
472	1	0.1955291	-1.414475	0.2053693	0.1572975
473	1	0.1027007	-2.167571	0.2311983	0.0921532
474	1	0.024147	-3.699154	0.2974299	0.0235639
475	1	0.1649053	-1.622173	0.2091607	0.1377116
476	1	0.1686084	-1.595522	0.2060694	0.1401796
477	1	0.4005603	-0.403131	0.1968538	0.2401117
478	0	0.4070956	-0.375985	0.2054932	0.2413688
479	1	0.3176202	-0.76473	0.1989799	0.2167376
480	1	0.0537399	-2.868362	0.2534773	0.0508519
481	1	0.605315	0.427661	0.2157459	0.2389088
482	1	0.3580855	-0.583683	0.202886	0.2298603
483	1	0.0441056	-3.07606	0.2636537	0.0421603
484	0	0.2302718	-1.206777	0.2028107	0.1772467
485	0	0.5547701	0.2199629	0.2093004	0.2470002
486	1	0.045243	-3.049408	0.2603649	0.0431961
487	1	0.1649053	-1.622173	0.2091607	0.1377116
488	1	0.024783	-3.672502	0.2941984	0.0241688
489	0	0.413544	-0.349334	0.2032753	0.2425254
490	1	0.0537399	-2.868362	0.2534773	0.0508519
491	0	0.5614648	0.2471089	0.2204207	0.2462221

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=HBAB7SHY Parameter=HbA1c <7.0% without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
492	1	0.1125739	-2.064715	0.2201607	0.099901
493	1	0.4005603	-0.403131	0.1968538	0.2401117
494	1	0.0370724	-3.257106	0.27114	0.035698
495	1	0.3176202	-0.76473	0.1989799	0.2167376
496	0	0.3518701	-0.610829	0.1952457	0.2280575
497	1	0.1382536	-1.829871	0.2141194	0.1191395
498	1	0.3118722	-0.791381	0.2015572	0.2146079
499	1	0.5547701	0.2199629	0.2093004	0.2470002
500	0	0.605315	0.427661	0.2157459	0.2389088
501	1	0.4512966	-0.195433	0.199773	0.247628
502	1	0.0197075	-3.906852	0.3095742	0.0193191
503	1	0.6657792	0.6891563	0.2342386	0.2225173
504	1	0.1153145	-2.037569	0.2201665	0.102017
505	0	0.3060764	-0.818527	0.1949811	0.2123936
506	0	0.8124717	1.4661511	0.2610623	0.1523615
507	1	0.1153145	-2.037569	0.2201665	0.102017
508	1	0.5098514	0.0394108	0.2143333	0.2499029
509	1	0.0441056	-3.07606	0.2636537	0.0421603
510	1	0.0441056	-3.07606	0.2636537	0.0421603
511	0	0.4512966	-0.195433	0.199773	0.247628
512	0	0.7460966	1.077901	0.2538586	0.1894365
513	1	0.0772643	-2.480112	0.2370091	0.0712945
514	1	0.079222	-2.452966	0.2351754	0.0729458
515	0	0.1686084	-1.595522	0.2060694	0.1401796
516	1	0.0980912	-2.218616	0.2239524	0.0884693

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=HBAB7SHY Parameter=HbA1c <7.0% without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
517	1	0.079222	-2.452966	0.2351754	0.0729458
518	1	0.0653348	-2.660664	0.2439579	0.0610662
519	0	0.6537036	0.635359	0.2231887	0.2263752
520	1	0.1955291	-1.414475	0.2053693	0.1572975
521	1	0.1414595	-1.80322	0.2109518	0.1214487
522	1	0.4512966	-0.195433	0.199773	0.247628
523	1	0.1125739	-2.064715	0.2201607	0.099901
524	0	0.0537399	-2.868362	0.2534773	0.0508519
525	0	0.0980912	-2.218616	0.2239524	0.0884693
526	1	0.0669813	-2.634012	0.240661	0.0624948
527	1	0.1382536	-1.829871	0.2141194	0.1191395
528	1	0.0669813	-2.634012	0.240661	0.0624948
529	0	0.7103026	0.8968543	0.243226	0.2057728
530	0	0.3176202	-0.76473	0.1989799	0.2167376
531	1	0.6991087	0.843057	0.2315327	0.2103557
532	1	0.1686084	-1.595522	0.2060694	0.1401796
533	1	0.1955291	-1.414475	0.2053693	0.1572975
534	1	0.4580272	-0.168287	0.209331	0.2482383
535	0	0.6180922	0.4814582	0.2260615	0.2360542
536	1	0.161201	-1.649319	0.2070683	0.1352152
537	1	0.5547701	0.2199629	0.2093004	0.2470002
538	1	0.161201	-1.649319	0.2070683	0.1352152
539	1	0.2743968	-0.972428	0.1987964	0.1991032
540	1	0.01275	-4.349394	0.3419573	0.0125874
541	1	0.1180613	-2.010918	0.2169425	0.1041229

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=HBAB7SHY Parameter=HbA1c <7.0% without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
542	1	0.1125739	-2.064715	0.2201607	0.099901
543	1	0.2254955	-1.233923	0.1984765	0.1746473
544	0	0.1997554	-1.387824	0.2023754	0.1598532
545	1	0.0669813	-2.634012	0.240661	0.0624948
546	1	0.0980912	-2.218616	0.2239524	0.0884693
547	1	0.4646501	-0.141636	0.2073057	0.2487504
548	1	0.079222	-2.452966	0.2351754	0.0729458
549	1	0.0669813	-2.634012	0.240661	0.0624948
550	1	0.0636965	-2.68781	0.246608	0.0596393
551	1	0.2638166	-1.026225	0.1960654	0.1942174
552	1	0.0551114	-2.84171	0.2501803	0.0520741
553	1	0.081188	-2.426314	0.2318891	0.0745965
554	1	0.035199	-3.310904	0.2791159	0.03396
555	1	0.0980912	-2.218616	0.2239524	0.0884693
556	1	0.1686084	-1.595522	0.2060694	0.1401796
557	1	0.0084526	-4.76479	0.3691035	0.0083812
558	1	0.2743968	-0.972428	0.1987964	0.1991032
559	1	0.2743968	-0.972428	0.1987964	0.1991032
560	0	0.6537036	0.635359	0.2231887	0.2263752
561	1	0.079222	-2.452966	0.2351754	0.0729458
562	1	0.0429752	-3.103206	0.2677344	0.0411284
563	1	0.2738492	-0.97518	0.2087956	0.1988558
564	1	0.3118722	-0.791381	0.2015572	0.2146079
565	0	0.5030662	0.0122649	0.2039469	0.2499906
566	1	0.045243	-3.049408	0.2603649	0.0431961

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=HBAB7SHY Parameter=HbA1c <7.0% without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
567	0	0.1177751	-2.01367	0.224674	0.1039041
568	1	0.1153145	-2.037569	0.2201665	0.102017
569	1	0.5547701	0.2199629	0.2093004	0.2470002
570	1	0.1649053	-1.622173	0.2091607	0.1377116
571	1	0.0164977	-4.087898	0.3189006	0.0162255
572	0	0.4580272	-0.168287	0.209331	0.2482383
573	1	0.1686084	-1.595522	0.2060694	0.1401796
574	1	0.1382536	-1.829871	0.2141194	0.1191395
575	1	0.1382536	-1.829871	0.2141194	0.1191395
576	1	0.1180613	-2.010918	0.2169425	0.1041229
577	1	0.1350511	-1.857017	0.2130971	0.1168123
578	1	0.1125739	-2.064715	0.2201607	0.099901
579	1	0.5098514	0.0394108	0.2143333	0.2499029
580	1	0.4580272	-0.168287	0.209331	0.2482383
581	1	0.161201	-1.649319	0.2070683	0.1352152
582	1	0.3060764	-0.818527	0.1949811	0.2123936
583	1	0.2743968	-0.972428	0.1987964	0.1991032
584	0	0.4194723	-0.32494	0.2178851	0.2435153
585	1	0.1177751	-2.01367	0.224674	0.1039041
586	1	0.1177751	-2.01367	0.224674	0.1039041
587	1	0.0072359	-4.921443	0.374002	0.0071835
588	0	0.6300668	0.5325034	0.2501644	0.2330826
589	1	0.0702427	-2.582967	0.2448615	0.0653087
590	0	0.1720556	-1.571128	0.2126476	0.1424525
591	1	0.1993158	-1.390576	0.2115819	0.159589

Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=HBAB7SHY Parameter=HbA1c <7.0% without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
592	0	0.317024	-0.767482	0.2092866	0.2165198
593	1	0.0310561	-3.440411	0.2782581	0.0300916
594	1	0.0578307	-2.790665	0.2529829	0.0544863
595	1	0.0830264	-2.40192	0.2329404	0.076133
596	1	0.0702427	-2.582967	0.2448615	0.0653087
597	1	0.1477731	-1.752175	0.2214886	0.1259362
598	0	0.3761348	-0.505987	0.2202848	0.2346574
599	1	0.0212659	-3.829155	0.3035215	0.0208137
600	1	0.1177751	-2.01367	0.224674	0.1039041
601	1	0.0463085	-3.025014	0.2580295	0.044164
602	1	0.2443308	-1.129081	0.2154497	0.1846332
603	0	0.5614648	0.2471089	0.2204207	0.2462221
604	1	0.0702427	-2.582967	0.2448615	0.0653087
605	1	0.0302496	-3.467557	0.2868096	0.0293345
606	1	0.0809829	-2.429066	0.2385842	0.0744247
607	1	0.0310561	-3.440411	0.2782581	0.0300916
608	1	0.1153145	-2.037569	0.2201665	0.102017
609	1	0.2846762	-0.921383	0.2158554	0.2036357
610	0	0.4194723	-0.32494	0.2178851	0.2435153
611	1	0.0451243	-3.05216	0.2655993	0.0430881
612	0	0.3229306	-0.740336	0.2112183	0.2186464
613	1	0.2345351	-1.182878	0.2095653	0.1795284
614	0	0.5804949	0.3248054	0.2423145	0.2435206
615	1	0.5292434	0.1171073	0.2353246	0.2491448
616	1	0.1477731	-1.752175	0.2214886	0.1259362

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Parameter Code=HBAB7SHY Parameter=HbA1c <7.0% without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
617	0	0.3699018	-0.532638	0.2139624	0.2330745
618	0	0.2345351	-1.182878	0.2095653	0.1795284
619	1	0.1720556	-1.571128	0.2126476	0.1424525
620	1	0.3761348	-0.505987	0.2202848	0.2346574
621	1	0.1002705	-2.194222	0.2262957	0.0902163
622	1	0.0702427	-2.582967	0.2448615	0.0653087
623	1	0.1002705	-2.194222	0.2262957	0.0902163
624	1	0.097848	-2.221368	0.231164	0.0882737
625	1	0.4128767	-0.352086	0.2139935	0.2424095
626	1	0.1477731	-1.752175	0.2214886	0.1259362
627	1	0.2036834	-1.36343	0.2104202	0.1621965
628	0	0.168223	-1.598274	0.2148103	0.139924
629	1	0.0093782	-4.659947	0.3523013	0.0092902
630	0	0.5673404	0.2710081	0.2296438	0.2454653
631	1	0.470723	-0.117242	0.2229241	0.2491429
632	1	0.0850781	-2.375269	0.2375737	0.0778398
633	1	0.2345351	-1.182878	0.2095653	0.1795284
634	1	0.1206251	-1.986524	0.2206481	0.1060747
635	1	0.3635974	-0.559784	0.2110294	0.2313943
636	1	0.0474999	-2.998363	0.2618603	0.0452436
637	1	0.0850781	-2.375269	0.2375737	0.0778398
638	1	0.4128767	-0.352086	0.2139935	0.2424095
639	0	0.1206251	-1.986524	0.2206481	0.1060747
640	1	0.2846762	-0.921383	0.2158554	0.2036357
641	0	0.4194723	-0.32494	0.2178851	0.2435153

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=HBAB7SHY Parameter=HbA1c <7.0% without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
642	1	0.0934336	-2.272413	0.2281631	0.0847037
643	1	0.3287851	-0.713685	0.2174761	0.2206855
644	1	0.2254955	-1.233923	0.1984765	0.1746473
645	1	0.1234808	-1.959873	0.2258125	0.1082333
646	1	0.1153145	-2.037569	0.2201665	0.102017
647	1	0.2443308	-1.129081	0.2154497	0.1846332
648	1	0.0046755	-5.360738	0.4027422	0.0046536
649	1	0.2254955	-1.233923	0.1984765	0.1746473
650	1	0.0957585	-2.245268	0.2272152	0.0865888
651	1	0.0247166	-3.675255	0.2981762	0.0241057
652	1	0.3229306	-0.740336	0.2112183	0.2186464
653	1	0.2394436	-1.155732	0.2094315	0.1821104
654	1	0.079222	-2.452966	0.2351754	0.0729458
655	1	0.2638166	-1.026225	0.1960654	0.1942174
656	1	0.0957585	-2.245268	0.2272152	0.0865888
657	0	0.3060764	-0.818527	0.1949811	0.2123936
658	1	0.3060764	-0.818527	0.1949811	0.2123936
659	1	0.1382536	-1.829871	0.2141194	0.1191395
660	1	0.0109512	-4.503295	0.3448935	0.0108313
661	1	0.0474999	-2.998363	0.2618603	0.0452436
662	1	0.0197075	-3.906852	0.3095742	0.0193191
663	1	0.2638166	-1.026225	0.1960654	0.1942174
664	1	0.161201	-1.649319	0.2070683	0.1352152
665	0	0.3060764	-0.818527	0.1949811	0.2123936
666	1	0.0164977	-4.087898	0.3189006	0.0162255

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=HBAB7SHY Parameter=HbA1c <7.0% without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
667	1	0.2743968	-0.972428	0.1987964	0.1991032
668	1	0.0934336	-2.272413	0.2281631	0.0847037
669	1	0.4005603	-0.403131	0.1968538	0.2401117
670	1	0.00334	-5.698438	0.4194859	0.0033288
671	1	0.1206251	-1.986524	0.2206481	0.1060747
672	1	0.0062101	-5.075343	0.3785172	0.0061716
673	1	0.0022072	-6.113834	0.4476609	0.0022023
674	1	0.0563956	-2.817316	0.2488894	0.0532151
675	1	0.2792803	-0.948034	0.2096992	0.2012828
676	1	0.0549683	-2.844462	0.2558819	0.0519468
677	1	0.2738492	-0.97518	0.2087956	0.1988558
678	1	0.0389383	-3.206061	0.2714194	0.0374221
679	1	0.0379531	-3.232713	0.2678428	0.0365126
680	1	0.2345351	-1.182878	0.2095653	0.1795284
681	1	0.2792803	-0.948034	0.2096992	0.2012828
682	1	0.1720556	-1.571128	0.2126476	0.1424525
683	1	0.097848	-2.221368	0.231164	0.0882737
684	1	0.1411256	-1.805972	0.2191969	0.1212092
685	1	0.5804949	0.3248054	0.2423145	0.2435206
686	1	0.0830264	-2.40192	0.2329404	0.076133
687	1	0.2080403	-1.336779	0.2162657	0.1647595
688	1	0.1411256	-1.805972	0.2191969	0.1212092
689	1	0.168223	-1.598274	0.2148103	0.139924
690	1	0.2345351	-1.182878	0.2095653	0.1795284
691	1	0.1993158	-1.390576	0.2115819	0.159589

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=HBAB7SHY Parameter=HbA1c <7.0% without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
692	1	0.1444481	-1.778826	0.2160756	0.1235829
693	0	0.0850781	-2.375269	0.2375737	0.0778398
694	1	0.2519621	-1.088175	0.2601566	0.1884772
695	1	0.4360071	-0.257383	0.2620523	0.2459049
696	1	0.1601017	-1.657472	0.2727135	0.1344691
697	1	0.6859187	0.7811072	0.2859588	0.2154342
698	1	0.019037	-3.94215	0.3564873	0.0186746
699	1	0.1529992	-1.711269	0.2692125	0.1295904
700	0	0.3043476	-0.82668	0.2665021	0.2117201
701	1	0.090527	-2.307217	0.2869353	0.0823319
702	1	0.0331547	-3.372853	0.3293314	0.0320555
703	1	0.3857812	-0.465081	0.2600634	0.2369541
704	1	0.1091436	-2.099519	0.2811743	0.0972312
705	0	0.5394213	0.1580131	0.2689423	0.248446
706	1	0.1279768	-1.918967	0.2740947	0.1115987
707	1	0.2194752	-1.268727	0.2669086	0.1713058
708	1	0.5010281	0.0041124	0.2758812	0.2499989
709	0	0.5394213	0.1580131	0.2689423	0.248446
710	1	0.0616521	-2.722613	0.3007648	0.0578511
711	1	0.6033656	0.4195084	0.2860378	0.2393155
712	1	0.3043476	-0.82668	0.2665021	0.2117201
713	0	0.3378749	-0.672779	0.2590789	0.2237154
714	0	0.5904222	0.3657112	0.2737703	0.2418238
715	1	0.3857812	-0.465081	0.2600634	0.2369541
716	0	0.0927453	-2.280566	0.2870905	0.0841436

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=HBAB7SHY Parameter=HbA1c <7.0% without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
717	1	0.185968	-1.476425	0.2690799	0.1513839
718	1	0.2148604	-1.295873	0.2622063	0.1686954
719	0	0.2571128	-1.061029	0.2657136	0.1910058
720	1	0.3378749	-0.672779	0.2590789	0.2237154
721	1	0.0331547	-3.372853	0.3293314	0.0320555
722	1	0.2194752	-1.268727	0.2669086	0.1713058
723	1	0.546158	0.1851591	0.2790293	0.2478694
724	1	0.4426937	-0.230237	0.2707959	0.246716
725	1	0.0533843	-2.875377	0.2529543	0.0505344
726	1	0.0732587	-2.537677	0.2687264	0.0678919
727	1	0.1095223	-2.09563	0.2464203	0.0975272
728	1	0.027221	-3.576167	0.3206735	0.02648
729	0	0.2578565	-1.05714	0.2210748	0.1913665
730	1	0.0603484	-2.745375	0.2779979	0.0567064
731	1	0.0495915	-2.953073	0.2878873	0.0471321
732	1	0.0438108	-3.083075	0.2634717	0.0418914
733	1	0.344231	-0.644496	0.1976904	0.225736
734	1	0.0748979	-2.513778	0.2433501	0.0692882
735	1	0.1146007	-2.044585	0.2180205	0.1014674
736	1	0.0083981	-4.77131	0.3631626	0.0083276
737	1	0.0105925	-4.536961	0.3495724	0.0104803
738	1	0.0279357	-3.549516	0.3153678	0.0271553
739	1	0.1861402	-1.475288	0.2067822	0.151492
740	1	0.0416117	-3.136872	0.274632	0.0398802
741	1	0.0787117	-2.459981	0.2338907	0.0725162

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
742	1	0.1095223	-2.09563	0.2464203	0.0975272
743	1	0.1095223	-2.09563	0.2464203	0.0975272
744	1	0.1567005	-1.682986	0.2121236	0.1321455
745	1	0.344231	-0.644496	0.1976904	0.225736
746	1	0.0349783	-3.317424	0.2738117	0.0337548
747	0	0.1865575	-1.472536	0.2281048	0.1517538
748	0	0.8072882	1.4324847	0.2584514	0.155574
749	1	0.3868205	-0.460697	0.2247758	0.2371904
750	1	0.5014361	0.0057444	0.2046979	0.2499979
751	1	0.039623	-3.187917	0.3060698	0.038053
752	1	0.1095223	-2.09563	0.2464203	0.0975272
753	1	0.0427078	-3.109726	0.2625858	0.0408839
754	1	0.0151781	-4.17261	0.3520883	0.0149477
755	1	0.2243587	-1.240444	0.1961757	0.1740219
756	1	0.0633088	-2.69433	0.2418472	0.0593008
757	1	0.5531589	0.2134424	0.2105138	0.2471741
758	1	0.0340734	-3.34457	0.2861441	0.0329124
759	0	0.1146007	-2.044585	0.2180205	0.1014674
760	1	0.0227547	-3.759966	0.3104379	0.0222369
761	0	0.3046932	-0.825048	0.1936868	0.2118553
762	0	0.2989729	-0.852194	0.198015	0.2095881
763	1	0.2243587	-1.240444	0.1961757	0.1740219
764	1	0.1119241	-2.071236	0.216224	0.0993971
765	0	0.4429743	-0.2291	0.2010136	0.2467481
766	1	0.4304183	-0.280145	0.2232771	0.2451584

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=HBAB7SHY Parameter=HbA1c <7.0% without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
767	1	0.2196701	-1.26759	0.2026046	0.1714152
768	1	0.0293558	-3.498471	0.2861153	0.028494
769	1	0.0286058	-3.525122	0.2855199	0.0277875
770	1	0.1092542	-2.098382	0.2259498	0.0973177
771	1	0.1902877	-1.448142	0.1994015	0.1540783
772	0	0.2196701	-1.26759	0.2026046	0.1714152
773	1	0.1902877	-1.448142	0.1994015	0.1540783
774	1	0.0427078	-3.109726	0.2625858	0.0408839
775	1	0.1311665	-1.890684	0.2185434	0.1139619
776	0	0.7776342	1.2519326	0.2535732	0.1729192
777	0	0.2290307	-1.213792	0.1987872	0.1765756
778	1	0.3503845	-0.61735	0.1944745	0.2276152
779	1	0.0438108	-3.083075	0.2634717	0.0418914
780	1	0.0533843	-2.875377	0.2529543	0.0505344
781	1	0.1314805	-1.887932	0.2393713	0.1141934
782	0	0.5531589	0.2134424	0.2105138	0.2471741
783	1	0.0906207	-2.30608	0.2342491	0.0824086
784	0	0.8447469	1.69398	0.2790961	0.1311496
785	1	0.1119241	-2.071236	0.216224	0.0993971
786	1	0.1865575	-1.472536	0.2281048	0.1517538
787	1	0.1314805	-1.887932	0.2393713	0.1141934
788	1	0.0928827	-2.278934	0.2239151	0.0842555
789	1	0.1865575	-1.472536	0.2281048	0.1517538
790	1	0.1311665	-1.890684	0.2185434	0.1139619
791	1	0.1603212	-1.65584	0.2038732	0.1346183

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
792	1	0.0533843	-2.875377	0.2529543	0.0505344
793	1	0.1092542	-2.098382	0.2259498	0.0973177
794	1	0.1861402	-1.475288	0.2067822	0.151492
795	0	0.1861402	-1.475288	0.2067822	0.151492
796	1	0.4054035	-0.383	0.1998402	0.2410515
797	0	0.3046932	-0.825048	0.1936868	0.2118553
798	0	0.4562863	-0.175302	0.2033697	0.2480891
799	0	0.2110455	-1.318635	0.2316056	0.1665053
800	1	0.3931607	-0.434046	0.2192989	0.2385854
801	0	0.6466725	0.6044447	0.2394452	0.2284872
802	1	0.29955	-0.849442	0.2192854	0.2098198
803	0	0.591482	0.3700953	0.2379326	0.241631
804	0	0.9183345	2.4199297	0.318894	0.0749963
805	0	0.7243302	0.9660434	0.2504125	0.199676
806	1	0.1535682	-1.706885	0.2391876	0.129985
807	1	0.0324328	-3.395615	0.3174329	0.0313809
808	1	0.0483275	-2.980219	0.2951627	0.045992
809	0	0.2527893	-1.083791	0.2269245	0.1888869
810	1	0.2527893	-1.083791	0.2269245	0.1888869
811	1	0.2883854	-0.903239	0.2248198	0.2052192
812	0	0.7033263	0.8631879	0.2374531	0.2086584
813	0	0.5080982	0.0323957	0.2081097	0.2499344
814	1	0.2243587	-1.240444	0.1961757	0.1740219
815	1	0.194428	-1.421491	0.2018157	0.1566258
816	1	0.0130059	-4.329263	0.3362716	0.0128367

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
817	1	0.2156009	-1.291489	0.2299408	0.1691171
818	1	0.0358891	-3.290773	0.2745469	0.0346011
819	1	0.1092542	-2.098382	0.2259498	0.0973177
820	1	0.1861402	-1.475288	0.2067822	0.151492
821	1	0.1311665	-1.890684	0.2185434	0.1139619
822	0	0.4496825	-0.201954	0.2000341	0.2474681
823	0	0.5014361	0.0057444	0.2046979	0.2499979
824	1	0.1374199	-1.836887	0.2115133	0.1185357
825	1	0.0239822	-3.706169	0.2981195	0.0234071
826	1	0.0906207	-2.30608	0.2342491	0.0824086
827	1	0.1314805	-1.887932	0.2393713	0.1141934
828	0	0.6101141	0.4477918	0.2208897	0.2378749
829	0	0.3046932	-0.825048	0.1936868	0.2118553
830	1	0.0349783	-3.317424	0.2738117	0.0337548
831	1	0.0906207	-2.30608	0.2342491	0.0824086
832	0	0.6460434	0.6016925	0.2222242	0.2286713
833	1	0.2625521	-1.032746	0.1942578	0.1936185
834	0	0.3989956	-0.409652	0.1966046	0.2397981
835	0	0.3103686	-0.798396	0.1966512	0.21404
836	1	0.2110455	-1.318635	0.2316056	0.1665053
837	0	0.3328016	-0.695541	0.2231283	0.2220447
838	1	0.0908477	-2.303328	0.2543119	0.0825944
839	1	0.0508628	-2.926422	0.2822995	0.0482758
840	1	0.2110455	-1.318635	0.2316056	0.1665053
841	1	0.10695	-2.122281	0.2523049	0.0955117

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
842	0	0.4304183	-0.280145	0.2232771	0.2451584
843	1	0.039623	-3.187917	0.3060698	0.038053
844	1	0.0908477	-2.303328	0.2543119	0.0825944
845	0	0.1785309	-1.526333	0.2366024	0.1466576
846	0	0.5471219	0.1890486	0.2281565	0.2477795
847	1	0.5337614	0.1352513	0.2280968	0.2488602
848	0	0.5405103	0.1623973	0.2330216	0.2483589
849	0	0.8610432	1.8239815	0.2959147	0.1196478
850	1	0.1314805	-1.887932	0.2393713	0.1141934
851	1	0.3448525	-0.641744	0.2186902	0.2259293
852	1	0.5405103	0.1623973	0.2330216	0.2483589
853	1	0.2527893	-1.083791	0.2269245	0.1888869
854	1	0.0748979	-2.513778	0.2433501	0.0692882
855	1	0.0906207	-2.30608	0.2342491	0.0824086
856	1	0.1342912	-1.863538	0.2095111	0.1162571
857	1	0.3989956	-0.409652	0.1966046	0.2397981
858	1	0.0787117	-2.459981	0.2338907	0.0725162
859	1	0.0438108	-3.083075	0.2634717	0.0418914
860	1	0.0732587	-2.537677	0.2687264	0.0678919
861	0	0.6466725	0.6044447	0.2394452	0.2284872
862	1	0.125458	-1.941729	0.2494826	0.1097183
863	0	0.3503845	-0.61735	0.1944745	0.2276152
864	0	0.3388563	-0.668395	0.2243221	0.2240327
865	1	0.652226	0.6288385	0.2252278	0.2268272
866	1	0.2625521	-1.032746	0.1942578	0.1936185

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=HBAB7SHY Parameter=HbA1c <7.0% without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
867	0	0.7729048	1.2247866	0.2482999	0.175523
868	0	0.6101141	0.4477918	0.2208897	0.2378749
869	1	0.3046932	-0.825048	0.1936868	0.2118553
870	1	0.1567005	-1.682986	0.2121236	0.1321455
871	1	0.2201422	-1.264838	0.2240297	0.1716796
872	0	0.1639416	-1.629189	0.2060827	0.1370647
873	1	0.2989729	-0.852194	0.198015	0.2095881
874	1	0.2989729	-0.852194	0.198015	0.2095881
875	1	0.3103686	-0.798396	0.1966512	0.21404
876	1	0.194428	-1.421491	0.2018157	0.1566258
877	0	0.4946498	-0.021402	0.2045968	0.2499714
878	0	0.3503845	-0.61735	0.1944745	0.2276152
879	1	0.2677449	-1.006094	0.1970543	0.1960576
880	0	0.6977353	0.8365365	0.2339321	0.2109008
881	0	0.6582465	0.6554898	0.2287454	0.224958
882	1	0.2677449	-1.006094	0.1970543	0.1960576
883	1	0.1639416	-1.629189	0.2060827	0.1370647
884	1	0.2573301	-1.059892	0.1996639	0.1911113
885	1	0.0416117	-3.136872	0.274632	0.0398802
886	1	0.2243587	-1.240444	0.1961757	0.1740219
887	1	0.0416117	-3.136872	0.274632	0.0398802
888	0	0.5597368	0.2400938	0.2139797	0.2464315
889	1	0.344231	-0.644496	0.1976904	0.225736
890	1	0.3989956	-0.409652	0.1966046	0.2397981
891	0	0.4496825	-0.201954	0.2000341	0.2474681

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
892	1	0.1861402	-1.475288	0.2067822	0.151492
893	0	0.5014361	0.0057444	0.2046979	0.2499979
894	0	0.1342912	-1.863538	0.2095111	0.1162571
895	1	0.1567005	-1.682986	0.2121236	0.1321455
896	1	0.5972439	0.3939945	0.2152868	0.2405436
897	1	0.0332955	-3.368469	0.3092788	0.0321869
898	1	0.3103686	-0.798396	0.1966512	0.21404
899	0	0.3046932	-0.825048	0.1936868	0.2118553
900	1	0.5531589	0.2134424	0.2105138	0.2471741
901	1	0.194428	-1.421491	0.2018157	0.1566258
902	1	0.2677449	-1.006094	0.1970543	0.1960576
903	1	0.6101141	0.4477918	0.2208897	0.2378749
904	1	0.0928827	-2.278934	0.2239151	0.0842555
905	0	0.6809944	0.7583454	0.2434049	0.217241
906	0	0.2476963	-1.110937	0.2276597	0.1863428
907	1	0.4496825	-0.201954	0.2000341	0.2474681
908	1	0.1570645	-1.680234	0.2332415	0.1323953
909	1	0.0886703	-2.329979	0.2601388	0.0808079
910	1	0.0714369	-2.564823	0.2749316	0.0663337
911	0	0.3046932	-0.825048	0.1936868	0.2118553
912	0	0.4818962	-0.072447	0.225115	0.2496723
913	1	0.10695	-2.122281	0.2523049	0.0955117
914	1	0.7686826	1.2008874	0.2667134	0.1778097
915	0	0.5979058	0.3967466	0.2333046	0.2404145
916	1	0.0865011	-2.357125	0.2657283	0.0790187

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Parameter Code=HBAB7SHY Parameter=HbA1c <7.0% without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
917	0	0.7638206	1.1737415	0.2582521	0.1803987
918	1	0.2677449	-1.006094	0.1970543	0.1960576
919	1	0.1146007	-2.044585	0.2180205	0.1014674
920	0	0.7733875	1.2275388	0.2630713	0.1752593
921	1	0.2573301	-1.059892	0.1996639	0.1911113
922	1	0.1314805	-1.887932	0.2393713	0.1141934
923	0	0.5080982	0.0323957	0.2081097	0.2499344
924	0	0.1902877	-1.448142	0.1994015	0.1540783
925	0	0.7733875	1.2275388	0.2630713	0.1752593
926	1	0.1119241	-2.071236	0.216224	0.0993971
927	1	0.1092542	-2.098382	0.2259498	0.0973177
928	1	0.3388563	-0.668395	0.2243221	0.2240327
929	1	0.0951528	-2.252283	0.2255111	0.0860987
930	0	0.5979058	0.3967466	0.2333046	0.2404145
931	1	0.4886767	-0.045301	0.2291583	0.2498718
932	1	0.3503845	-0.61735	0.1944745	0.2276152
933	1	0.0265113	-3.603313	0.329205	0.0258085
934	1	0.0417216	-3.13412	0.2928373	0.0399809
935	1	0.3448525	-0.641744	0.2186902	0.2259293
936	1	0.1861402	-1.475288	0.2067822	0.151492
937	1	0.2201422	-1.264838	0.2240297	0.1716796
938	1	0.4886767	-0.045301	0.2291583	0.2498718
939	1	0.0633088	-2.69433	0.2418472	0.0593008
940	1	0.0787117	-2.459981	0.2338907	0.0725162
941	0	0.2110455	-1.318635	0.2316056	0.1665053

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=HBAB7SHY Parameter=HbA1c <7.0% without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
942	0	0.0649077	-2.667679	0.2430674	0.0606947
943	1	0.0928827	-2.278934	0.2239151	0.0842555
944	1	0.194428	-1.421491	0.2018157	0.1566258
945	1	0.6582465	0.6554898	0.2287454	0.224958
946	1	0.0750888	-2.511026	0.2629704	0.0694505
947	1	0.1119241	-2.071236	0.216224	0.0993971
948	1	0.3046932	-0.825048	0.1936868	0.2118553
949	1	0.5014361	0.0057444	0.2046979	0.2499979
950	0	0.1785309	-1.526333	0.2366024	0.1466576
951	1	0.1146007	-2.044585	0.2180205	0.1014674
952	1	0.0908477	-2.303328	0.2543119	0.0825944
953	1	0.2989729	-0.852194	0.198015	0.2095881
954	0	0.5972439	0.3939945	0.2152868	0.2405436
955	1	0.0928827	-2.278934	0.2239151	0.0842555
956	0	0.2677449	-1.006094	0.1970543	0.1960576
957	1	0.5471219	0.1890486	0.2281565	0.2477795
958	1	0.0649077	-2.667679	0.2430674	0.0606947
959	0	0.5014361	0.0057444	0.2046979	0.2499979
960	0	0.1119241	-2.071236	0.216224	0.0993971
961	0	0.2290307	-1.213792	0.1987872	0.1765756
962	1	0.4436535	-0.226347	0.2211014	0.2468251
963	1	0.0649077	-2.667679	0.2430674	0.0606947
964	1	0.2989729	-0.852194	0.198015	0.2095881
965	1	0.1570645	-1.680234	0.2332415	0.1323953
966	0	0.6460434	0.6016925	0.2222242	0.2286713

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=HBAB7SHY Parameter=HbA1c <7.0% without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
967	1	0.0438108	-3.083075	0.2634717	0.0418914
968	1	0.0951528	-2.252283	0.2255111	0.0860987
969	1	0.0438108	-3.083075	0.2634717	0.0418914
970	1	0.0278611	-3.552268	0.2980964	0.0270848
971	0	0.6342858	0.5506474	0.237303	0.2319673
972	1	0.0928827	-2.278934	0.2239151	0.0842555
973	1	0.0732587	-2.537677	0.2687264	0.0678919
974	1	0.039623	-3.187917	0.3060698	0.038053
975	0	0.3868205	-0.460697	0.2247758	0.2371904
976	1	0.0417216	-3.13412	0.2928373	0.0399809
977	0	0.8865101	2.0555788	0.2922219	0.1006099
978	0	0.3804019	-0.487843	0.2226113	0.2356963
979	1	0.0159603	-4.121565	0.3232391	0.0157055
980	1	0.125458	-1.941729	0.2494826	0.1097183
981	1	0.29955	-0.849442	0.2192854	0.2098198
982	0	0.7733875	1.2275388	0.2630713	0.1752593
983	1	0.2196701	-1.26759	0.2026046	0.1714152
984	1	0.5080982	0.0323957	0.2081097	0.2499344
985	1	0.344231	-0.644496	0.1976904	0.225736
986	0	0.2939881	-0.876093	0.2250421	0.2075591
987	1	0.3503845	-0.61735	0.1944745	0.2276152
988	1	0.4946498	-0.021402	0.2045968	0.2499714
989	1	0.1567005	-1.682986	0.2121236	0.1321455
990	1	0.1374199	-1.836887	0.2115133	0.1185357
991	1	0.1567005	-1.682986	0.2121236	0.1321455

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=HBAB7SHY Parameter=HbA1c <7.0% without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
992	0	0.5972439	0.3939945	0.2152868	0.2405436
993	1	0.5014361	0.0057444	0.2046979	0.2499979
994	1	0.0185663	-3.967664	0.3231242	0.0182216
995	1	0.2625521	-1.032746	0.1942578	0.1936185
996	1	0.0520534	-2.902028	0.2519068	0.0493438
997	1	0.1092542	-2.098382	0.2259498	0.0973177
998	1	0.5979058	0.3967466	0.2333046	0.2404145
999	1	0.0906207	-2.30608	0.2342491	0.0824086
1000	1	0.7033263	0.8631879	0.2374531	0.2086584
1001	0	0.4436535	-0.226347	0.2211014	0.2468251
1002	1	0.0732587	-2.537677	0.2687264	0.0678919
1003	1	0.4946498	-0.021402	0.2045968	0.2499714
1004	1	0.2243587	-1.240444	0.1961757	0.1740219
1005	0	0.7344051	1.0170886	0.2388218	0.1950542
1006	1	0.3103686	-0.798396	0.1966512	0.21404
1007	1	0.0438108	-3.083075	0.2634717	0.0418914
1008	1	0.1861402	-1.475288	0.2067822	0.151492
1009	1	0.4946498	-0.021402	0.2045968	0.2499714
1010	1	0.0427078	-3.109726	0.2625858	0.0408839
1011	1	0.194428	-1.421491	0.2018157	0.1566258
1012	1	0.5080982	0.0323957	0.2081097	0.2499344
1013	1	0.1146007	-2.044585	0.2180205	0.1014674
1014	1	0.5014361	0.0057444	0.2046979	0.2499979
1015	1	0.5597368	0.2400938	0.2139797	0.2464315
1016	1	0.1902877	-1.448142	0.1994015	0.1540783

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Parameter Code=HBAB7SHY Parameter=HbA1c <7.0% without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
1017	1	0.3503845	-0.61735	0.1944745	0.2276152
1018	1	0.3925043	-0.436798	0.1986966	0.2384447
1019	0	0.6925659	0.8121427	0.246504	0.2129184
1020	1	0.3564746	-0.590698	0.1975861	0.2294005
1021	1	0.1342912	-1.863538	0.2095111	0.1162571
1022	1	0.5597368	0.2400938	0.2139797	0.2464315
1023	0	0.5972439	0.3939945	0.2152868	0.2405436
1024	0	0.344231	-0.644496	0.1976904	0.225736
1025	1	0.0617179	-2.721476	0.2531663	0.0579088

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Parameter Code=HBA_BL7 Parameter=HbA1c <7.0% Study Identifier=NN1218-4131

The GENMOD Procedure

Model Information

Data Set	WORK.ENDPOINT
Distribution	Binomial
Link Function	Logit
Dependent Variable	aval

Number of Observations Read	1025
Number of Observations Used	1025
Number of Events	302
Number of Trials	1025

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Response Profile

Ordered Value	aval	Total Frequency
1	0	302
2	1	723

PROC GENMOD is modeling the probability that aval='0'. One way to change this to model the probability that aval='1' is to

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Parameter Code=HBA_BL7 Parameter=HbA1c <7.0% Study Identifier=NN1218-4131

The GENMOD Procedure

specify the DESCENDING option in the PROC statement.

Parameter Information

Parameter	Effect	TRTPN	REGION1	BOLAD1
Prm1	Intercept			
Prm2	TRTPN	2		
Prm3	TRTPN	3		
Prm4	TRTPN	4		
Prm5	REGION1		ASIA (EXCLUDING JAPAN)	
Prm6	REGION1		EUROPE	
Prm7	REGION1		JAPAN	
Prm8	REGION1		NORTH AMERICA	
Prm9	BOLAD1			BOLUS INSULIN ALGORITHM (SLIDING SCALE)
Prm10	BOLAD1			CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY
Prm11	HBA1CBL			

Criteria For Assessing Goodness Of Fit

Criterion	DF	Value	Value/DF
Log Likelihood		-482.7250	
Full Log Likelihood		-482.7250	
AIC (smaller is better)		981.4499	
AICC (smaller is better)		981.5917	
BIC (smaller is better)		1020.9095	

Algorithm converged.

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The GENMOD Procedure

Analysis Of Maximum Likelihood Parameter Estimates

Parameter		DF	Estimate	Standard Error	Wald 95% Confidence Limits		Wald Chi-Square
Intercept		1	15.0138	1.1955	12.6706	17.3570	157.71
TRTPN	2	1	-0.1131	0.1952	-0.4957	0.2695	0.34
TRTPN	3	1	-0.2037	0.1931	-0.5821	0.1747	1.11
TRTPN	4	0	0.0000	0.0000	0.0000	0.0000	.
REGION1	ASIA (EXCLUDING JAPAN)	1	-0.0148	0.2935	-0.5901	0.5604	0.00
REGION1	EUROPE	1	-0.6127	0.2119	-1.0281	-0.1974	8.36
REGION1	JAPAN	1	0.0267	0.2219	-0.4083	0.4617	0.01
REGION1	NORTH AMERICA	0	0.0000	0.0000	0.0000	0.0000	.
BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	1	0.2192	0.1794	-0.1324	0.5708	1.49
BOLAD1	CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY	0	0.0000	0.0000	0.0000	0.0000	.
HBA1CBL	Scale	1	-2.1632	0.1629	-2.4825	-1.8439	176.31
		0	1.0000	0.0000	1.0000	1.0000	

Analysis Of Maximum Likelihood Parameter Estimates

Parameter		Pr > ChiSq
Intercept		<.0001
TRTPN	2	0.5624
TRTPN	3	0.2914
TRTPN	4	.
REGION1	ASIA (EXCLUDING JAPAN)	0.9597
REGION1	EUROPE	0.0038
REGION1	JAPAN	0.9042
REGION1	NORTH AMERICA	.
BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.2217
BOLAD1	CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY	.
HBA1CBL		<.0001

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=HBA_BL7 Parameter=HbA1c <7.0% Study Identifier=NN1218-4131

The GENMOD Procedure

Analysis Of Maximum Likelihood Parameter Estimates

Parameter Pr > ChiSq

Scale

NOTE: The scale parameter was held fixed.

Coefficients for TRTPN Least Squares Means Using WORK.ENDPOINT Margins

Parameter	Geographic Region Grouping Method 1
Intercept	
Planned Treatment (N) 2	
Planned Treatment (N) 3	
Planned Treatment (N) 4	
Geographic Region Grouping Method 1 ASIA (EXCLUDING JAPAN)	ASIA (EXCLUDING JAPAN)

Coefficients for TRTPN Least Squares Means Using WORK.ENDPOINT Margins

Bolus Adjustment Method at Timepoint 1	Planned Treatment (N)	Row		
		Row1	Row2	Row3
	2	1	1	1
	3	1	1	
	4			1
		0.1307	0.1307	0.1307

Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

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Coefficients for TRTPN Least Squares Means Using WORK.ENDPOINT Margins

Parameter	Geographic Region Grouping Method 1
Geographic Region Grouping Method 1 EUROPE	EUROPE
Geographic Region Grouping Method 1 JAPAN	JAPAN
Geographic Region Grouping Method 1 NORTH AMERICA	NORTH AMERICA
Bolus Adjustment Method at Timepoint 1 BOLUS INSULIN ALGORITHM (SLIDING SCALE)	
Bolus Adjustment Method at Timepoint 1 CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY	
HbA1c at Baseline	

Coefficients for TRTPN Least Squares Means Using WORK.ENDPOINT Margins

	Planned Treatment (N)	Row1	Row2	Row3
Bolus Adjustment Method at Timepoint 1				
		0.3366	0.3366	0.3366
		0.239	0.239	0.239
		0.2937	0.2937	0.2937
BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.5824	0.5824	0.5824
CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0.4176	0.4176	0.4176
		7.4245	7.4245	7.4245

Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

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TRTPN Least Squares Means

Planned Treatment (N)	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
2	WORK.ENDPOINT	-1.2343	0.1465	-8.42	<.0001	0.05	-1.5215	-0.9471
3	WORK.ENDPOINT	-1.3249	0.1453	-9.12	<.0001	0.05	-1.6098	-1.0400
4	WORK.ENDPOINT	-1.1212	0.1414	-7.93	<.0001	0.05	-1.3984	-0.8440

Differences of TRTPN Least Squares Means

Planned Treatment (N)	Planned Treatment (N)	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
2	4	WORK.ENDPOINT	-0.1131	0.1952	-0.58	0.5624	0.05	-0.4957	0.2695
3	4	WORK.ENDPOINT	-0.2037	0.1931	-1.06	0.2914	0.05	-0.5821	0.1747

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) / NovoRapid (meal)	WORK.ENDPOINT	-0.1131	0.1952	-0.58	0.5624	0.05	-0.4957	0.2695

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Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
TRTPN	Faster aspart (post) / NovoRapid (meal)	WORK.ENDPOINT	-0.2037	0.1931	-1.06	0.2914	0.05	-0.5821	0.1747

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
1	1	0.606775	0.4337761	0.2466149	0.2385991
2	0	0.606775	0.4337761	0.2466149	0.2385991
3	0	0.3434768	-0.647839	0.2342134	0.2255005
4	1	0.2964706	-0.864161	0.2350655	0.2085758
5	1	0.2964706	-0.864161	0.2350655	0.2085758
6	1	0.3944473	-0.428656	0.1999822	0.2388586
7	0	0.372355	-0.522127	0.2225916	0.2337068
8	1	0.1674593	-1.603742	0.2345191	0.1394167
9	1	0.084833	-2.378422	0.270033	0.0776364
10	1	0.6340708	0.5497209	0.2022398	0.232025
11	0	0.6570328	0.6500991	0.2521983	0.2253407
12	0	0.7295092	0.9921337	0.2533938	0.1973255
13	0	0.531668	0.1268419	0.2294462	0.2489971
14	0	0.7270104	0.9795071	0.2506236	0.1984663
15	1	0.1506575	-1.729453	0.249326	0.1279598
16	1	0.2343836	-1.183722	0.2317486	0.1794479

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Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
17	1	0.3441219	-0.644979	0.2010382	0.225702
18	0	0.2002778	-1.384559	0.2092737	0.1601666
19	1	0.4217555	-0.315571	0.1932704	0.2438778
20	1	0.1141521	-2.049014	0.2548107	0.1011214
21	1	0.0305555	-3.457177	0.306963	0.0296219
22	1	0.1141521	-2.049014	0.2548107	0.1011214
23	1	0.4776447	-0.089481	0.226013	0.2495002
24	0	0.237174	-1.168236	0.2040092	0.1809225
25	1	0.0780578	-2.469033	0.2625182	0.0719648
26	1	0.1674593	-1.603742	0.2345191	0.1394167
27	1	0.0951159	-2.25271	0.2542448	0.0860689
28	1	0.4783582	-0.086621	0.1967323	0.2495316
29	1	0.084833	-2.378422	0.270033	0.0776364
30	0	0.32121	-0.748217	0.1968874	0.2180341
31	0	0.6853935	0.7786704	0.2143023	0.2156293
32	1	0.084833	-2.378422	0.270033	0.0776364
33	1	0.1674593	-1.603742	0.2345191	0.1394167
34	0	0.32121	-0.748217	0.1968874	0.2180341
35	1	0.3233432	-0.73845	0.2226563	0.2187924
36	0	0.6334071	0.5468613	0.2382114	0.2322026
37	1	0.3694089	-0.534753	0.2255332	0.232946
38	1	0.1998202	-1.387419	0.2298851	0.1598921
39	0	0.531668	0.1268419	0.2294462	0.2489971
40	1	0.1394261	-1.820064	0.2401711	0.1199865
41	0	0.4776447	-0.089481	0.226013	0.2495002

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=HBA_BL7 Parameter=HbA1c <7.0% Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
42	0	0.5856532	0.3460245	0.2031081	0.2426635
43	0	0.6853935	0.7786704	0.2143023	0.2156293
44	0	0.5825859	0.333398	0.1980349	0.2431796
45	0	0.4471153	-0.212333	0.2002504	0.2472032
46	1	0.2151854	-1.293948	0.2118294	0.1688806
47	0	0.8499965	1.7345734	0.2548594	0.1275025
48	0	0.4783582	-0.086621	0.1967323	0.2495316
49	1	0.1661021	-1.613508	0.2189906	0.1385122
50	0	0.8202807	1.5182505	0.2450889	0.1474203
51	0	0.8499965	1.7345734	0.2548594	0.1275025
52	1	0.4783582	-0.086621	0.1967323	0.2495316
53	0	0.6369955	0.5623475	0.2081437	0.2312322
54	1	0.3700753	-0.531894	0.1944059	0.2331196
55	0	0.2002778	-1.384559	0.2092737	0.1601666
56	0	0.3944473	-0.428656	0.1999822	0.2388586
57	1	0.1678584	-1.600882	0.2156432	0.139682
58	1	0.1253278	-1.942916	0.2326036	0.1096207
59	1	0.2759702	-0.96454	0.2006651	0.1998107
60	0	0.0640141	-2.682497	0.2607621	0.0599163
61	0	0.8363525	1.6313356	0.2393298	0.136867
62	1	0.1808987	-1.510271	0.2177578	0.1481744
63	1	0.237174	-1.168236	0.2040092	0.1809225
64	0	0.8045554	1.4150127	0.2300903	0.157246
65	0	0.6853935	0.7786704	0.2143023	0.2156293
66	1	0.6853935	0.7786704	0.2143023	0.2156293

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=HBA_BL7 Parameter=HbA1c <7.0% Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
67	1	0.3239692	-0.73559	0.1971315	0.2190132
68	0	0.6853935	0.7786704	0.2143023	0.2156293
69	0	0.5548565	0.2203129	0.2047129	0.2469908
70	1	0.0247589	-3.6735	0.3195016	0.0241459
71	0	0.6074571	0.4366358	0.2088234	0.238453
72	0	0.5292354	0.117075	0.1951039	0.2491453
73	0	0.53238	0.1297016	0.1992808	0.2489515
74	1	0.5825859	0.333398	0.1980349	0.2431796
75	0	0.3944473	-0.428656	0.1999822	0.2388586
76	0	0.4217555	-0.315571	0.1932704	0.2438778
77	0	0.53238	0.1297016	0.1992808	0.2489515
78	1	0.7275776	0.9823668	0.2141485	0.1982084
79	1	0.0696625	-2.591885	0.2609877	0.0648096
80	0	0.7861592	1.3019275	0.2360395	0.1681129
81	1	0.0632617	-2.695123	0.2671903	0.0592597
82	1	0.2970674	-0.861302	0.2033978	0.2088184
83	0	0.7275776	0.9823668	0.2141485	0.1982084
84	1	0.6340708	0.5497209	0.2022398	0.232025
85	0	0.2970674	-0.861302	0.2033978	0.2088184
86	1	0.0640141	-2.682497	0.2607621	0.0599163
87	1	0.2151854	-1.293948	0.2118294	0.1688806
88	0	0.53238	0.1297016	0.1992808	0.2489515
89	0	0.863852	1.8476585	0.2492926	0.1176118
90	0	0.6369955	0.5623475	0.2081437	0.2312322
91	1	0.2759702	-0.96454	0.2006651	0.1998107

Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

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Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
92	1	0.4217555	-0.315571	0.1932704	0.2438778
93	1	0.3700753	-0.531894	0.1944059	0.2331196
94	1	0.32121	-0.748217	0.1968874	0.2180341
95	0	0.6074571	0.4366358	0.2088234	0.238453
96	0	0.4217555	-0.315571	0.1932704	0.2438778
97	1	0.5856532	0.3460245	0.2031081	0.2426635
98	1	0.2343836	-1.183722	0.2317486	0.1794479
99	1	0.4471153	-0.212333	0.2002504	0.2472032
100	1	0.277926	-0.954773	0.2239094	0.2006831
101	0	0.9072327	2.2803044	0.2710633	0.0841616
102	1	0.4464085	-0.215193	0.2358997	0.2471279
103	1	0.1674593	-1.603742	0.2345191	0.1394167
104	0	0.6826645	0.7660439	0.2076412	0.2166337
105	1	0.1657064	-1.616368	0.2413635	0.1382478
106	1	0.3205868	-0.751076	0.2264549	0.2178109
107	0	0.3700753	-0.531894	0.1944059	0.2331196
108	0	0.1678584	-1.600882	0.2156432	0.139682
109	0	0.6369955	0.5623475	0.2081437	0.2312322
110	0	0.2964706	-0.864161	0.2350655	0.2085758
111	0	0.7677821	1.1958301	0.2581515	0.1782927
112	0	0.7270104	0.9795071	0.2506236	0.1984663
113	0	0.5818904	0.3305383	0.2334677	0.243294
114	0	0.3205868	-0.751076	0.2264549	0.2178109
115	0	0.103206	-2.162099	0.2623018	0.0925545
116	1	0.1674593	-1.603742	0.2345191	0.1394167

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Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
117	0	0.2343836	-1.183722	0.2317486	0.1794479
118	1	0.0694774	-2.594745	0.2785036	0.0646503
119	0	0.5285228	0.1142154	0.2297835	0.2491864
120	0	0.6570328	0.6500991	0.2521983	0.2253407
121	1	0.1978089	-1.400045	0.2360433	0.1586806
122	0	0.3937645	-0.431516	0.2344928	0.238714
123	1	0.372355	-0.522127	0.2225916	0.2337068
124	1	0.0180584	-3.99592	0.3481796	0.0177323
125	0	0.1804754	-1.51313	0.2442136	0.147904
126	1	0.0780578	-2.469033	0.2625182	0.0719648
127	0	0.236657	-1.171096	0.2263313	0.1806505
128	1	0.1998202	-1.387419	0.2298851	0.1598921
129	1	0.0522119	-2.89882	0.2718241	0.0494859
130	1	0.1506575	-1.729453	0.249326	0.1279598
131	1	0.0162042	-4.106146	0.3455194	0.0159417
132	1	0.236657	-1.171096	0.2263313	0.1806505
133	1	0.0423708	-3.118002	0.2914221	0.0405755
134	1	0.32121	-0.748217	0.1968874	0.2180341
135	1	0.4210583	-0.31843	0.2257864	0.2437682
136	1	0.3205868	-0.751076	0.2264549	0.2178109
137	1	0.7295092	0.9921337	0.2533938	0.1973255
138	1	0.32121	-0.748217	0.1968874	0.2180341
139	1	0.3434768	-0.647839	0.2342134	0.2255005
140	1	0.3694089	-0.534753	0.2255332	0.232946
141	0	0.277926	-0.954773	0.2239094	0.2006831

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Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
142	0	0.7295092	0.9921337	0.2533938	0.1973255
143	1	0.5292354	0.117075	0.1951039	0.2491453
144	1	0.6074571	0.4366358	0.2088234	0.238453
145	1	0.2970674	-0.861302	0.2033978	0.2088184
146	1	0.2759702	-0.96454	0.2006651	0.1998107
147	1	0.6853935	0.7786704	0.2143023	0.2156293
148	1	0.1397696	-1.817205	0.2230231	0.1202341
149	1	0.5292354	0.117075	0.1951039	0.2491453
150	1	0.2539558	-1.077625	0.2070163	0.1894622
151	0	0.2785002	-0.951913	0.1999372	0.2009379
152	1	0.1382584	-1.829831	0.2271167	0.119143
153	0	0.863852	1.8476585	0.2492926	0.1176118
154	1	0.0424869	-3.115142	0.2833913	0.0406818
155	1	0.2348971	-1.180863	0.2056675	0.1797205
156	1	0.3441219	-0.644979	0.2010382	0.225702
157	1	0.4783582	-0.086621	0.1967323	0.2495316
158	1	0.4783582	-0.086621	0.1967323	0.2495316
159	0	0.4471153	-0.212333	0.2002504	0.2472032
160	1	0.2970674	-0.861302	0.2033978	0.2088184
161	0	0.4471153	-0.212333	0.2002504	0.2472032
162	0	0.7705318	1.2113163	0.2296113	0.1768126
163	0	0.3239692	-0.73559	0.1971315	0.2190132
164	0	0.6853935	0.7786704	0.2143023	0.2156293
165	1	0.5825859	0.333398	0.1980349	0.2431796
166	1	0.1678584	-1.600882	0.2156432	0.139682

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Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
167	0	0.5292354	0.117075	0.1951039	0.2491453
168	1	0.2348971	-1.180863	0.2056675	0.1797205
169	1	0.1661021	-1.613508	0.2189906	0.1385122
170	1	0.3441219	-0.644979	0.2010382	0.225702
171	1	0.6369955	0.5623475	0.2081437	0.2312322
172	0	0.5548565	0.2203129	0.2047129	0.2469908
173	1	0.0850553	-2.375562	0.2508261	0.0778209
174	1	0.0632617	-2.695123	0.2671903	0.0592597
175	1	0.32121	-0.748217	0.1968874	0.2180341
176	1	0.2759702	-0.96454	0.2006651	0.1998107
177	1	0.1678584	-1.600882	0.2156432	0.139682
178	1	0.0463299	-3.024531	0.283035	0.0441834
179	1	0.2002778	-1.384559	0.2092737	0.1601666
180	0	0.4752084	-0.099248	0.1935048	0.2493854
181	1	0.3944473	-0.428656	0.1999822	0.2388586
182	1	0.5292354	0.117075	0.1951039	0.2491453
183	1	0.4783582	-0.086621	0.1967323	0.2495316
184	1	0.0424869	-3.115142	0.2833913	0.0406818
185	1	0.2002778	-1.384559	0.2092737	0.1601666
186	1	0.32121	-0.748217	0.1968874	0.2180341
187	1	0.103471	-2.159239	0.2413373	0.0927647
188	0	0.5009975	0.0039899	0.2018375	0.249999
189	1	0.0953623	-2.249851	0.2404297	0.0862684
190	1	0.1808987	-1.510271	0.2177578	0.1481744
191	1	0.5818904	0.3305383	0.2334677	0.243294

Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=HBA_BL7 Parameter=HbA1c <7.0% Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
192	1	0.5292354	0.117075	0.1951039	0.2491453
193	1	0.0463299	-3.024531	0.283035	0.0441834
194	1	0.8363525	1.6313356	0.2393298	0.136867
195	0	0.1157274	-2.033528	0.2313168	0.1023346
196	1	0.5285228	0.1142154	0.2297835	0.2491864
197	1	0.0419762	-3.127769	0.2906543	0.0402142
198	0	0.2759702	-0.96454	0.2006651	0.1998107
199	0	0.4471153	-0.212333	0.2002504	0.2472032
200	1	0.0515906	-2.911446	0.2786932	0.048929
201	1	0.103471	-2.159239	0.2413373	0.0927647
202	1	0.32121	-0.748217	0.1968874	0.2180341
203	1	0.5856532	0.3460245	0.2031081	0.2426635
204	1	0.5009975	0.0039899	0.2018375	0.249999
205	1	0.4783582	-0.086621	0.1967323	0.2495316
206	1	0.0568822	-2.808208	0.2717467	0.0536466
207	1	0.103471	-2.159239	0.2413373	0.0927647
208	1	0.0953623	-2.249851	0.2404297	0.0862684
209	1	0.3441219	-0.644979	0.2010382	0.225702
210	1	0.0942786	-2.262477	0.2458143	0.0853902
211	1	0.0050604	-5.281231	0.4156927	0.0050348
212	1	0.0522119	-2.89882	0.2718241	0.0494859
213	1	0.2785002	-0.951913	0.1999372	0.2009379
214	1	0.1154351	-2.036387	0.2467709	0.1021098
215	1	0.53238	0.1297016	0.1992808	0.2489515
216	1	0.3434768	-0.647839	0.2342134	0.2255005

Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=HBA_BL7 Parameter=HbA1c <7.0% Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
217	0	0.4210583	-0.31843	0.2257864	0.2437682
218	1	0.1250147	-1.945776	0.255377	0.109386
219	1	0.0514509	-2.914306	0.2909343	0.0488037
220	1	0.3205868	-0.751076	0.2264549	0.2178109
221	0	0.863852	1.8476585	0.2492926	0.1176118
222	0	0.6074571	0.4366358	0.2088234	0.238453
223	1	0.7300731	0.9949933	0.2214904	0.1970664
224	0	0.3730236	-0.519267	0.1956467	0.233877
225	0	0.6074571	0.4366358	0.2088234	0.238453
226	0	0.6074571	0.4366358	0.2088234	0.238453
227	1	0.4783582	-0.086621	0.1967323	0.2495316
228	1	0.0942786	-2.262477	0.2458143	0.0853902
229	1	0.0276413	-3.560415	0.3157412	0.0268772
230	0	0.3239692	-0.73559	0.1971315	0.2190132
231	0	0.0424869	-3.115142	0.2833913	0.0406818
232	1	0.2759702	-0.96454	0.2006651	0.1998107
233	1	0.0040917	-5.494695	0.4312653	0.004075
234	1	0.2151854	-1.293948	0.2118294	0.1688806
235	1	0.1397696	-1.817205	0.2230231	0.1202341
236	1	0.8380733	1.6439621	0.248275	0.1357064
237	1	0.1678584	-1.600882	0.2156432	0.139682
238	1	0.5292354	0.117075	0.1951039	0.2491453
239	1	0.237174	-1.168236	0.2040092	0.1809225
240	1	0.0568822	-2.808208	0.2717467	0.0536466
241	1	0.5548565	0.2203129	0.2047129	0.2469908

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=HBA_BL7 Parameter=HbA1c <7.0% Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
242	1	0.0463299	-3.024531	0.283035	0.0441834
243	0	0.4217555	-0.315571	0.1932704	0.2438778
244	1	0.0515906	-2.911446	0.2786932	0.048929
245	0	0.3239692	-0.73559	0.1971315	0.2190132
246	0	0.1333861	-1.871346	0.2669012	0.1155942
247	0	0.1604312	-1.655023	0.2610038	0.134693
248	0	0.075321	-2.507688	0.2888173	0.0696477
249	1	0.2677528	-1.006054	0.2489338	0.1960612
250	1	0.1115463	-2.075042	0.2744272	0.0991038
251	0	0.0744463	-2.520315	0.2894149	0.068904
252	1	0.1208473	-1.984431	0.2739576	0.1062432
253	0	0.4680098	-0.128136	0.2551724	0.2489766
254	0	0.6273425	0.5208329	0.2669619	0.2337839
255	0	0.6482702	0.6114442	0.2700522	0.228016
256	1	0.1348524	-1.858719	0.2684287	0.1166672
257	1	0.0293495	-3.498692	0.3340535	0.0284881
258	1	0.1621392	-1.642396	0.263303	0.1358501
259	1	0.1115463	-2.075042	0.2744272	0.0991038
260	1	0.0217612	-3.805626	0.3470886	0.0212876
261	1	0.0608458	-2.736638	0.2983246	0.0571435
262	1	0.1621392	-1.642396	0.263303	0.1358501
263	0	0.0818797	-2.417077	0.2878166	0.0751754
264	1	0.1103011	-2.087669	0.2736427	0.0981348
265	1	0.0907929	-2.303992	0.2811677	0.0825495
266	1	0.0073925	-4.899867	0.4129872	0.0073379

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=HBA_BL7 Parameter=HbA1c <7.0% Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
267	1	0.0173856	-4.034575	0.3627178	0.0170833
268	1	0.1103011	-2.087669	0.2736427	0.0981348
269	0	0.1457778	-1.768108	0.2682465	0.1245266
270	1	0.4147268	-0.344459	0.2532246	0.2427285
271	1	0.8709497	1.9093818	0.317065	0.1123963
272	1	0.1348524	-1.858719	0.2684287	0.1166672
273	1	0.1937112	-1.426074	0.2591019	0.1561872
274	1	0.0670196	-2.6334	0.2958503	0.0625279
275	1	0.1333861	-1.871346	0.2669012	0.1155942
276	0	0.5220325	0.088187	0.2581357	0.2495146
277	1	0.6273425	0.5208329	0.2669619	0.2337839
278	0	0.6273425	0.5208329	0.2669619	0.2337839
279	0	0.3348136	-0.686493	0.2538419	0.2227134
280	1	0.0670196	-2.6334	0.2958503	0.0625279
281	1	0.0501953	-2.940334	0.3060128	0.0476758
282	0	0.8933766	2.1257047	0.3270909	0.0952549
283	1	0.9281325	2.5583506	0.3485647	0.0667026
284	0	0.8140791	1.4767359	0.2986742	0.1513543
285	1	0.0615713	-2.724011	0.2970929	0.0577803
286	1	0.0495968	-2.952961	0.3078392	0.0471369
287	0	0.6736036	0.7245293	0.2625093	0.2198618
288	1	0.0495968	-2.952961	0.3078392	0.0471369
289	1	0.0059631	-5.11619	0.4261854	0.0059275
290	1	2.6487E-8	-17.4466	1.3001506	2.6487E-8
291	0	0.6736036	0.7245293	0.2625093	0.2198618

Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=HBA_BL7 Parameter=HbA1c <7.0% Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
292	1	0.1115463	-2.075042	0.2744272	0.0991038
293	0	0.3845759	-0.470171	0.2540158	0.2366773
294	1	0.1103011	-2.087669	0.2736427	0.0981348
295	1	0.1348524	-1.858719	0.2684287	0.1166672
296	1	0.0608458	-2.736638	0.2983246	0.0571435
297	0	0.5188811	0.0755605	0.2496524	0.2496435
298	0	0.7218142	0.9534787	0.2793323	0.2007984
299	1	0.2082573	-1.335462	0.2595294	0.1648862
300	1	0.3348136	-0.686493	0.2538419	0.2227134
301	1	0.7192718	0.9408522	0.2686405	0.2019199
302	1	0.0176026	-4.021949	0.3584748	0.0172928
303	1	0.2702356	-0.993428	0.2536472	0.1972083
304	1	0.1604312	-1.655023	0.2610038	0.134693
305	1	0.1748286	-1.551785	0.2634207	0.1442635
306	1	0.1748286	-1.551785	0.2634207	0.1442635
307	1	0.3604507	-0.573408	0.2460059	0.230526
308	1	0.036181	-3.282369	0.3236965	0.034872
309	1	0.0996828	-2.200754	0.2804998	0.0897461
310	1	0.5445809	0.1787983	0.2607184	0.2480125
311	0	0.5220325	0.088187	0.2581357	0.2495146
312	1	0.1604312	-1.655023	0.2610038	0.134693
313	1	0.2275184	-1.222377	0.25197	0.1757538
314	1	0.0331507	-3.37298	0.3255695	0.0320517
315	1	0.3348136	-0.686493	0.2538419	0.2227134
316	1	0.3604507	-0.573408	0.2460059	0.230526

Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=HBA_BL7 Parameter=HbA1c <7.0% Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
317	1	0.1937112	-1.426074	0.2591019	0.1561872
318	1	0.246171	-1.119139	0.2566153	0.1855708
319	1	0.1348524	-1.858719	0.2684287	0.1166672
320	1	0.036181	-3.282369	0.3236965	0.034872
321	0	0.2275184	-1.222377	0.25197	0.1757538
322	1	0.2702356	-0.993428	0.2536472	0.1972083
323	1	0.2082573	-1.335462	0.2595294	0.1648862
324	0	0.5724572	0.2918834	0.2529633	0.24475
325	1	0.246171	-1.119139	0.2566153	0.1855708
326	1	0.1748286	-1.551785	0.2634207	0.1442635
327	0	0.021494	-3.818252	0.350917	0.021032
328	1	0.1333861	-1.871346	0.2669012	0.1155942
329	1	0.1917467	-1.4387	0.2560088	0.1549799
330	1	0.0615713	-2.724011	0.2970929	0.0577803
331	0	0.3122264	-0.789731	0.2469374	0.2147411
332	0	0.5975149	0.3951212	0.2649259	0.2404908
333	1	0.2297452	-1.209751	0.2558709	0.1769623
334	1	0.2082573	-1.335462	0.2595294	0.1648862
335	1	0.0053289	-5.229275	0.4303486	0.0053005
336	1	0.1604312	-1.655023	0.2610038	0.134693
337	0	0.1604312	-1.655023	0.2610038	0.134693
338	0	0.5975149	0.3951212	0.2649259	0.2404908
339	0	0.1917467	-1.4387	0.2560088	0.1549799
340	0	0.6763736	0.7371558	0.2727309	0.2188924
341	0	0.246171	-1.119139	0.2566153	0.1855708

Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=HBA_BL7 Parameter=HbA1c <7.0% Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
342	0	0.6736036	0.7245293	0.2625093	0.2198618
343	0	0.8933766	2.1257047	0.3270909	0.0952549
344	1	0.0744463	-2.520315	0.2894149	0.068904
345	1	0.0293495	-3.498692	0.3340535	0.0284881
346	1	0.6763736	0.7371558	0.2727309	0.2188924
347	1	0.760819	1.1571751	0.2755995	0.1819734
348	0	0.6958826	0.8277671	0.2760461	0.21163
349	1	0.0185077	-3.970888	0.3092134	0.0181652
350	0	0.4494764	-0.202786	0.2021814	0.2474474
351	1	0.1043599	-2.149693	0.2208751	0.0934689
352	0	0.5033841	0.0135365	0.2065253	0.2499885
353	0	0.3462798	-0.635432	0.197279	0.2263701
354	0	0.1823176	-1.500724	0.2034017	0.1490779
355	0	0.5849056	0.3429446	0.2092218	0.242791
356	0	0.2778818	-0.954993	0.1949336	0.2006635
357	1	0.5026692	0.0106769	0.2284364	0.2499929
358	1	0.3745888	-0.51258	0.213249	0.234272
359	1	0.1993282	-1.390499	0.2111926	0.1595965
360	0	0.0700971	-2.585198	0.243433	0.0651835
361	1	0.1164135	-2.026841	0.2210509	0.1028614
362	1	0.1040929	-2.152552	0.2297216	0.0932576
363	1	0.5309011	0.123762	0.2228156	0.2490451
364	1	0.2984657	-0.854615	0.21459	0.2093839
365	1	0.2984657	-0.854615	0.21459	0.2093839
366	0	0.1818916	-1.503584	0.2168449	0.1488071

Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=HBA_BL7 Parameter=HbA1c <7.0% Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
367	0	0.3960457	-0.421969	0.2192131	0.2391935
368	1	0.236101	-1.174176	0.2091184	0.1803573
369	1	0.1260627	-1.93623	0.224331	0.1101709
370	1	0.0077547	-4.851666	0.3615843	0.0076946
371	1	0.1040929	-2.152552	0.2297216	0.0932576
372	1	0.2798459	-0.945226	0.2092586	0.2015322
373	1	0.0959408	-2.243164	0.2268718	0.0867361
374	1	0.5340444	0.1363885	0.2280029	0.248841
375	1	0.0700971	-2.585198	0.243433	0.0651835
376	1	0.064416	-2.67581	0.2414083	0.0602665
377	1	0.0347309	-3.324778	0.2692022	0.0335246
378	0	0.771712	1.2180032	0.2710204	0.1761726
379	0	0.1993282	-1.390499	0.2111926	0.1595965
380	0	0.2798459	-0.945226	0.2092586	0.2015322
381	1	0.0525439	-2.892133	0.2499555	0.049783
382	1	0.1405755	-1.810518	0.216303	0.1208141
383	0	0.5842111	0.3400849	0.2291086	0.2429085
384	1	0.2557687	-1.068078	0.1976967	0.1903511
385	1	0.4768763	-0.092561	0.2175631	0.2494653
386	1	0.1164135	-2.026841	0.2210509	0.1028614
387	0	0.0085909	-4.748428	0.3514925	0.0085171
388	0	0.0149193	-4.19007	0.3143625	0.0146967
389	1	0.0959408	-2.243164	0.2268718	0.0867361
390	0	0.1687945	-1.594195	0.2127	0.1403029
391	1	0.0096095	-4.635343	0.3483938	0.0095172

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=HBA_BL7 Parameter=HbA1c <7.0% Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
392	1	0.2018112	-1.375012	0.2043211	0.1610835
393	0	0.7319502	1.0045399	0.2439652	0.1961991
394	1	0.1823176	-1.500724	0.2034017	0.1490779
395	1	0.2990648	-0.851755	0.1968148	0.209625
396	0	0.4271723	-0.293398	0.2046043	0.2446961
397	1	0.0700971	-2.585198	0.243433	0.0651835
398	1	0.3967299	-0.419109	0.1990797	0.2393353
399	1	0.1823176	-1.500724	0.2034017	0.1490779
400	1	0.3967299	-0.419109	0.1990797	0.2393353
401	0	0.0858011	-2.366016	0.2287327	0.0784393
402	1	0.375259	-0.509721	0.2019359	0.2344397
403	1	0.1154126	-2.036608	0.2185967	0.1020925
404	1	0.2389055	-1.158689	0.2017638	0.1818297
405	1	0.5033841	0.0135365	0.2065253	0.2499885
406	1	0.0961891	-2.240304	0.2262946	0.0869368
407	0	0.659823	0.6625053	0.2261941	0.2244566
408	1	0.0249905	-3.663953	0.2909689	0.0243659
409	0	0.3745888	-0.51258	0.213249	0.234272
410	1	0.2163168	-1.287261	0.2148642	0.1695239
411	0	0.5340444	0.1363885	0.2280029	0.248841
412	1	0.2984657	-0.854615	0.21459	0.2093839
413	0	0.2383859	-1.161549	0.2091468	0.1815581
414	1	0.0778364	-2.472113	0.238587	0.0717779
415	1	0.064416	-2.67581	0.2414083	0.0602665
416	0	0.4233872	-0.308884	0.2134278	0.2441305

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=HBA_BL7 Parameter=HbA1c <7.0% Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
417	0	0.8056047	1.4216996	0.2732631	0.1566058
418	1	0.6868336	0.7853573	0.2515411	0.2150932
419	1	0.2798459	-0.945226	0.2092586	0.2015322
420	0	0.9383412	2.7224969	0.3224786	0.057857
421	0	0.5347559	0.1392482	0.2136001	0.248792
422	0	0.8376549	1.6408822	0.2620267	0.1359891
423	1	0.199785	-1.387639	0.2008004	0.1598709
424	0	0.9629731	3.2583806	0.3646671	0.0356559
425	1	0.1823176	-1.500724	0.2034017	0.1490779
426	0	0.2804226	-0.942367	0.2005018	0.2017858
427	0	0.7493505	1.0951512	0.2439097	0.1878243
428	0	0.0702838	-2.582339	0.2374496	0.065344
429	1	0.2804226	-0.942367	0.2005018	0.2017858
430	0	0.2366172	-1.171316	0.197217	0.1806295
431	1	0.0645885	-2.67295	0.2431568	0.0604168
432	0	0.4775897	-0.089701	0.1993128	0.2494978
433	1	0.2990648	-0.851755	0.1968148	0.209625
434	1	0.3723036	-0.522347	0.1944241	0.2336936
435	0	0.7294657	0.9919134	0.2320069	0.1973455
436	0	0.2778818	-0.954993	0.1949336	0.2006635
437	0	0.5026692	0.0106769	0.2284364	0.2499929
438	1	0.2366172	-1.171316	0.197217	0.1806295
439	1	0.1260627	-1.93623	0.224331	0.1101709
440	0	0.139057	-1.823144	0.2189484	0.1197201
441	0	0.3967299	-0.419109	0.1990797	0.2393353

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Parameter Code=HBA_BL7 Parameter=HbA1c <7.0% Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
442	1	0.0855771	-2.368875	0.2361152	0.0782537
443	0	0.4240855	-0.306024	0.1962084	0.244237
444	1	0.0638298	-2.685577	0.2450012	0.0597556
445	1	0.0700971	-2.585198	0.243433	0.0651835
446	1	0.2984657	-0.854615	0.21459	0.2093839
447	1	0.1691961	-1.591335	0.2081259	0.1405688
448	1	0.0427598	-3.108456	0.2592458	0.0409314
449	0	0.9589986	3.1522831	0.3711692	0.0393203
450	1	0.0858011	-2.366016	0.2287327	0.0784393
451	1	0.0225946	-3.767191	0.3017347	0.0220841
452	1	0.0423618	-3.118222	0.2661586	0.0405673
453	1	0.064416	-2.67581	0.2414083	0.0602665
454	1	0.1518832	-1.719907	0.2200174	0.1288147
455	1	0.0427598	-3.108456	0.2592458	0.0409314
456	0	0.1674286	-1.603962	0.2056159	0.1393963
457	1	0.057242	-2.801521	0.2515942	0.0539654
458	1	0.0281651	-3.541101	0.2797536	0.0273719
459	1	0.0959408	-2.243164	0.2268718	0.0867361
460	0	0.8060522	1.4245592	0.2513635	0.1563321
461	1	0.0780419	-2.469254	0.2354026	0.0719514
462	1	0.0307542	-3.45049	0.2803653	0.0298084
463	1	0.042246	-3.121082	0.2658693	0.0404612
464	1	0.3462798	-0.635432	0.197279	0.2263701
465	1	0.3716355	-0.525207	0.2104755	0.2335226
466	1	0.3260635	-0.726044	0.2005595	0.2197461

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
467	1	0.3723036	-0.522347	0.1944241	0.2336936
468	1	0.0645885	-2.67295	0.2431568	0.0604168
469	1	0.2804226	-0.942367	0.2005018	0.2017858
470	1	0.064416	-2.67581	0.2414083	0.0602665
471	1	0.0308396	-3.44763	0.2791865	0.0298885
472	1	0.2018112	-1.375012	0.2043211	0.1610835
473	1	0.1040929	-2.152552	0.2297216	0.0932576
474	1	0.0228751	-3.754565	0.2969926	0.0223518
475	1	0.1691961	-1.591335	0.2081259	0.1405688
476	1	0.1823176	-1.500724	0.2034017	0.1490779
477	1	0.4240855	-0.306024	0.1962084	0.244237
478	0	0.4271723	-0.293398	0.2046043	0.2446961
479	1	0.3462798	-0.635432	0.197279	0.2263701
480	1	0.0526864	-2.889273	0.2527439	0.0499105
481	1	0.636283	0.5592675	0.2158567	0.2314269
482	1	0.375259	-0.509721	0.2019359	0.2344397
483	1	0.042877	-3.105596	0.2629915	0.0410386
484	0	0.2389055	-1.158689	0.2017638	0.1818297
485	0	0.5849056	0.3429446	0.2092218	0.242791
486	1	0.0467535	-3.014985	0.2571032	0.0445676
487	1	0.1691961	-1.591335	0.2081259	0.1405688
488	1	0.0249905	-3.663953	0.2909689	0.0243659
489	0	0.4494764	-0.202786	0.2021814	0.2474474
490	1	0.0526864	-2.889273	0.2527439	0.0499105
491	0	0.5879679	0.3555711	0.2197778	0.2422616

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Parameter Code=HBA_BL7 Parameter=HbA1c <7.0% Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
492	1	0.1154126	-2.036608	0.2185967	0.1020925
493	1	0.4240855	-0.306024	0.1962084	0.244237
494	1	0.0380044	-3.231308	0.2678772	0.0365601
495	1	0.3462798	-0.635432	0.197279	0.2263701
496	0	0.3723036	-0.522347	0.1944241	0.2336936
497	1	0.1409214	-1.807658	0.2131115	0.1210625
498	1	0.3260635	-0.726044	0.2005595	0.2197461
499	1	0.5849056	0.3429446	0.2092218	0.242791
500	0	0.636283	0.5592675	0.2158567	0.2314269
501	1	0.4775897	-0.089701	0.1993128	0.2494978
502	1	0.0185077	-3.970888	0.3092134	0.0181652
503	1	0.7065793	0.8788283	0.2346539	0.207325
504	1	0.116708	-2.023981	0.2191973	0.1030872
505	0	0.323295	-0.73867	0.1939962	0.2187754
506	0	0.8376549	1.6408822	0.2620267	0.1359891
507	1	0.116708	-2.023981	0.2191973	0.1030872
508	1	0.5347559	0.1392482	0.2136001	0.248792
509	1	0.042877	-3.105596	0.2629915	0.0410386
510	1	0.042877	-3.105596	0.2629915	0.0410386
511	0	0.4775897	-0.089701	0.1993128	0.2494978
512	0	0.7722154	1.2208629	0.2536131	0.1758988
513	1	0.0780419	-2.469254	0.2354026	0.0719514
514	1	0.0789553	-2.456627	0.2343114	0.0727213
515	0	0.1823176	-1.500724	0.2034017	0.1490779
516	1	0.1043599	-2.149693	0.2208751	0.0934689

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
517	1	0.0789553	-2.456627	0.2343114	0.0727213
518	1	0.0645885	-2.67295	0.2431568	0.0604168
519	0	0.684729	0.7755904	0.2234843	0.2158752
520	1	0.2018112	-1.375012	0.2043211	0.1610835
521	1	0.1522519	-1.717047	0.2081168	0.1290713
522	1	0.4775897	-0.089701	0.1993128	0.2494978
523	1	0.1154126	-2.036608	0.2185967	0.1020925
524	0	0.0526864	-2.889273	0.2527439	0.0499105
525	0	0.1043599	-2.149693	0.2208751	0.0934689
526	1	0.0702838	-2.582339	0.2374496	0.065344
527	1	0.1409214	-1.807658	0.2131115	0.1210625
528	1	0.0702838	-2.582339	0.2374496	0.065344
529	0	0.7493505	1.0951512	0.2439097	0.1878243
530	0	0.3462798	-0.635432	0.197279	0.2263701
531	1	0.7294657	0.9919134	0.2320069	0.1973455
532	1	0.1823176	-1.500724	0.2034017	0.1490779
533	1	0.2018112	-1.375012	0.2043211	0.1610835
534	1	0.4807408	-0.077075	0.2085151	0.2496291
535	0	0.659823	0.6625053	0.2261941	0.2244566
536	1	0.1674286	-1.603962	0.2056159	0.1393963
537	1	0.5849056	0.3429446	0.2092218	0.242791
538	1	0.1674286	-1.603962	0.2056159	0.1393963
539	1	0.2990648	-0.851755	0.1968148	0.209625
540	1	0.0119363	-4.41616	0.3406239	0.0117939
541	1	0.1263781	-1.93337	0.2139715	0.1104066

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
542	1	0.1154126	-2.036608	0.2185967	0.1020925
543	1	0.2366172	-1.171316	0.197217	0.1806295
544	0	0.216802	-1.284401	0.1999067	0.1697989
545	1	0.0702838	-2.582339	0.2374496	0.065344
546	1	0.1043599	-2.149693	0.2208751	0.0934689
547	1	0.5033841	0.0135365	0.2065253	0.2499885
548	1	0.0789553	-2.456627	0.2343114	0.0727213
549	1	0.0702838	-2.582339	0.2374496	0.065344
550	1	0.0638298	-2.685577	0.2450012	0.0597556
551	1	0.2778818	-0.954993	0.1949336	0.2006635
552	1	0.0573965	-2.798662	0.2469347	0.0541022
553	1	0.0858011	-2.366016	0.2287327	0.0784393
554	1	0.0344049	-3.334545	0.2775681	0.0332212
555	1	0.1043599	-2.149693	0.2208751	0.0934689
556	1	0.1823176	-1.500724	0.2034017	0.1490779
557	1	0.0077768	-4.848806	0.3678758	0.0077163
558	1	0.2990648	-0.851755	0.1968148	0.209625
559	1	0.2990648	-0.851755	0.1968148	0.209625
560	0	0.684729	0.7755904	0.2234843	0.2158752
561	1	0.0789553	-2.456627	0.2343114	0.0727213
562	1	0.0423618	-3.118222	0.2661586	0.0405673
563	1	0.2773083	-0.957853	0.2083014	0.2004084
564	1	0.3260635	-0.726044	0.2005595	0.2197461
565	0	0.5316132	0.1266216	0.2036769	0.2490006
566	1	0.0467535	-3.014985	0.2571032	0.0445676

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
567	0	0.115121	-2.039467	0.2245055	0.1018681
568	1	0.116708	-2.023981	0.2191973	0.1030872
569	1	0.5849056	0.3429446	0.2092218	0.242791
570	1	0.1691961	-1.591335	0.2081259	0.1405688
571	1	0.0163571	-4.096599	0.3157386	0.0160896
572	0	0.4807408	-0.077075	0.2085151	0.2496291
573	1	0.1823176	-1.500724	0.2034017	0.1490779
574	1	0.1409214	-1.807658	0.2131115	0.1210625
575	1	0.1409214	-1.807658	0.2131115	0.1210625
576	1	0.1263781	-1.93337	0.2139715	0.1104066
577	1	0.1393997	-1.820285	0.2115792	0.1199674
578	1	0.1154126	-2.036608	0.2185967	0.1020925
579	1	0.5347559	0.1392482	0.2136001	0.248792
580	1	0.4807408	-0.077075	0.2085151	0.2496291
581	1	0.1674286	-1.603962	0.2056159	0.1393963
582	1	0.323295	-0.73867	0.1939962	0.2187754
583	1	0.2990648	-0.851755	0.1968148	0.209625
584	0	0.4264727	-0.296257	0.2170585	0.2445937
585	1	0.115121	-2.039467	0.2245055	0.1018681
586	1	0.115121	-2.039467	0.2245055	0.1018681
587	1	0.0062557	-5.067988	0.3750187	0.0062166
588	0	0.6591808	0.6596457	0.249715	0.2246615
589	1	0.0700971	-2.585198	0.243433	0.0651835
590	0	0.1687945	-1.594195	0.2127	0.1403029
591	1	0.1993282	-1.390499	0.2111926	0.1595965

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
592	0	0.3226697	-0.74153	0.2087566	0.218554
593	1	0.0281651	-3.541101	0.2797536	0.0273719
594	1	0.057242	-2.801521	0.2515942	0.0539654
595	1	0.0787476	-2.459487	0.2336856	0.0725464
596	1	0.0700971	-2.585198	0.243433	0.0651835
597	1	0.1518832	-1.719907	0.2200174	0.1288147
598	0	0.3960457	-0.421969	0.2192131	0.2391935
599	1	0.0201709	-3.883136	0.3024272	0.0197641
600	1	0.115121	-2.039467	0.2245055	0.1018681
601	1	0.0427598	-3.108456	0.2592458	0.0409314
602	1	0.2552248	-1.070938	0.2141082	0.1900851
603	0	0.5879679	0.3555711	0.2197778	0.2422616
604	1	0.0700971	-2.585198	0.243433	0.0651835
605	1	0.0278216	-3.553728	0.2872555	0.0270475
606	1	0.0778364	-2.472113	0.238587	0.0717779
607	1	0.0281651	-3.541101	0.2797536	0.0273719
608	1	0.116708	-2.023981	0.2191973	0.1030872
609	1	0.2984657	-0.854615	0.21459	0.2093839
610	0	0.4264727	-0.296257	0.2170585	0.2445937
611	1	0.042246	-3.121082	0.2658693	0.0404612
612	0	0.3254355	-0.728903	0.2106341	0.2195272
613	1	0.236101	-1.174176	0.2091184	0.1803573
614	0	0.6090505	0.4433227	0.2417339	0.238108
615	1	0.5565075	0.2269998	0.2346142	0.2468069
616	1	0.1518832	-1.719907	0.2200174	0.1288147

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Parameter Code=HBA_BL7 Parameter=HbA1c <7.0% Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
617	0	0.3745888	-0.51258	0.213249	0.234272
618	0	0.236101	-1.174176	0.2091184	0.1803573
619	1	0.1687945	-1.594195	0.2127	0.1403029
620	1	0.3960457	-0.421969	0.2192131	0.2391935
621	1	0.0959408	-2.243164	0.2268718	0.0867361
622	1	0.0700971	-2.585198	0.243433	0.0651835
623	1	0.0959408	-2.243164	0.2268718	0.0867361
624	1	0.0948512	-2.25579	0.2310797	0.0858544
625	1	0.4233872	-0.308884	0.2134278	0.2441305
626	1	0.1518832	-1.719907	0.2200174	0.1288147
627	1	0.201351	-1.377872	0.2103008	0.1608088
628	0	0.1670304	-1.606822	0.2144877	0.1391312
629	1	0.0085909	-4.748428	0.3514925	0.0085171
630	0	0.5842111	0.3400849	0.2291086	0.2429085
631	1	0.480027	-0.079934	0.222001	0.2496011
632	1	0.0855771	-2.368875	0.2361152	0.0782537
633	1	0.236101	-1.174176	0.2091184	0.1803573
634	1	0.1164135	-2.026841	0.2210509	0.1028614
635	1	0.3716355	-0.525207	0.2104755	0.2335226
636	1	0.0466262	-3.017844	0.2605197	0.0444522
637	1	0.0855771	-2.368875	0.2361152	0.0782537
638	1	0.4233872	-0.308884	0.2134278	0.2441305
639	0	0.1164135	-2.026841	0.2210509	0.1028614
640	1	0.2984657	-0.854615	0.21459	0.2093839
641	0	0.4264727	-0.296257	0.2170585	0.2445937

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Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
642	1	0.095097	-2.252931	0.2265702	0.0860535
643	1	0.3456328	-0.638292	0.2163012	0.2261708
644	1	0.2366172	-1.171316	0.197217	0.1806295
645	1	0.1260627	-1.93623	0.224331	0.1101709
646	1	0.116708	-2.023981	0.2191973	0.1030872
647	1	0.2552248	-1.070938	0.2141082	0.1900851
648	1	0.0041308	-5.485148	0.4029073	0.0041137
649	1	0.2366172	-1.171316	0.197217	0.1806295
650	1	0.0961891	-2.240304	0.2262946	0.0869368
651	1	0.0225315	-3.770051	0.2987082	0.0220238
652	1	0.3254355	-0.728903	0.2106341	0.2195272
653	1	0.2383859	-1.161549	0.2091468	0.1815581
654	1	0.0789553	-2.456627	0.2343114	0.0727213
655	1	0.2778818	-0.954993	0.1949336	0.2006635
656	1	0.0961891	-2.240304	0.2262946	0.0869368
657	0	0.323295	-0.73867	0.1939962	0.2187754
658	1	0.323295	-0.73867	0.1939962	0.2187754
659	1	0.1409214	-1.807658	0.2131115	0.1210625
660	1	0.0106737	-4.529245	0.3418218	0.0105597
661	1	0.0466262	-3.017844	0.2605197	0.0444522
662	1	0.0185077	-3.970888	0.3092134	0.0181652
663	1	0.2778818	-0.954993	0.1949336	0.2006635
664	1	0.1674286	-1.603962	0.2056159	0.1393963
665	0	0.323295	-0.73867	0.1939962	0.2187754
666	1	0.0163571	-4.096599	0.3157386	0.0160896

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Parameter Code=HBA_BL7 Parameter=HbA1c <7.0% Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
667	1	0.2990648	-0.851755	0.1968148	0.209625
668	1	0.095097	-2.252931	0.2265702	0.0860535
669	1	0.4240855	-0.306024	0.1962084	0.244237
670	1	0.0029293	-5.830042	0.4190424	0.0029208
671	1	0.1164135	-2.026841	0.2210509	0.1028614
672	1	0.0055905	-5.181074	0.3778549	0.0055593
673	1	0.0019025	-6.262688	0.4473612	0.0018989
674	1	0.0525439	-2.892133	0.2499555	0.049783
675	1	0.2798459	-0.945226	0.2092586	0.2015322
676	1	0.0519188	-2.904759	0.2560626	0.0492232
677	1	0.2773083	-0.957853	0.2083014	0.2004084
678	1	0.0379	-3.234167	0.2701337	0.0364636
679	1	0.0347309	-3.324778	0.2692022	0.0335246
680	1	0.236101	-1.174176	0.2091184	0.1803573
681	1	0.2798459	-0.945226	0.2092586	0.2015322
682	1	0.1687945	-1.594195	0.2127	0.1403029
683	1	0.0948512	-2.25579	0.2310797	0.0858544
684	1	0.139057	-1.823144	0.2189484	0.1197201
685	1	0.6090505	0.4433227	0.2417339	0.238108
686	1	0.0787476	-2.459487	0.2336856	0.0725464
687	1	0.2163168	-1.287261	0.2148642	0.1695239
688	1	0.139057	-1.823144	0.2189484	0.1197201
689	1	0.1670304	-1.606822	0.2144877	0.1391312
690	1	0.236101	-1.174176	0.2091184	0.1803573
691	1	0.1993282	-1.390499	0.2111926	0.1595965

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
692	1	0.1405755	-1.810518	0.216303	0.1208141
693	0	0.0855771	-2.368875	0.2361152	0.0782537
694	1	0.3604507	-0.573408	0.2460059	0.230526
695	1	0.5724572	0.2918834	0.2529633	0.24475
696	1	0.246171	-1.119139	0.2566153	0.1855708
697	0	0.7979447	1.3734981	0.2833255	0.1612289
698	1	0.0293495	-3.498692	0.3340535	0.0284881
699	1	0.2275184	-1.222377	0.25197	0.1757538
700	0	0.4368767	-0.253848	0.2552317	0.2460154
701	1	0.1348524	-1.858719	0.2684287	0.1166672
702	1	0.0495968	-2.952961	0.3078392	0.0471369
703	1	0.5188811	0.0755605	0.2496524	0.2496435
704	1	0.1621392	-1.642396	0.263303	0.1358501
705	0	0.6736036	0.7245293	0.2625093	0.2198618
706	1	0.1917467	-1.4387	0.2560088	0.1549799
707	1	0.3149442	-0.777105	0.2524573	0.2157544
708	1	0.6482702	0.6114442	0.2700522	0.228016
709	0	0.6736036	0.7245293	0.2625093	0.2198618
710	1	0.0918406	-2.291365	0.2812427	0.0834059
711	1	0.7396384	1.04409	0.2828526	0.1925734
712	1	0.4368767	-0.253848	0.2552317	0.2460154
713	0	0.4648674	-0.140762	0.2473722	0.2487657
714	0	0.7192718	0.9408522	0.2686405	0.2019199
715	1	0.5188811	0.0755605	0.2496524	0.2496435
716	0	0.1457778	-1.768108	0.2682465	0.1245266

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
717	1	0.2702356	-0.993428	0.2536472	0.1972083
718	1	0.3122264	-0.789731	0.2469374	0.2147411
719	0	0.3633666	-0.560782	0.2523158	0.2313313
720	1	0.4648674	-0.140762	0.2473722	0.2487657
721	1	0.0495968	-2.952961	0.3078392	0.0471369
722	1	0.3149442	-0.777105	0.2524573	0.2157544
723	1	0.6763736	0.7371558	0.2727309	0.2188924
724	1	0.5755446	0.3045099	0.26208	0.244293
725	1	0.0553172	-2.837765	0.2498575	0.0522572
726	1	0.0763595	-2.492871	0.2661598	0.0705287
727	1	0.1224304	-1.969614	0.2423497	0.1074412
728	1	0.0272656	-3.574486	0.3180753	0.0265222
729	0	0.2915229	-0.887999	0.2185866	0.2065373
730	1	0.062433	-2.709194	0.2754007	0.0585351
731	1	0.0509065	-2.925517	0.2852734	0.048315
732	1	0.0450413	-3.054088	0.2603474	0.0430126
733	1	0.3632118	-0.561451	0.1966106	0.231289
734	1	0.0752744	-2.508357	0.2414738	0.0696081
735	1	0.1221234	-1.972474	0.2152419	0.1072093
736	1	0.0075751	-4.875283	0.3629731	0.0075177
737	1	0.0102685	-4.568349	0.3465655	0.0101631
738	1	0.0297745	-3.483875	0.3104231	0.028888
739	1	0.1936067	-1.426743	0.2051404	0.1561232
740	1	0.0408036	-3.157326	0.2727923	0.0391386
741	1	0.0827831	-2.40512	0.2309054	0.0759301

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
742	1	0.1224304	-1.969614	0.2423497	0.1074412
743	1	0.1224304	-1.969614	0.2423497	0.1074412
744	1	0.1620484	-1.643066	0.2103956	0.1357887
745	1	0.3632118	-0.561451	0.1966106	0.231289
746	1	0.0335361	-3.361023	0.2731091	0.0324114
747	0	0.210711	-1.320645	0.2248754	0.1663119
748	0	0.8322668	1.6017784	0.2593187	0.1395988
749	1	0.4183278	-0.329642	0.2235866	0.2433296
750	1	0.5250152	0.1001444	0.2039761	0.2493742
751	1	0.0409156	-3.154466	0.3025137	0.0392416
752	1	0.1224304	-1.969614	0.2423497	0.1074412
753	1	0.0413006	-3.1447	0.2618129	0.0395949
754	1	0.0157841	-4.132843	0.3470614	0.0155349
755	1	0.231868	-1.197793	0.195064	0.1781052
756	1	0.0622658	-2.712054	0.2409427	0.0583888
757	1	0.5784631	0.3164674	0.2098972	0.2438435
758	1	0.0331292	-3.373649	0.2843343	0.0320317
759	0	0.1221234	-1.972474	0.2152419	0.1072093
760	1	0.0217469	-3.806295	0.3087056	0.021274
761	0	0.3175298	-0.765147	0.192645	0.2167046
762	0	0.3147999	-0.777774	0.1967644	0.2157009
763	1	0.231868	-1.197793	0.195064	0.1781052
764	1	0.1127369	-2.063085	0.215164	0.1000273
765	0	0.4678432	-0.128805	0.2003179	0.2489659
766	1	0.4685552	-0.125945	0.2224052	0.2490112

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Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
767	1	0.2296268	-1.21042	0.2010712	0.1768983
768	1	0.029692	-3.486734	0.2829791	0.0288104
769	1	0.0271898	-3.577345	0.2848894	0.0264506
770	1	0.11148	-2.075711	0.2241123	0.0990522
771	1	0.1955856	-1.414116	0.1982804	0.1573319
772	0	0.2296268	-1.21042	0.2010712	0.1768983
773	1	0.1955856	-1.414116	0.1982804	0.1573319
774	1	0.0413006	-3.1447	0.2618129	0.0395949
775	1	0.1347743	-1.859389	0.2167508	0.1166102
776	0	0.8018794	1.3980821	0.2535194	0.1588689
777	0	0.2483966	-1.107182	0.1967804	0.1866958
778	1	0.3661372	-0.548824	0.1934926	0.2320808
779	1	0.0450413	-3.054088	0.2603474	0.0430126
780	1	0.0553172	-2.837765	0.2498575	0.0522572
781	1	0.1476326	-1.753291	0.2355442	0.1258372
782	0	0.5784631	0.3164674	0.2098972	0.2438435
783	1	0.0917848	-2.292034	0.2323845	0.0833604
784	0	0.8722877	1.9213392	0.2810393	0.1114019
785	1	0.1127369	-2.063085	0.215164	0.1000273
786	1	0.210711	-1.320645	0.2248754	0.1663119
787	1	0.1476326	-1.753291	0.2355442	0.1258372
788	1	0.0928428	-2.279408	0.2228991	0.084223
789	1	0.210711	-1.320645	0.2248754	0.1663119
790	1	0.1347743	-1.859389	0.2167508	0.1166102
791	1	0.1637702	-1.630439	0.2027588	0.1369495

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
792	1	0.0553172	-2.837765	0.2498575	0.0522572
793	1	0.11148	-2.075711	0.2241123	0.0990522
794	1	0.1936067	-1.426743	0.2051404	0.1561232
795	0	0.1936067	-1.426743	0.2051404	0.1561232
796	0	0.4398206	-0.24189	0.1990204	0.2463784
797	0	0.3175298	-0.765147	0.192645	0.2167046
798	0	0.4936085	-0.025567	0.2028739	0.2499591
799	0	0.2301331	-1.20756	0.229213	0.1771718
800	1	0.4405253	-0.23903	0.2181238	0.2464628
801	0	0.6990092	0.8425842	0.2405359	0.2103953
802	1	0.3381216	-0.671676	0.2172139	0.2237954
803	0	0.6307999	0.53565	0.2377267	0.2328914
804	0	0.9362106	2.6862528	0.3218329	0.0597203
805	0	0.7635049	1.1719922	0.2515786	0.1805652
806	1	0.1641622	-1.627579	0.2369202	0.137213
807	1	0.0332209	-3.370789	0.313846	0.0321173
808	1	0.0502999	-2.938144	0.2916515	0.0477698
809	0	0.2731676	-0.978611	0.2251052	0.198547
810	1	0.2731676	-0.978611	0.2251052	0.198547
811	1	0.315417	-0.774914	0.2229716	0.2159291
812	0	0.7419345	1.0560475	0.238461	0.1914677
813	0	0.5475448	0.1907557	0.2079359	0.2477395
814	1	0.231868	-1.197793	0.195064	0.1781052
815	1	0.2102358	-1.323505	0.1995694	0.1660367
816	1	0.0127169	-4.352026	0.3332265	0.0125552

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
817	1	0.2323777	-1.194934	0.2279499	0.1783783
818	1	0.0366003	-3.270411	0.2714103	0.0352607
819	1	0.111148	-2.075711	0.2241123	0.0990522
820	1	0.1936067	-1.426743	0.2051404	0.1561232
821	1	0.1347743	-1.859389	0.2167508	0.1166102
822	0	0.470988	-0.116178	0.1992146	0.2491583
823	0	0.5250152	0.1001444	0.2039761	0.2493742
824	1	0.1472731	-1.756151	0.2088808	0.1255837
825	1	0.0240551	-3.703057	0.2949943	0.0234765
826	1	0.0917848	-2.292034	0.2323845	0.0833604
827	1	0.1476326	-1.753291	0.2355442	0.1258372
828	0	0.6509918	0.6234016	0.2213342	0.2272015
829	0	0.3175298	-0.765147	0.192645	0.2167046
830	1	0.0335361	-3.361023	0.2731091	0.0324114
831	1	0.0917848	-2.292034	0.2323845	0.0833604
832	0	0.6762271	0.7364867	0.2223514	0.218944
833	1	0.2726002	-0.98147	0.1931725	0.1982893
834	0	0.4176321	-0.332501	0.1956975	0.2432155
835	0	0.3374819	-0.674536	0.1952029	0.2235879
836	1	0.2301331	-1.20756	0.229213	0.1771718
837	0	0.3638735	-0.558591	0.2215884	0.2314696
838	1	0.1010205	-2.185937	0.250033	0.0908153
839	1	0.0554668	-2.834906	0.2775803	0.0523903
840	0	0.2301331	-1.20756	0.229213	0.1771718
841	1	0.1130232	-2.060225	0.2498489	0.100249

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
842	0	0.4685552	-0.125945	0.2224052	0.2490112
843	1	0.0409156	-3.154466	0.3025137	0.0392416
844	1	0.1010205	-2.185937	0.250033	0.0908153
845	0	0.1940536	-1.423883	0.2339786	0.1563968
846	0	0.6010731	0.4099383	0.2283709	0.2397842
847	1	0.5760797	0.3067005	0.2279255	0.2442119
848	0	0.5791602	0.319327	0.2325661	0.2437337
849	0	0.8859386	2.0499105	0.2972639	0.1010514
850	1	0.1476326	-1.753291	0.2355442	0.1258372
851	1	0.3880887	-0.455353	0.2170588	0.2374759
852	0	0.5791602	0.319327	0.2325661	0.2437337
853	1	0.2731676	-0.978611	0.2251052	0.198547
854	1	0.0752744	-2.508357	0.2414738	0.0696081
855	1	0.0917848	-2.292034	0.2323845	0.0833604
856	1	0.1362535	-1.846762	0.2084177	0.1176885
857	1	0.4176321	-0.332501	0.1956975	0.2432155
858	1	0.0827831	-2.40512	0.2309054	0.0759301
859	1	0.0450413	-3.054088	0.2603474	0.0430126
860	1	0.0763595	-2.492871	0.2661598	0.0705287
861	0	0.6990092	0.8425842	0.2405359	0.2103953
862	1	0.1351082	-1.856529	0.2464816	0.1168539
863	0	0.3661372	-0.548824	0.1934926	0.2320808
864	0	0.3668011	-0.545965	0.2229065	0.2322581
865	1	0.6789854	0.7491132	0.2248343	0.2179642
866	1	0.2726002	-0.98147	0.1931725	0.1982893

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
867	0	0.7998658	1.3854555	0.2489949	0.1600805
868	0	0.6509918	0.6234016	0.2213342	0.2272015
869	1	0.3175298	-0.765147	0.192645	0.2167046
870	1	0.1620484	-1.643066	0.2103956	0.1357887
871	1	0.2489309	-1.104322	0.221154	0.1869643
872	0	0.1765603	-1.539828	0.2036275	0.1453868
873	1	0.3147999	-0.777774	0.1967644	0.2157009
874	1	0.3147999	-0.777774	0.1967644	0.2157009
875	1	0.3374819	-0.674536	0.1952029	0.2235879
876	1	0.2102358	-1.323505	0.1995694	0.1660367
877	0	0.5218655	0.0875179	0.204106	0.2495219
878	0	0.3661372	-0.548824	0.1934926	0.2320808
879	1	0.2909326	-0.890859	0.195315	0.2062908
880	0	0.7242089	0.9654362	0.2336525	0.1997304
881	0	0.6984072	0.8397245	0.2294795	0.2106346
882	1	0.2909326	-0.890859	0.195315	0.2062908
883	1	0.1765603	-1.539828	0.2036275	0.1453868
884	0	0.2701036	-0.994097	0.1982612	0.1971477
885	1	0.0408036	-3.157326	0.2727923	0.0391386
886	1	0.231868	-1.197793	0.195064	0.1781052
887	1	0.0408036	-3.157326	0.2727923	0.0391386
888	0	0.6003872	0.4070787	0.2141207	0.2399224
889	1	0.3632118	-0.561451	0.1966106	0.231289
890	1	0.4176321	-0.332501	0.1956975	0.2432155
891	0	0.470988	-0.116178	0.1992146	0.2491583

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=HBA_BL7 Parameter=HbA1c <7.0% Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
892	1	0.1936067	-1.426743	0.2051404	0.1561232
893	0	0.5250152	0.1001444	0.2039761	0.2493742
894	0	0.1362535	-1.846762	0.2084177	0.1176885
895	1	0.1620484	-1.643066	0.2103956	0.1357887
896	1	0.6271861	0.5201638	0.2152108	0.2338237
897	1	0.0336289	-3.358163	0.3066661	0.032498
898	1	0.3374819	-0.674536	0.1952029	0.2235879
899	0	0.3175298	-0.765147	0.192645	0.2167046
900	1	0.5784631	0.3164674	0.2098972	0.2438435
901	1	0.2102358	-1.323505	0.1995694	0.1660367
902	1	0.2909326	-0.890859	0.195315	0.2062908
903	0	0.6509918	0.6234016	0.2213342	0.2272015
904	1	0.0928428	-2.279408	0.2228991	0.084223
905	0	0.7222539	0.9556693	0.2442542	0.2006032
906	0	0.2706678	-0.991237	0.2255262	0.1974067
907	1	0.470988	-0.116178	0.1992146	0.2491583
908	1	0.1769765	-1.536968	0.2296946	0.1456558
909	1	0.0930839	-2.276548	0.2576186	0.0844193
910	1	0.0754737	-2.505498	0.2715606	0.0697774
911	0	0.3175298	-0.765147	0.192645	0.2167046
912	0	0.522579	0.0903776	0.2245922	0.2494902
913	1	0.1130232	-2.060225	0.2498489	0.100249
914	1	0.8023333	1.4009417	0.2674511	0.1585946
915	0	0.6516412	0.6262613	0.2339658	0.2270049
916	1	0.0920235	-2.289175	0.262457	0.0835552

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=HBA_BL7 Parameter=HbA1c <7.0% Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
917	0	0.8003231	1.3883152	0.2597196	0.159806
918	1	0.2909326	-0.890859	0.195315	0.2062908
919	1	0.1221234	-1.972474	0.2152419	0.1072093
920	0	0.8163113	1.491553	0.2653208	0.1499472
921	1	0.2701036	-0.994097	0.1982612	0.1971477
922	1	0.1476326	-1.753291	0.2355442	0.1258372
923	0	0.5475448	0.1907557	0.2079359	0.2477395
924	0	0.1955856	-1.414116	0.1982804	0.1573319
925	0	0.8163113	1.491553	0.2653208	0.1499472
926	1	0.1127369	-2.063085	0.215164	0.1000273
927	1	0.111148	-2.075711	0.2241123	0.0990522
928	1	0.3668011	-0.545965	0.2229065	0.2322581
929	1	0.1007611	-2.188797	0.2226158	0.0906083
930	0	0.6516412	0.6262613	0.2339658	0.2270049
931	1	0.5257283	0.1030041	0.2284531	0.2493381
932	1	0.3661372	-0.548824	0.1934926	0.2320808
933	1	0.0269327	-3.587112	0.3255993	0.0262073
934	1	0.0451645	-3.051229	0.288023	0.0431246
935	1	0.3880887	-0.455353	0.2170588	0.2374759
936	1	0.1936067	-1.426743	0.2051404	0.1561232
937	1	0.2489309	-1.104322	0.221154	0.1869643
938	1	0.5257283	0.1030041	0.2284531	0.2493381
939	1	0.0622658	-2.712054	0.2409427	0.0583888
940	1	0.0827831	-2.40512	0.2309054	0.0759301
941	0	0.2301331	-1.20756	0.229213	0.1771718

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=HBA_BL7 Parameter=HbA1c <7.0% Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
942	0	0.0677711	-2.621442	0.2400159	0.0631782
943	1	0.0928428	-2.279408	0.2228991	0.084223
944	1	0.2102358	-1.323505	0.1995694	0.1660367
945	1	0.6984072	0.8397245	0.2294795	0.2106346
946	1	0.0830005	-2.40226	0.2585159	0.0761114
947	1	0.1127369	-2.063085	0.215164	0.1000273
948	1	0.3175298	-0.765147	0.192645	0.2167046
949	1	0.5250152	0.1001444	0.2039761	0.2493742
950	0	0.1940536	-1.423883	0.2339786	0.1563968
951	1	0.1221234	-1.972474	0.2152419	0.1072093
952	1	0.1010205	-2.185937	0.250033	0.0908153
953	1	0.3147999	-0.777774	0.1967644	0.2157009
954	0	0.6271861	0.5201638	0.2152108	0.2338237
955	1	0.0928428	-2.279408	0.2228991	0.084223
956	0	0.2909326	-0.890859	0.195315	0.2062908
957	1	0.6010731	0.4099383	0.2283709	0.2397842
958	1	0.0677711	-2.621442	0.2400159	0.0631782
959	0	0.5250152	0.1001444	0.2039761	0.2493742
960	0	0.1127369	-2.063085	0.215164	0.1000273
961	0	0.2483966	-1.107182	0.1967804	0.1866958
962	1	0.4943234	-0.022708	0.2203911	0.2499678
963	1	0.0677711	-2.621442	0.2400159	0.0631782
964	1	0.3147999	-0.777774	0.1967644	0.2157009
965	1	0.1769765	-1.536968	0.2296946	0.1456558
966	0	0.6762271	0.7364867	0.2223514	0.218944

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=HBA_BL7 Parameter=HbA1c <7.0% Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
967	1	0.0450413	-3.054088	0.2603474	0.0430126
968	1	0.1007611	-2.188797	0.2226158	0.0906083
969	1	0.0450413	-3.054088	0.2603474	0.0430126
970	1	0.0268579	-3.589972	0.2963227	0.0261365
971	0	0.6768529	0.7393464	0.2378219	0.218723
972	1	0.0928428	-2.279408	0.2228991	0.084223
973	1	0.0763595	-2.492871	0.2661598	0.0705287
974	1	0.0409156	-3.154466	0.3025137	0.0392416
975	0	0.4183278	-0.329642	0.2235866	0.2433296
976	1	0.0451645	-3.051229	0.288023	0.0431246
977	0	0.904715	2.2507473	0.2935547	0.0862058
978	0	0.4152586	-0.342268	0.2213986	0.2428189
979	1	0.0157397	-4.135703	0.3201609	0.015492
980	1	0.1351082	-1.856529	0.2464816	0.1168539
981	1	0.3381216	-0.671676	0.2172139	0.2237954
982	0	0.8163113	1.491553	0.2653208	0.1499472
983	1	0.2296268	-1.21042	0.2010712	0.1768983
984	1	0.5475448	0.1907557	0.2079359	0.2477395
985	1	0.3632118	-0.561451	0.1966106	0.231289
986	0	0.3181498	-0.762288	0.2234154	0.2169305
987	1	0.3661372	-0.548824	0.1934926	0.2320808
988	1	0.5218655	0.0875179	0.204106	0.2495219
989	1	0.1620484	-1.643066	0.2103956	0.1357887
990	1	0.1472731	-1.756151	0.2088808	0.1255837
991	1	0.1620484	-1.643066	0.2103956	0.1357887

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=HBA_BL7 Parameter=HbA1c <7.0% Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
992	0	0.6271861	0.5201638	0.2152108	0.2338237
993	1	0.5250152	0.1001444	0.2039761	0.2493742
994	1	0.017591	-4.022618	0.3214373	0.0172816
995	1	0.2726002	-0.98147	0.1931725	0.1982893
996	1	0.0507685	-2.928377	0.2510663	0.0481911
997	1	0.11148	-2.075711	0.2241123	0.0990522
998	1	0.6516412	0.6262613	0.2339658	0.2270049
999	1	0.0917848	-2.292034	0.2323845	0.0833604
1000	1	0.7419345	1.0560475	0.238461	0.1914677
1001	0	0.4943234	-0.022708	0.2203911	0.2499678
1002	1	0.0763595	-2.492871	0.2661598	0.0705287
1003	1	0.5218655	0.0875179	0.204106	0.2495219
1004	1	0.231868	-1.197793	0.195064	0.1781052
1005	0	0.7629882	1.1691326	0.2393356	0.1808372
1006	1	0.3374819	-0.674536	0.1952029	0.2235879
1007	1	0.0450413	-3.054088	0.2603474	0.0430126
1008	1	0.1936067	-1.426743	0.2051404	0.1561232
1009	1	0.5218655	0.0875179	0.204106	0.2495219
1010	1	0.0413006	-3.1447	0.2618129	0.0395949
1011	1	0.2102358	-1.323505	0.1995694	0.1660367
1012	1	0.5475448	0.1907557	0.2079359	0.2477395
1013	1	0.1221234	-1.972474	0.2152419	0.1072093
1014	1	0.5250152	0.1001444	0.2039761	0.2493742
1015	1	0.6003872	0.4070787	0.2141207	0.2399224
1016	1	0.1955856	-1.414116	0.1982804	0.1573319

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Subjects achieving HbA1c targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=HBA_BL7 Parameter=HbA1c <7.0% Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
1017	1	0.3661372	-0.548824	0.1934926	0.2320808
1018	1	0.4145644	-0.345128	0.1978031	0.2427008
1019	0	0.7424816	1.0589071	0.2480039	0.1912027
1020	1	0.3874098	-0.458213	0.1964465	0.2373235
1021	1	0.1362535	-1.846762	0.2084177	0.1176885
1022	1	0.6003872	0.4070787	0.2141207	0.2399224
1023	0	0.6271861	0.5201638	0.2152108	0.2338237
1024	0	0.3632118	-0.561451	0.1966106	0.231289
1025	1	0.0615326	-2.72468	0.2512916	0.0577464

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10: Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG120 Parameter=PPG at 2 hours (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Model Information

Data Set	WORK.ENDPOINT_2
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Dimensions

Covariance Parameters	1
Columns in X	10
Columns in Z	0
Subjects	1
Max Obs per Subject	985

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG120 Parameter=PPG at 2 hours (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Number of Observations

Number of Observations Read	985
Number of Observations Used	985
Number of Observations Not Used	0

Covariance Parameter
Estimates

Cov Parm	Estimate
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Residual	20.4031
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Fit Statistics

-2 Res Log Likelihood	5766.6
AIC (Smaller is Better)	5768.6
AICC (Smaller is Better)	5768.6
BIC (Smaller is Better)	5773.5

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			2	6.7623	0.4864	977
TRTPN			3	7.7194	0.4784	977
TRTPN			4	7.4322	0.4875	977

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG120 Parameter=PPG at 2 hours (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
REGION1	ASIA (EXCLUDING JAPAN)			-0.6751	0.5268	977
REGION1	EUROPE			-0.8820	0.3719	977
REGION1	JAPAN			0.4589	0.4204	977
REGION1	NORTH AMERICA			0	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.2622	0.3240	977
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0	.	.
BASE				0.4396	0.02823	977

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
TRTPN			2	13.90	<.0001	0.05
TRTPN			3	16.14	<.0001	0.05
TRTPN			4	15.25	<.0001	0.05
REGION1	ASIA (EXCLUDING JAPAN)			-1.28	0.2003	0.05
REGION1	EUROPE			-2.37	0.0179	0.05
REGION1	JAPAN			1.09	0.2753	0.05
REGION1	NORTH AMERICA			.	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.81	0.4186	0.05
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.	.
BASE				15.58	<.0001	0.05

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG120 Parameter=PPG at 2 hours (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Lower	Upper
TRTPN			2	5.8077	7.7168
TRTPN			3	6.7806	8.6582
TRTPN			4	6.4757	8.3888
REGION1	ASIA (EXCLUDING JAPAN)			-1.7090	0.3587
REGION1	EUROPE			-1.6117	-0.1522
REGION1	JAPAN			-0.3661	1.2838
REGION1	NORTH AMERICA			.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.3736	0.8980
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.
BASE				0.3843	0.4950

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	2	977	3.89	0.0209
REGION1	3	977	4.69	0.0029
BOLAD1	1	977	0.65	0.4186
BASE	1	977	242.61	<.0001

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG120 Parameter=PPG at 2 hours (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) - NovoRapid (meal)	WORK.ENDPOINT_2	-0.6700	0.3544	977	-1.89	0.0590	0.05	-1.3654	0.02547

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (post) - NovoRapid (meal)	WORK.ENDPOINT_2	0.2872	0.3534	977	0.81	0.4166	0.05	-0.4062	0.9806

Least Squares Means

Effect	Planned Treatment for Period 30 (N)	Margins	BASE	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	2	WORK.ENDPOINT_2	12.38	12.0824	0.2494	977	48.45	<.0001	0.05	11.5930	12.5718
TRTPN	3	WORK.ENDPOINT_2	12.38	13.0396	0.2479	977	52.60	<.0001	0.05	12.5531	13.5261
TRTPN	4	WORK.ENDPOINT_2	12.38	12.7524	0.2516	977	50.69	<.0001	0.05	12.2587	13.2460

Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG120C Parameter=PPG at 2 hours (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Model Information

Data Set	WORK.ENDPOINT_2
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Dimensions

Covariance Parameters	1
Columns in X	10
Columns in Z	0
Subjects	1
Max Obs per Subject	985

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG120C Parameter=PPG at 2 hours (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Number of Observations

Number of Observations Read	985
Number of Observations Used	985
Number of Observations Not Used	0

Covariance Parameter
Estimates

Cov Parm	Estimate
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Residual	6625.29
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Fit Statistics

-2 Res Log Likelihood	11422.4
AIC (Smaller is Better)	11424.4
AICC (Smaller is Better)	11424.4
BIC (Smaller is Better)	11429.3

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			2	121.86	8.7651	977
TRTPN			3	139.10	8.6206	977
TRTPN			4	133.93	8.7841	977

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG120C Parameter=PPG at 2 hours (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
REGION1	ASIA (EXCLUDING JAPAN)			-12.1655	9.4935	977
REGION1	EUROPE			-15.8932	6.7013	977
REGION1	JAPAN			8.2692	7.5752	977
REGION1	NORTH AMERICA			0	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		4.7241	5.8383	977
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0	.	.
BASE				0.4396	0.02823	977

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
TRTPN			2	13.90	<.0001	0.05
TRTPN			3	16.14	<.0001	0.05
TRTPN			4	15.25	<.0001	0.05
REGION1	ASIA (EXCLUDING JAPAN)			-1.28	0.2003	0.05
REGION1	EUROPE			-2.37	0.0179	0.05
REGION1	JAPAN			1.09	0.2753	0.05
REGION1	NORTH AMERICA			.	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.81	0.4186	0.05
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.	.
BASE				15.58	<.0001	0.05

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 682 of 4425	Novo Nordisk
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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG120C Parameter=PPG at 2 hours (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Lower	Upper
TRTPN			2	104.66	139.06
TRTPN			3	122.19	156.02
TRTPN			4	116.69	151.17
REGION1	ASIA (EXCLUDING JAPAN)			-30.7955	6.4646
REGION1	EUROPE			-29.0437	-2.7427
REGION1	JAPAN			-6.5962	23.1347
REGION1	NORTH AMERICA			.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-6.7330	16.1812
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.
BASE				0.3843	0.4950

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	2	977	3.89	0.0209
REGION1	3	977	4.69	0.0029
BOLAD1	1	977	0.65	0.4186
BASE	1	977	242.61	<.0001

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG120C Parameter=PPG at 2 hours (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) - NovoRapid (meal)	WORK.ENDPOINT_2	-12.0731	6.3861	977	-1.89	0.0590	0.05	-24.6052	0.4589

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (post) - NovoRapid (meal)	WORK.ENDPOINT_2	5.1751	6.3675	977	0.81	0.4166	0.05	-7.3205	17.6706

Least Squares Means

Effect	Planned Treatment for Period	30 (N)	Margins	BASE	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	2		WORK.ENDPOINT_2	223.16	217.72	4.4942	977	48.45	<.0001	0.05	208.91	226.54
TRTPN	3		WORK.ENDPOINT_2	223.16	234.97	4.4673	977	52.60	<.0001	0.05	226.21	243.74
TRTPN	4		WORK.ENDPOINT_2	223.16	229.80	4.5332	977	50.69	<.0001	0.05	220.90	238.69

Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG180 Parameter=PPG at 3 hours (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Model Information

Data Set	WORK.ENDPOINT_2
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Dimensions

Covariance Parameters	1
Columns in X	10
Columns in Z	0
Subjects	1
Max Obs per Subject	983

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG180 Parameter=PPG at 3 hours (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Number of Observations

Number of Observations Read	983
Number of Observations Used	983
Number of Observations Not Used	0

Covariance Parameter
Estimates

Cov Parm	Estimate
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Residual	20.1790
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Fit Statistics

-2 Res Log Likelihood	5744.1
AIC (Smaller is Better)	5746.1
AICC (Smaller is Better)	5746.1
BIC (Smaller is Better)	5751.0

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			2	5.7431	0.4507	975
TRTPN			3	6.5761	0.4462	975
TRTPN			4	6.2724	0.4524	975

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG180 Parameter=PPG at 3 hours (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
REGION1	ASIA (EXCLUDING JAPAN)			-0.1611	0.5275	975
REGION1	EUROPE			-0.9475	0.3706	975
REGION1	JAPAN			0.5515	0.4238	975
REGION1	NORTH AMERICA			0	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.1113	0.3224	975
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0	.	.
BASE				0.4934	0.02817	975

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
TRTPN			2	12.74	<.0001	0.05
TRTPN			3	14.74	<.0001	0.05
TRTPN			4	13.87	<.0001	0.05
REGION1	ASIA (EXCLUDING JAPAN)			-0.31	0.7601	0.05
REGION1	EUROPE			-2.56	0.0107	0.05
REGION1	JAPAN			1.30	0.1934	0.05
REGION1	NORTH AMERICA			.	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.35	0.7301	0.05
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.	.
BASE				17.52	<.0001	0.05

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG180 Parameter=PPG at 3 hours (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Lower	Upper
TRTPN			2	4.8586	6.6275
TRTPN			3	5.7005	7.4516
TRTPN			4	5.3847	7.1601
REGION1	ASIA (EXCLUDING JAPAN)			-1.1964	0.8741
REGION1	EUROPE			-1.6748	-0.2202
REGION1	JAPAN			-0.2801	1.3831
REGION1	NORTH AMERICA			.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.5214	0.7439
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.
BASE				0.4382	0.5487

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	2	975	2.89	0.0562
REGION1	3	975	5.22	0.0014
BOLAD1	1	975	0.12	0.7301
BASE	1	975	306.81	<.0001

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG180 Parameter=PPG at 3 hours (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) - NovoRapid (meal)	WORK.ENDPOINT_2	-0.5294	0.3515	975	-1.51	0.1324	0.05	-1.2191	0.1604

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (post) - NovoRapid (meal)	WORK.ENDPOINT_2	0.3037	0.3526	975	0.86	0.3894	0.05	-0.3883	0.9957

Least Squares Means

Effect	Planned Treatment for Period 30 (N)	Margins	BASE	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	2	WORK.ENDPOINT_2	11.09	11.0708	0.2470	975	44.82	<.0001	0.05	10.5861	11.5555
TRTPN	3	WORK.ENDPOINT_2	11.09	11.9038	0.2488	975	47.85	<.0001	0.05	11.4156	12.3920
TRTPN	4	WORK.ENDPOINT_2	11.09	11.6001	0.2498	975	46.44	<.0001	0.05	11.1100	12.0903

Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG180C Parameter=PPG at 3 hours (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Model Information

Data Set	WORK.ENDPOINT_2
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Dimensions

Covariance Parameters	1
Columns in X	10
Columns in Z	0
Subjects	1
Max Obs per Subject	983

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG180C Parameter=PPG at 3 hours (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Number of Observations

Number of Observations Read	983
Number of Observations Used	983
Number of Observations Not Used	0

Covariance Parameter
Estimates

Cov Parm	Estimate
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Residual	6552.53
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Fit Statistics

-2 Res Log Likelihood	11388.3
AIC (Smaller is Better)	11390.3
AICC (Smaller is Better)	11390.3
BIC (Smaller is Better)	11395.2

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			2	103.49	8.1212	975
TRTPN			3	118.50	8.0398	975
TRTPN			4	113.03	8.1514	975

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG180C Parameter=PPG at 3 hours (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
REGION1	ASIA (EXCLUDING JAPAN)			-2.9034	9.5064	975
REGION1	EUROPE			-17.0739	6.6782	975
REGION1	JAPAN			9.9385	7.6363	975
REGION1	NORTH AMERICA			0	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		2.0048	5.8095	975
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0	.	.
BASE				0.4934	0.02817	975

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
TRTPN			2	12.74	<.0001	0.05
TRTPN			3	14.74	<.0001	0.05
TRTPN			4	13.87	<.0001	0.05
REGION1	ASIA (EXCLUDING JAPAN)			-0.31	0.7601	0.05
REGION1	EUROPE			-2.56	0.0107	0.05
REGION1	JAPAN			1.30	0.1934	0.05
REGION1	NORTH AMERICA			.	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.35	0.7301	0.05
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.	.
BASE				17.52	<.0001	0.05

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG180C Parameter=PPG at 3 hours (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Lower	Upper
TRTPN			2	87.5528	119.43
TRTPN			3	102.72	134.28
TRTPN			4	97.0325	129.03
REGION1	ASIA (EXCLUDING JAPAN)			-21.5588	15.7519
REGION1	EUROPE			-30.1792	-3.9685
REGION1	JAPAN			-5.0471	24.9241
REGION1	NORTH AMERICA			.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-9.3959	13.4054
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.
BASE				0.4382	0.5487

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	2	975	2.89	0.0562
REGION1	3	975	5.22	0.0014
BOLAD1	1	975	0.12	0.7301
BASE	1	975	306.81	<.0001

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG180C Parameter=PPG at 3 hours (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) - NovoRapid (meal)	WORK.ENDPOINT_2	-9.5391	6.3337	975	-1.51	0.1324	0.05	-21.9684	2.8903

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (post) - NovoRapid (meal)	WORK.ENDPOINT_2	5.4722	6.3545	975	0.86	0.3894	0.05	-6.9980	17.9424

Least Squares Means

Effect	Planned Treatment for Period 30 (N)	Margins	BASE	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	2	WORK.ENDPOINT_2	199.76	199.50	4.4507	975	44.82	<.0001	0.05	190.76	208.23
TRTPN	3	WORK.ENDPOINT_2	199.76	214.51	4.4832	975	47.85	<.0001	0.05	205.71	223.30
TRTPN	4	WORK.ENDPOINT_2	199.76	209.03	4.5011	975	46.44	<.0001	0.05	200.20	217.87

Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG240 Parameter=PPG at 4 hours (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Model Information

Data Set	WORK.ENDPOINT_2
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Dimensions

Covariance Parameters	1
Columns in X	10
Columns in Z	0
Subjects	1
Max Obs per Subject	983

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG240 Parameter=PPG at 4 hours (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Number of Observations

Number of Observations Read	983
Number of Observations Used	983
Number of Observations Not Used	0

Covariance Parameter
Estimates

Cov Parm	Estimate
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Residual	16.3549
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Fit Statistics

-2 Res Log Likelihood	5539.1
AIC (Smaller is Better)	5541.1
AICC (Smaller is Better)	5541.1
BIC (Smaller is Better)	5545.9

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			2	4.5173	0.3894	975
TRTPN			3	5.2695	0.3879	975
TRTPN			4	4.9862	0.3910	975

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG240 Parameter=PPG at 4 hours (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
REGION1	ASIA (EXCLUDING JAPAN)			0.2054	0.4779	975
REGION1	EUROPE			-0.5970	0.3323	975
REGION1	JAPAN			0.4822	0.3810	975
REGION1	NORTH AMERICA			0	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.08663	0.2897	975
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0	.	.
BASE				0.5209	0.02826	975

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
TRTPN			2	11.60	<.0001	0.05
TRTPN			3	13.58	<.0001	0.05
TRTPN			4	12.75	<.0001	0.05
REGION1	ASIA (EXCLUDING JAPAN)			0.43	0.6674	0.05
REGION1	EUROPE			-1.80	0.0727	0.05
REGION1	JAPAN			1.27	0.2059	0.05
REGION1	NORTH AMERICA			.	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.30	0.7650	0.05
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.	.
BASE				18.43	<.0001	0.05

Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG240 Parameter=PPG at 4 hours (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Lower	Upper
TRTPN			2	3.7532	5.2814
TRTPN			3	4.5083	6.0307
TRTPN			4	4.2188	5.7535
REGION1	ASIA (EXCLUDING JAPAN)			-0.7325	1.1433
REGION1	EUROPE			-1.2490	0.05499
REGION1	JAPAN			-0.2654	1.2299
REGION1	NORTH AMERICA			.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.4818	0.6551
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.
BASE				0.4654	0.5763

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	2	975	2.89	0.0560
REGION1	3	975	3.33	0.0191
BOLAD1	1	975	0.09	0.7650
BASE	1	975	339.78	<.0001

Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG240 Parameter=PPG at 4 hours (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) - NovoRapid (meal)	WORK.ENDPOINT_2	-0.4689	0.3165	975	-1.48	0.1387	0.05	-1.0899	0.1521

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (post) - NovoRapid (meal)	WORK.ENDPOINT_2	0.2833	0.3169	975	0.89	0.3716	0.05	-0.3386	0.9052

Least Squares Means

Effect	Planned Treatment for Period 30 (N)	Margins	BASE	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	2	WORK.ENDPOINT_2	9.31	9.3567	0.2229	975	41.98	<.0001	0.05	8.9193	9.7942
TRTPN	3	WORK.ENDPOINT_2	9.31	10.1089	0.2236	975	45.22	<.0001	0.05	9.6702	10.5477
TRTPN	4	WORK.ENDPOINT_2	9.31	9.8257	0.2245	975	43.77	<.0001	0.05	9.3852	10.2662

Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG240C Parameter=PPG at 4 hours (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Model Information

Data Set	WORK.ENDPOINT_2
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Dimensions

Covariance Parameters	1
Columns in X	10
Columns in Z	0
Subjects	1
Max Obs per Subject	983

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG240C Parameter=PPG at 4 hours (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Number of Observations

Number of Observations Read	983
Number of Observations Used	983
Number of Observations Not Used	0

Covariance Parameter
Estimates

Cov Parm	Estimate
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Residual	5310.76
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Fit Statistics

-2 Res Log Likelihood	11183.2
AIC (Smaller is Better)	11185.2
AICC (Smaller is Better)	11185.2
BIC (Smaller is Better)	11190.1

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			2	81.4014	7.0164	975
TRTPN			3	94.9559	6.9898	975
TRTPN			4	89.8512	7.0463	975

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG240C Parameter=PPG at 4 hours (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
REGION1	ASIA (EXCLUDING JAPAN)			3.7014	8.6123	975
REGION1	EUROPE			-10.7584	5.9872	975
REGION1	JAPAN			8.6899	6.8656	975
REGION1	NORTH AMERICA			0	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		1.5610	5.2201	975
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0	.	.
BASE				0.5209	0.02826	975

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
TRTPN			2	11.60	<.0001	0.05
TRTPN			3	13.58	<.0001	0.05
TRTPN			4	12.75	<.0001	0.05
REGION1	ASIA (EXCLUDING JAPAN)			0.43	0.6674	0.05
REGION1	EUROPE			-1.80	0.0727	0.05
REGION1	JAPAN			1.27	0.2059	0.05
REGION1	NORTH AMERICA			.	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.30	0.7650	0.05
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.	.
BASE				18.43	<.0001	0.05

Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG240C Parameter=PPG at 4 hours (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Lower	Upper
TRTPN			2	67.6324	95.1705
TRTPN			3	81.2391	108.67
TRTPN			4	76.0235	103.68
REGION1	ASIA (EXCLUDING JAPAN)			-13.1994	20.6023
REGION1	EUROPE			-22.5077	0.9910
REGION1	JAPAN			-4.7832	22.1629
REGION1	NORTH AMERICA			.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-8.6829	11.8049
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.
BASE				0.4654	0.5763

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	2	975	2.89	0.0560
REGION1	3	975	3.33	0.0191
BOLAD1	1	975	0.09	0.7650
BASE	1	975	339.78	<.0001

Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG240C Parameter=PPG at 4 hours (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) - NovoRapid (meal)	WORK.ENDPOINT_2	-8.4498	5.7026	975	-1.48	0.1387	0.05	-19.6405	2.7410

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (post) - NovoRapid (meal)	WORK.ENDPOINT_2	5.1048	5.7105	975	0.89	0.3716	0.05	-6.1015	16.3110

Least Squares Means

Effect	Planned Treatment for Period 30 (N)	Margins	BASE	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	2	WORK.ENDPOINT_2	167.71	168.61	4.0167	975	41.98	<.0001	0.05	160.73	176.49
TRTPN	3	WORK.ENDPOINT_2	167.71	182.16	4.0286	975	45.22	<.0001	0.05	174.26	190.07
TRTPN	4	WORK.ENDPOINT_2	167.71	177.06	4.0450	975	43.77	<.0001	0.05	169.12	185.00

Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG30 Parameter=PPG at 30 min (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Model Information

Data Set	WORK.ENDPOINT_2
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Dimensions

Covariance Parameters	1
Columns in X	10
Columns in Z	0
Subjects	1
Max Obs per Subject	990

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG30 Parameter=PPG at 30 min (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Number of Observations

Number of Observations Read	990
Number of Observations Used	990
Number of Observations Not Used	0

Covariance Parameter
Estimates

Cov Parm	Estimate
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Residual	9.0063
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Fit Statistics

-2 Res Log Likelihood	4991.9
AIC (Smaller is Better)	4993.9
AICC (Smaller is Better)	4993.9
BIC (Smaller is Better)	4998.8

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			2	6.1002	0.3790	982
TRTPN			3	7.8168	0.3778	982
TRTPN			4	6.9160	0.3859	982

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG30 Parameter=PPG at 30 min (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
REGION1	ASIA (EXCLUDING JAPAN)			-0.2161	0.3481	982
REGION1	EUROPE			0.08006	0.2457	982
REGION1	JAPAN			0.7672	0.2781	982
REGION1	NORTH AMERICA			0	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.2286	0.2144	982
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0	.	.
BASE				0.3517	0.03047	982

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
TRTPN			2	16.10	<.0001	0.05
TRTPN			3	20.69	<.0001	0.05
TRTPN			4	17.92	<.0001	0.05
REGION1	ASIA (EXCLUDING JAPAN)			-0.62	0.5348	0.05
REGION1	EUROPE			0.33	0.7446	0.05
REGION1	JAPAN			2.76	0.0059	0.05
REGION1	NORTH AMERICA			.	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-1.07	0.2867	0.05
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.	.
BASE				11.54	<.0001	0.05

Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG30 Parameter=PPG at 30 min (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Lower	Upper
TRTPN			2	5.3565	6.8438
TRTPN			3	7.0754	8.5582
TRTPN			4	6.1586	7.6733
REGION1	ASIA (EXCLUDING JAPAN)			-0.8993	0.4670
REGION1	EUROPE			-0.4021	0.5622
REGION1	JAPAN			0.2214	1.3129
REGION1	NORTH AMERICA			.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.6493	0.1922
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.
BASE				0.2919	0.4115

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	2	982	27.06	<.0001
REGION1	3	982	4.16	0.0061
BOLAD1	1	982	1.14	0.2867
BASE	1	982	133.26	<.0001

Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG30 Parameter=PPG at 30 min (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) - NovoRapid (meal)	WORK.ENDPOINT_2	-0.8158	0.2342	982	-3.48	0.0005	0.05	-1.2754	-0.3561

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (post) - NovoRapid (meal)	WORK.ENDPOINT_2	0.9008	0.2346	982	3.84	0.0001	0.05	0.4404	1.3613

Least Squares Means

Effect	Planned Treatment for Period (N)	Margins	BASE	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	2	WORK.ENDPOINT_2	10.25	9.7537	0.1647	982	59.23	<.0001	0.05	9.4306	10.0768
TRTPN	3	WORK.ENDPOINT_2	10.25	11.4703	0.1652	982	69.44	<.0001	0.05	11.1461	11.7945
TRTPN	4	WORK.ENDPOINT_2	10.25	10.5695	0.1664	982	63.51	<.0001	0.05	10.2429	10.8961

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG30C Parameter=PPG at 30 min (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Model Information

Data Set	WORK.ENDPOINT_2
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Dimensions

Covariance Parameters	1
Columns in X	10
Columns in Z	0
Subjects	1
Max Obs per Subject	990

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG30C Parameter=PPG at 30 min (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Number of Observations

Number of Observations Read	990
Number of Observations Used	990
Number of Observations Not Used	0

Covariance Parameter
Estimates

Cov Parm	Estimate
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Residual	2924.54
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Fit Statistics

-2 Res Log Likelihood	10676.6
AIC (Smaller is Better)	10678.6
AICC (Smaller is Better)	10678.6
BIC (Smaller is Better)	10683.5

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			2	109.92	6.8287	982
TRTPN			3	140.86	6.8080	982
TRTPN			4	124.63	6.9547	982

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG30C Parameter=PPG at 30 min (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
REGION1	ASIA (EXCLUDING JAPAN)			-3.8948	6.2734	982
REGION1	EUROPE			1.4427	4.4273	982
REGION1	JAPAN			13.8246	5.0116	982
REGION1	NORTH AMERICA			0	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-4.1185	3.8634	982
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0	.	.
BASE				0.3517	0.03047	982

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
TRTPN			2	16.10	<.0001	0.05
TRTPN			3	20.69	<.0001	0.05
TRTPN			4	17.92	<.0001	0.05
REGION1	ASIA (EXCLUDING JAPAN)			-0.62	0.5348	0.05
REGION1	EUROPE			0.33	0.7446	0.05
REGION1	JAPAN			2.76	0.0059	0.05
REGION1	NORTH AMERICA			.	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-1.07	0.2867	0.05
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.	.
BASE				11.54	<.0001	0.05

Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG30C Parameter=PPG at 30 min (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Lower	Upper
TRTPN			2	96.5245	123.33
TRTPN			3	127.50	154.22
TRTPN			4	110.98	138.27
REGION1	ASIA (EXCLUDING JAPAN)			-16.2057	8.4161
REGION1	EUROPE			-7.2453	10.1307
REGION1	JAPAN			3.9900	23.6592
REGION1	NORTH AMERICA			.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-11.7001	3.4630
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.
BASE				0.2919	0.4115

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	2	982	27.06	<.0001
REGION1	3	982	4.16	0.0061
BOLAD1	1	982	1.14	0.2867
BASE	1	982	133.26	<.0001

Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG30C Parameter=PPG at 30 min (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) - NovoRapid (meal)	WORK.ENDPOINT_2	-14.7006	4.2209	982	-3.48	0.0005	0.05	-22.9836	-6.4176

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (post) - NovoRapid (meal)	WORK.ENDPOINT_2	16.2328	4.2283	982	3.84	0.0001	0.05	7.9353	24.5303

Least Squares Means

Effect	Planned Treatment for Period 30 (N)	Margins	BASE	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	2	WORK.ENDPOINT_2	184.67	175.76	2.9673	982	59.23	<.0001	0.05	169.94	181.58
TRTPN	3	WORK.ENDPOINT_2	184.67	206.69	2.9767	982	69.44	<.0001	0.05	200.85	212.54
TRTPN	4	WORK.ENDPOINT_2	184.67	190.46	2.9988	982	63.51	<.0001	0.05	184.58	196.35

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG60 Parameter=PPG at 1 hour (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Model Information

Data Set	WORK.ENDPOINT_2
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Dimensions

Covariance Parameters	1
Columns in X	10
Columns in Z	0
Subjects	1
Max Obs per Subject	992

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG60 Parameter=PPG at 1 hour (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Number of Observations

Number of Observations Read	992
Number of Observations Used	992
Number of Observations Not Used	0

Covariance Parameter
Estimates

Cov Parm	Estimate
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Residual	13.7987
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Fit Statistics

-2 Res Log Likelihood	5422.4
AIC (Smaller is Better)	5424.4
AICC (Smaller is Better)	5424.4
BIC (Smaller is Better)	5429.3

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			2	6.4435	0.4350	984
TRTPN			3	8.6450	0.4281	984
TRTPN			4	7.6812	0.4377	984

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG60 Parameter=PPG at 1 hour (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
REGION1	ASIA (EXCLUDING JAPAN)			-0.4343	0.4301	984
REGION1	EUROPE			-0.5447	0.3037	984
REGION1	JAPAN			0.3801	0.3424	984
REGION1	NORTH AMERICA			0	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.008207	0.2651	984
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0	.	.
BASE				0.3891	0.02831	984

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
TRTPN			2	14.81	<.0001	0.05
TRTPN			3	20.20	<.0001	0.05
TRTPN			4	17.55	<.0001	0.05
REGION1	ASIA (EXCLUDING JAPAN)			-1.01	0.3130	0.05
REGION1	EUROPE			-1.79	0.0732	0.05
REGION1	JAPAN			1.11	0.2672	0.05
REGION1	NORTH AMERICA			.	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.03	0.9753	0.05
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.	.
BASE				13.74	<.0001	0.05

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG60 Parameter=PPG at 1 hour (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Lower	Upper
TRTPN			2	5.5898	7.2972
TRTPN			3	7.8050	9.4850
TRTPN			4	6.8222	8.5402
REGION1	ASIA (EXCLUDING JAPAN)			-1.2784	0.4099
REGION1	EUROPE			-1.1407	0.05135
REGION1	JAPAN			-0.2918	1.0521
REGION1	NORTH AMERICA			.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.5119	0.5284
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.
BASE				0.3335	0.4446

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	2	984	29.23	<.0001
REGION1	3	984	3.25	0.0213
BOLAD1	1	984	0.00	0.9753
BASE	1	984	188.85	<.0001

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG60 Parameter=PPG at 1 hour (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) - NovoRapid (meal)	WORK.ENDPOINT_2	-1.2377	0.2898	984	-4.27	<.0001	0.05	-1.8065	-0.6689

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (post) - NovoRapid (meal)	WORK.ENDPOINT_2	0.9638	0.2900	984	3.32	0.0009	0.05	0.3946	1.5329

Least Squares Means

Effect	Planned Treatment for Period	30 (N)	Margins	BASE	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	2		WORK.ENDPOINT_2	11.89	10.9251	0.2038	984	53.60	<.0001	0.05	10.5251	11.3251
TRTPN	3		WORK.ENDPOINT_2	11.89	13.1266	0.2039	984	64.37	<.0001	0.05	12.7264	13.5268
TRTPN	4		WORK.ENDPOINT_2	11.89	12.1628	0.2059	984	59.06	<.0001	0.05	11.7587	12.5670

Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG60C Parameter=PPG at 1 hour (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Model Information

Data Set	WORK.ENDPOINT_2
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Dimensions

Covariance Parameters	1
Columns in X	10
Columns in Z	0
Subjects	1
Max Obs per Subject	992

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG60C Parameter=PPG at 1 hour (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Number of Observations

Number of Observations Read	992
Number of Observations Used	992
Number of Observations Not Used	0

Covariance Parameter
Estimates

Cov Parm	Estimate
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Residual	4480.73
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Fit Statistics

-2 Res Log Likelihood	11118.6
AIC (Smaller is Better)	11120.6
AICC (Smaller is Better)	11120.6
BIC (Smaller is Better)	11125.5

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			2	116.11	7.8394	984
TRTPN			3	155.78	7.7136	984
TRTPN			4	138.42	7.8879	984

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG60C Parameter=PPG at 1 hour (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
REGION1	ASIA (EXCLUDING JAPAN)			-7.8253	7.7513	984
REGION1	EUROPE			-9.8154	5.4734	984
REGION1	JAPAN			6.8495	6.1703	984
REGION1	NORTH AMERICA			0	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.1479	4.7765	984
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0	.	.
BASE				0.3891	0.02831	984

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
TRTPN			2	14.81	<.0001	0.05
TRTPN			3	20.20	<.0001	0.05
TRTPN			4	17.55	<.0001	0.05
REGION1	ASIA (EXCLUDING JAPAN)			-1.01	0.3130	0.05
REGION1	EUROPE			-1.79	0.0732	0.05
REGION1	JAPAN			1.11	0.2672	0.05
REGION1	NORTH AMERICA			.	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.03	0.9753	0.05
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.	.
BASE				13.74	<.0001	0.05

Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG60C Parameter=PPG at 1 hour (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Lower	Upper
TRTPN			2	100.73	131.50
TRTPN			3	140.65	170.92
TRTPN			4	122.94	153.89
REGION1	ASIA (EXCLUDING JAPAN)			-23.0362	7.3856
REGION1	EUROPE			-20.5562	0.9254
REGION1	JAPAN			-5.2590	18.9580
REGION1	NORTH AMERICA			.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-9.2253	9.5211
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.
BASE				0.3335	0.4446

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	2	984	29.23	<.0001
REGION1	3	984	3.25	0.0213
BOLAD1	1	984	0.00	0.9753
BASE	1	984	188.85	<.0001

Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG60C Parameter=PPG at 1 hour (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) - NovoRapid (meal)	WORK.ENDPOINT_2	-22.3034	5.2230	984	-4.27	<.0001	0.05	-32.5530	-12.0539

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (post) - NovoRapid (meal)	WORK.ENDPOINT_2	17.3674	5.2265	984	3.32	0.0009	0.05	7.1111	27.6237

Least Squares Means

Effect	Planned Treatment for Period 30 (N)	Margins	BASE	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	2	WORK.ENDPOINT_2	214.28	196.87	3.6733	984	53.60	<.0001	0.05	189.66	204.08
TRTPN	3	WORK.ENDPOINT_2	214.28	236.54	3.6749	984	64.37	<.0001	0.05	229.33	243.75
TRTPN	4	WORK.ENDPOINT_2	214.28	219.17	3.7111	984	59.06	<.0001	0.05	211.89	226.46

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG120 Parameter=PPG at 2 hours (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Model Information

Data Set	WORK.ENDPOINT_2
Dependent Variable	CHG
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Dimensions

Covariance Parameters	1
Columns in X	10
Columns in Z	0
Subjects	1
Max Obs per Subject	985

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG120 Parameter=PPG at 2 hours (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Number of Observations

Number of Observations Read	985
Number of Observations Used	985
Number of Observations Not Used	0

Covariance Parameter
Estimates

Cov Parm	Estimate
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Residual	20.4031
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Fit Statistics

-2 Res Log Likelihood	5766.6
AIC (Smaller is Better)	5768.6
AICC (Smaller is Better)	5768.6
BIC (Smaller is Better)	5773.5

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			2	6.7623	0.4864	977
TRTPN			3	7.7194	0.4784	977
TRTPN			4	7.4322	0.4875	977

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG120 Parameter=PPG at 2 hours (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
REGION1	ASIA (EXCLUDING JAPAN)			-0.6751	0.5268	977
REGION1	EUROPE			-0.8820	0.3719	977
REGION1	JAPAN			0.4589	0.4204	977
REGION1	NORTH AMERICA			0	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.2622	0.3240	977
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0	.	.
BASE				-0.5604	0.02823	977

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
TRTPN			2	13.90	<.0001	0.05
TRTPN			3	16.14	<.0001	0.05
TRTPN			4	15.25	<.0001	0.05
REGION1	ASIA (EXCLUDING JAPAN)			-1.28	0.2003	0.05
REGION1	EUROPE			-2.37	0.0179	0.05
REGION1	JAPAN			1.09	0.2753	0.05
REGION1	NORTH AMERICA			.	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.81	0.4186	0.05
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.	.
BASE				-19.85	<.0001	0.05

Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG120 Parameter=PPG at 2 hours (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Lower	Upper
TRTPN			2	5.8077	7.7168
TRTPN			3	6.7806	8.6582
TRTPN			4	6.4757	8.3888
REGION1	ASIA (EXCLUDING JAPAN)			-1.7090	0.3587
REGION1	EUROPE			-1.6117	-0.1522
REGION1	JAPAN			-0.3661	1.2838
REGION1	NORTH AMERICA			.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.3736	0.8980
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.
BASE				-0.6157	-0.5050

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	2	977	3.89	0.0209
REGION1	3	977	4.69	0.0029
BOLAD1	1	977	0.65	0.4186
BASE	1	977	394.12	<.0001

Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG120 Parameter=PPG at 2 hours (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) - NovoRapid (meal)	WORK.ENDPOINT_2	-0.6700	0.3544	977	-1.89	0.0590	0.05	-1.3654	0.02547

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (post) - NovoRapid (meal)	WORK.ENDPOINT_2	0.2872	0.3534	977	0.81	0.4166	0.05	-0.4062	0.9806

Least Squares Means

Effect	Planned Treatment for Period 30 (N)	Margins	BASE	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	2	WORK.ENDPOINT_2	12.38	-0.3016	0.2494	977	-1.21	0.2269	0.05	-0.7910	0.1879
TRTPN	3	WORK.ENDPOINT_2	12.38	0.6556	0.2479	977	2.64	0.0083	0.05	0.1691	1.1421
TRTPN	4	WORK.ENDPOINT_2	12.38	0.3684	0.2516	977	1.46	0.1434	0.05	-0.1252	0.8621

Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG120C Parameter=PPG at 2 hours (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Model Information

Data Set	WORK.ENDPOINT_2
Dependent Variable	CHG
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Dimensions

Covariance Parameters	1
Columns in X	10
Columns in Z	0
Subjects	1
Max Obs per Subject	985

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG120C Parameter=PPG at 2 hours (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Number of Observations

Number of Observations Read	985
Number of Observations Used	985
Number of Observations Not Used	0

Covariance Parameter
Estimates

Cov Parm	Estimate
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Residual	6625.29
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Fit Statistics

-2 Res Log Likelihood	11422.4
AIC (Smaller is Better)	11424.4
AICC (Smaller is Better)	11424.4
BIC (Smaller is Better)	11429.3

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			2	121.86	8.7651	977
TRTPN			3	139.10	8.6206	977
TRTPN			4	133.93	8.7841	977

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG120C Parameter=PPG at 2 hours (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
REGION1	ASIA (EXCLUDING JAPAN)			-12.1655	9.4935	977
REGION1	EUROPE			-15.8932	6.7013	977
REGION1	JAPAN			8.2692	7.5752	977
REGION1	NORTH AMERICA			0	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		4.7241	5.8383	977
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0	.	.
BASE				-0.5604	0.02823	977

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
TRTPN			2	13.90	<.0001	0.05
TRTPN			3	16.14	<.0001	0.05
TRTPN			4	15.25	<.0001	0.05
REGION1	ASIA (EXCLUDING JAPAN)			-1.28	0.2003	0.05
REGION1	EUROPE			-2.37	0.0179	0.05
REGION1	JAPAN			1.09	0.2753	0.05
REGION1	NORTH AMERICA			.	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.81	0.4186	0.05
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.	.
BASE				-19.85	<.0001	0.05

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG120C Parameter=PPG at 2 hours (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Lower	Upper
TRTPN			2	104.66	139.06
TRTPN			3	122.19	156.02
TRTPN			4	116.69	151.17
REGION1	ASIA (EXCLUDING JAPAN)			-30.7955	6.4646
REGION1	EUROPE			-29.0437	-2.7427
REGION1	JAPAN			-6.5962	23.1347
REGION1	NORTH AMERICA			.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-6.7330	16.1812
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.
BASE				-0.6157	-0.5050

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	2	977	3.89	0.0209
REGION1	3	977	4.69	0.0029
BOLAD1	1	977	0.65	0.4186
BASE	1	977	394.12	<.0001

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG120C Parameter=PPG at 2 hours (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) - NovoRapid (meal)	WORK.ENDPOINT_2	-12.0731	6.3861	977	-1.89	0.0590	0.05	-24.6052	0.4589

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (post) - NovoRapid (meal)	WORK.ENDPOINT_2	5.1751	6.3675	977	0.81	0.4166	0.05	-7.3205	17.6706

Least Squares Means

Effect	Planned Treatment for Period	30 (N)	Margins	BASE	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	2		WORK.ENDPOINT_2	223.16	-5.4342	4.4942	977	-1.21	0.2269	0.05	-14.2536	3.3852
TRTPN	3		WORK.ENDPOINT_2	223.16	11.8140	4.4673	977	2.64	0.0083	0.05	3.0474	20.5806
TRTPN	4		WORK.ENDPOINT_2	223.16	6.6389	4.5332	977	1.46	0.1434	0.05	-2.2569	15.5347

Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG180 Parameter=PPG at 3 hours (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Model Information

Data Set	WORK.ENDPOINT_2
Dependent Variable	CHG
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Dimensions

Covariance Parameters	1
Columns in X	10
Columns in Z	0
Subjects	1
Max Obs per Subject	983

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG180 Parameter=PPG at 3 hours (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Number of Observations

Number of Observations Read	983
Number of Observations Used	983
Number of Observations Not Used	0

Covariance Parameter
Estimates

Cov Parm	Estimate
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Residual	20.1790
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Fit Statistics

-2 Res Log Likelihood	5744.1
AIC (Smaller is Better)	5746.1
AICC (Smaller is Better)	5746.1
BIC (Smaller is Better)	5751.0

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			2	5.7431	0.4507	975
TRTPN			3	6.5761	0.4462	975
TRTPN			4	6.2724	0.4524	975

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG180 Parameter=PPG at 3 hours (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
REGION1	ASIA (EXCLUDING JAPAN)			-0.1611	0.5275	975
REGION1	EUROPE			-0.9475	0.3706	975
REGION1	JAPAN			0.5515	0.4238	975
REGION1	NORTH AMERICA			0	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.1113	0.3224	975
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0	.	.
BASE				-0.5066	0.02817	975

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
TRTPN			2	12.74	<.0001	0.05
TRTPN			3	14.74	<.0001	0.05
TRTPN			4	13.87	<.0001	0.05
REGION1	ASIA (EXCLUDING JAPAN)			-0.31	0.7601	0.05
REGION1	EUROPE			-2.56	0.0107	0.05
REGION1	JAPAN			1.30	0.1934	0.05
REGION1	NORTH AMERICA			.	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.35	0.7301	0.05
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.	.
BASE				-17.98	<.0001	0.05

Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG180 Parameter=PPG at 3 hours (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Lower	Upper
TRTPN			2	4.8586	6.6275
TRTPN			3	5.7005	7.4516
TRTPN			4	5.3847	7.1601
REGION1	ASIA (EXCLUDING JAPAN)			-1.1964	0.8741
REGION1	EUROPE			-1.6748	-0.2202
REGION1	JAPAN			-0.2801	1.3831
REGION1	NORTH AMERICA			.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.5214	0.7439
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.
BASE				-0.5618	-0.4513

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	2	975	2.89	0.0562
REGION1	3	975	5.22	0.0014
BOLAD1	1	975	0.12	0.7301
BASE	1	975	323.32	<.0001

Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG180 Parameter=PPG at 3 hours (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) - NovoRapid (meal)	WORK.ENDPOINT_2	-0.5294	0.3515	975	-1.51	0.1324	0.05	-1.2191	0.1604

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (post) - NovoRapid (meal)	WORK.ENDPOINT_2	0.3037	0.3526	975	0.86	0.3894	0.05	-0.3883	0.9957

Least Squares Means

Effect	Planned Treatment for Period 30 (N)	Margins	BASE	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	2	WORK.ENDPOINT_2	11.09	-0.01487	0.2470	975	-0.06	0.9520	0.05	-0.4996	0.4698
TRTPN	3	WORK.ENDPOINT_2	11.09	0.8182	0.2488	975	3.29	0.0010	0.05	0.3299	1.3064
TRTPN	4	WORK.ENDPOINT_2	11.09	0.5145	0.2498	975	2.06	0.0397	0.05	0.02432	1.0047

Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG180C Parameter=PPG at 3 hours (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Model Information

Data Set	WORK.ENDPOINT_2
Dependent Variable	CHG
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Dimensions

Covariance Parameters	1
Columns in X	10
Columns in Z	0
Subjects	1
Max Obs per Subject	983

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG180C Parameter=PPG at 3 hours (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Number of Observations

Number of Observations Read	983
Number of Observations Used	983
Number of Observations Not Used	0

Covariance Parameter
Estimates

Cov Parm	Estimate
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Residual	6552.53
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Fit Statistics

-2 Res Log Likelihood	11388.3
AIC (Smaller is Better)	11390.3
AICC (Smaller is Better)	11390.3
BIC (Smaller is Better)	11395.2

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			2	103.49	8.1212	975
TRTPN			3	118.50	8.0398	975
TRTPN			4	113.03	8.1514	975

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG180C Parameter=PPG at 3 hours (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
REGION1	ASIA (EXCLUDING JAPAN)			-2.9034	9.5064	975
REGION1	EUROPE			-17.0739	6.6782	975
REGION1	JAPAN			9.9385	7.6363	975
REGION1	NORTH AMERICA			0	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		2.0048	5.8095	975
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0	.	.
BASE				-0.5066	0.02817	975

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
TRTPN			2	12.74	<.0001	0.05
TRTPN			3	14.74	<.0001	0.05
TRTPN			4	13.87	<.0001	0.05
REGION1	ASIA (EXCLUDING JAPAN)			-0.31	0.7601	0.05
REGION1	EUROPE			-2.56	0.0107	0.05
REGION1	JAPAN			1.30	0.1934	0.05
REGION1	NORTH AMERICA			.	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.35	0.7301	0.05
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.	.
BASE				-17.98	<.0001	0.05

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG180C Parameter=PPG at 3 hours (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Lower	Upper
TRTPN			2	87.5528	119.43
TRTPN			3	102.72	134.28
TRTPN			4	97.0325	129.03
REGION1	ASIA (EXCLUDING JAPAN)			-21.5588	15.7519
REGION1	EUROPE			-30.1792	-3.9685
REGION1	JAPAN			-5.0471	24.9241
REGION1	NORTH AMERICA			.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-9.3959	13.4054
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.
BASE				-0.5618	-0.4513

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	2	975	2.89	0.0562
REGION1	3	975	5.22	0.0014
BOLAD1	1	975	0.12	0.7301
BASE	1	975	323.32	<.0001

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG180C Parameter=PPG at 3 hours (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) - NovoRapid (meal)	WORK.ENDPOINT_2	-9.5391	6.3337	975	-1.51	0.1324	0.05	-21.9684	2.8903

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (post) - NovoRapid (meal)	WORK.ENDPOINT_2	5.4722	6.3545	975	0.86	0.3894	0.05	-6.9980	17.9424

Least Squares Means

Effect	Planned Treatment for Period	30 (N)	Margins	BASE	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	2		WORK.ENDPOINT_2	199.76	-0.2679	4.4507	975	-0.06	0.9520	0.05	-9.0019	8.4660
TRTPN	3		WORK.ENDPOINT_2	199.76	14.7434	4.4832	975	3.29	0.0010	0.05	5.9456	23.5412
TRTPN	4		WORK.ENDPOINT_2	199.76	9.2712	4.5011	975	2.06	0.0397	0.05	0.4383	18.1041

Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG240 Parameter=PPG at 4 hours (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Model Information

Data Set	WORK.ENDPOINT_2
Dependent Variable	CHG
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Dimensions

Covariance Parameters	1
Columns in X	10
Columns in Z	0
Subjects	1
Max Obs per Subject	983

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG240 Parameter=PPG at 4 hours (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Number of Observations

Number of Observations Read	983
Number of Observations Used	983
Number of Observations Not Used	0

Covariance Parameter
Estimates

Cov Parm	Estimate
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Residual	16.3549
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Fit Statistics

-2 Res Log Likelihood	5539.1
AIC (Smaller is Better)	5541.1
AICC (Smaller is Better)	5541.1
BIC (Smaller is Better)	5545.9

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			2	4.5173	0.3894	975
TRTPN			3	5.2695	0.3879	975
TRTPN			4	4.9862	0.3910	975

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG240 Parameter=PPG at 4 hours (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
REGION1	ASIA (EXCLUDING JAPAN)			0.2054	0.4779	975
REGION1	EUROPE			-0.5970	0.3323	975
REGION1	JAPAN			0.4822	0.3810	975
REGION1	NORTH AMERICA			0	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.08663	0.2897	975
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0	.	.
BASE				-0.4791	0.02826	975

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
TRTPN			2	11.60	<.0001	0.05
TRTPN			3	13.58	<.0001	0.05
TRTPN			4	12.75	<.0001	0.05
REGION1	ASIA (EXCLUDING JAPAN)			0.43	0.6674	0.05
REGION1	EUROPE			-1.80	0.0727	0.05
REGION1	JAPAN			1.27	0.2059	0.05
REGION1	NORTH AMERICA			.	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.30	0.7650	0.05
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.	.
BASE				-16.96	<.0001	0.05

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG240 Parameter=PPG at 4 hours (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Lower	Upper
TRTPN			2	3.7532	5.2814
TRTPN			3	4.5083	6.0307
TRTPN			4	4.2188	5.7535
REGION1	ASIA (EXCLUDING JAPAN)			-0.7325	1.1433
REGION1	EUROPE			-1.2490	0.05499
REGION1	JAPAN			-0.2654	1.2299
REGION1	NORTH AMERICA			.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.4818	0.6551
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.
BASE				-0.5346	-0.4237

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	2	975	2.89	0.0560
REGION1	3	975	3.33	0.0191
BOLAD1	1	975	0.09	0.7650
BASE	1	975	287.50	<.0001

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG240 Parameter=PPG at 4 hours (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) - NovoRapid (meal)	WORK.ENDPOINT_2	-0.4689	0.3165	975	-1.48	0.1387	0.05	-1.0899	0.1521

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (post) - NovoRapid (meal)	WORK.ENDPOINT_2	0.2833	0.3169	975	0.89	0.3716	0.05	-0.3386	0.9052

Least Squares Means

Effect	Planned Treatment for Period 30 (N)	Margins	BASE	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	2	WORK.ENDPOINT_2	9.31	0.05014	0.2229	975	0.22	0.8221	0.05	-0.3873	0.4876
TRTPN	3	WORK.ENDPOINT_2	9.31	0.8023	0.2236	975	3.59	0.0003	0.05	0.3636	1.2411
TRTPN	4	WORK.ENDPOINT_2	9.31	0.5190	0.2245	975	2.31	0.0210	0.05	0.07854	0.9595

Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG240C Parameter=PPG at 4 hours (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Model Information

Data Set	WORK.ENDPOINT_2
Dependent Variable	CHG
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Dimensions

Covariance Parameters	1
Columns in X	10
Columns in Z	0
Subjects	1
Max Obs per Subject	983

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG240C Parameter=PPG at 4 hours (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Number of Observations

Number of Observations Read	983
Number of Observations Used	983
Number of Observations Not Used	0

Covariance Parameter
Estimates

Cov Parm	Estimate
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Residual	5310.76
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Fit Statistics

-2 Res Log Likelihood	11183.2
AIC (Smaller is Better)	11185.2
AICC (Smaller is Better)	11185.2
BIC (Smaller is Better)	11190.1

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			2	81.4014	7.0164	975
TRTPN			3	94.9559	6.9898	975
TRTPN			4	89.8512	7.0463	975

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG240C Parameter=PPG at 4 hours (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
REGION1	ASIA (EXCLUDING JAPAN)			3.7014	8.6123	975
REGION1	EUROPE			-10.7584	5.9872	975
REGION1	JAPAN			8.6899	6.8656	975
REGION1	NORTH AMERICA			0	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		1.5610	5.2201	975
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0	.	.
BASE				-0.4791	0.02826	975

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
TRTPN			2	11.60	<.0001	0.05
TRTPN			3	13.58	<.0001	0.05
TRTPN			4	12.75	<.0001	0.05
REGION1	ASIA (EXCLUDING JAPAN)			0.43	0.6674	0.05
REGION1	EUROPE			-1.80	0.0727	0.05
REGION1	JAPAN			1.27	0.2059	0.05
REGION1	NORTH AMERICA			.	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.30	0.7650	0.05
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.	.
BASE				-16.96	<.0001	0.05

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG240C Parameter=PPG at 4 hours (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Lower	Upper
TRTPN			2	67.6324	95.1705
TRTPN			3	81.2391	108.67
TRTPN			4	76.0235	103.68
REGION1	ASIA (EXCLUDING JAPAN)			-13.1994	20.6023
REGION1	EUROPE			-22.5077	0.9910
REGION1	JAPAN			-4.7832	22.1629
REGION1	NORTH AMERICA			.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-8.6829	11.8049
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.
BASE				-0.5346	-0.4237

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	2	975	2.89	0.0560
REGION1	3	975	3.33	0.0191
BOLAD1	1	975	0.09	0.7650
BASE	1	975	287.50	<.0001

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG240C Parameter=PPG at 4 hours (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) - NovoRapid (meal)	WORK.ENDPOINT_2	-8.4498	5.7026	975	-1.48	0.1387	0.05	-19.6405	2.7410

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (post) - NovoRapid (meal)	WORK.ENDPOINT_2	5.1048	5.7105	975	0.89	0.3716	0.05	-6.1015	16.3110

Least Squares Means

Effect	Planned Treatment for Period	30 (N)	Margins	BASE	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	2		WORK.ENDPOINT_2	167.71	0.9035	4.0167	975	0.22	0.8221	0.05	-6.9789	8.7859
TRTPN	3		WORK.ENDPOINT_2	167.71	14.4580	4.0286	975	3.59	0.0003	0.05	6.5522	22.3637
TRTPN	4		WORK.ENDPOINT_2	167.71	9.3532	4.0450	975	2.31	0.0210	0.05	1.4154	17.2911

Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG30 Parameter=PPG at 30 min (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Model Information

Data Set	WORK.ENDPOINT_2
Dependent Variable	CHG
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Dimensions

Covariance Parameters	1
Columns in X	10
Columns in Z	0
Subjects	1
Max Obs per Subject	990

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 755 of 4425	Novo Nordisk
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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG30 Parameter=PPG at 30 min (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Number of Observations

Number of Observations Read	990
Number of Observations Used	990
Number of Observations Not Used	0

Covariance Parameter
Estimates

Cov Parm	Estimate
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Residual	9.0063
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Fit Statistics

-2 Res Log Likelihood	4991.9
AIC (Smaller is Better)	4993.9
AICC (Smaller is Better)	4993.9
BIC (Smaller is Better)	4998.8

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			2	6.1002	0.3790	982
TRTPN			3	7.8168	0.3778	982
TRTPN			4	6.9160	0.3859	982

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG30 Parameter=PPG at 30 min (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
REGION1	ASIA (EXCLUDING JAPAN)			-0.2161	0.3481	982
REGION1	EUROPE			0.08006	0.2457	982
REGION1	JAPAN			0.7672	0.2781	982
REGION1	NORTH AMERICA			0	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.2286	0.2144	982
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0	.	.
BASE				-0.6483	0.03047	982

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
TRTPN			2	16.10	<.0001	0.05
TRTPN			3	20.69	<.0001	0.05
TRTPN			4	17.92	<.0001	0.05
REGION1	ASIA (EXCLUDING JAPAN)			-0.62	0.5348	0.05
REGION1	EUROPE			0.33	0.7446	0.05
REGION1	JAPAN			2.76	0.0059	0.05
REGION1	NORTH AMERICA			.	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-1.07	0.2867	0.05
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.	.
BASE				-21.28	<.0001	0.05

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG30 Parameter=PPG at 30 min (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Lower	Upper
TRTPN			2	5.3565	6.8438
TRTPN			3	7.0754	8.5582
TRTPN			4	6.1586	7.6733
REGION1	ASIA (EXCLUDING JAPAN)			-0.8993	0.4670
REGION1	EUROPE			-0.4021	0.5622
REGION1	JAPAN			0.2214	1.3129
REGION1	NORTH AMERICA			.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.6493	0.1922
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.
BASE				-0.7081	-0.5885

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	2	982	27.06	<.0001
REGION1	3	982	4.16	0.0061
BOLAD1	1	982	1.14	0.2867
BASE	1	982	452.79	<.0001

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG30 Parameter=PPG at 30 min (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) - NovoRapid (meal)	WORK.ENDPOINT_2	-0.8158	0.2342	982	-3.48	0.0005	0.05	-1.2754	-0.3561

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (post) - NovoRapid (meal)	WORK.ENDPOINT_2	0.9008	0.2346	982	3.84	0.0001	0.05	0.4404	1.3613

Least Squares Means

Effect	Planned Treatment for Period 30 (N)	Margins	BASE	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	2	WORK.ENDPOINT_2	10.25	-0.4944	0.1647	982	-3.00	0.0027	0.05	-0.8175	-0.1713
TRTPN	3	WORK.ENDPOINT_2	10.25	1.2222	0.1652	982	7.40	<.0001	0.05	0.8981	1.5464
TRTPN	4	WORK.ENDPOINT_2	10.25	0.3214	0.1664	982	1.93	0.0537	0.05	-0.00517	0.6480

Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG30C Parameter=PPG at 30 min (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Model Information

Data Set	WORK.ENDPOINT_2
Dependent Variable	CHG
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Dimensions

Covariance Parameters	1
Columns in X	10
Columns in Z	0
Subjects	1
Max Obs per Subject	990

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG30C Parameter=PPG at 30 min (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Number of Observations

Number of Observations Read	990
Number of Observations Used	990
Number of Observations Not Used	0

Covariance Parameter
Estimates

Cov Parm	Estimate
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Residual	2924.54
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Fit Statistics

-2 Res Log Likelihood	10676.6
AIC (Smaller is Better)	10678.6
AICC (Smaller is Better)	10678.6
BIC (Smaller is Better)	10683.5

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			2	109.92	6.8287	982
TRTPN			3	140.86	6.8080	982
TRTPN			4	124.63	6.9547	982

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG30C Parameter=PPG at 30 min (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
REGION1	ASIA (EXCLUDING JAPAN)			-3.8948	6.2734	982
REGION1	EUROPE			1.4427	4.4273	982
REGION1	JAPAN			13.8246	5.0116	982
REGION1	NORTH AMERICA			0	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-4.1185	3.8634	982
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0	.	.
BASE				-0.6483	0.03047	982

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
TRTPN			2	16.10	<.0001	0.05
TRTPN			3	20.69	<.0001	0.05
TRTPN			4	17.92	<.0001	0.05
REGION1	ASIA (EXCLUDING JAPAN)			-0.62	0.5348	0.05
REGION1	EUROPE			0.33	0.7446	0.05
REGION1	JAPAN			2.76	0.0059	0.05
REGION1	NORTH AMERICA			.	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-1.07	0.2867	0.05
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.	.
BASE				-21.28	<.0001	0.05

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG30C Parameter=PPG at 30 min (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Lower	Upper
TRTPN			2	96.5245	123.33
TRTPN			3	127.50	154.22
TRTPN			4	110.98	138.27
REGION1	ASIA (EXCLUDING JAPAN)			-16.2057	8.4161
REGION1	EUROPE			-7.2453	10.1307
REGION1	JAPAN			3.9900	23.6592
REGION1	NORTH AMERICA			.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-11.7001	3.4630
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.
BASE				-0.7081	-0.5885

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	2	982	27.06	<.0001
REGION1	3	982	4.16	0.0061
BOLAD1	1	982	1.14	0.2867
BASE	1	982	452.79	<.0001

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG30C Parameter=PPG at 30 min (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) - NovoRapid (meal)	WORK.ENDPOINT_2	-14.7006	4.2209	982	-3.48	0.0005	0.05	-22.9836	-6.4176

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (post) - NovoRapid (meal)	WORK.ENDPOINT_2	16.2328	4.2283	982	3.84	0.0001	0.05	7.9353	24.5303

Least Squares Means

Effect	Planned Treatment for Period 30 (N)	Margins	BASE	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	2	WORK.ENDPOINT_2	184.67	-8.9089	2.9673	982	-3.00	0.0027	0.05	-14.7318	-3.0860
TRTPN	3	WORK.ENDPOINT_2	184.67	22.0244	2.9767	982	7.40	<.0001	0.05	16.1829	27.8659
TRTPN	4	WORK.ENDPOINT_2	184.67	5.7916	2.9988	982	1.93	0.0537	0.05	-0.09315	11.6764

Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG60 Parameter=PPG at 1 hour (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Model Information

Data Set	WORK.ENDPOINT_2
Dependent Variable	CHG
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Dimensions

Covariance Parameters	1
Columns in X	10
Columns in Z	0
Subjects	1
Max Obs per Subject	992

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG60 Parameter=PPG at 1 hour (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Number of Observations

Number of Observations Read	992
Number of Observations Used	992
Number of Observations Not Used	0

Covariance Parameter
Estimates

Cov Parm	Estimate
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Residual	13.7987
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Fit Statistics

-2 Res Log Likelihood	5422.4
AIC (Smaller is Better)	5424.4
AICC (Smaller is Better)	5424.4
BIC (Smaller is Better)	5429.3

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			2	6.4435	0.4350	984
TRTPN			3	8.6450	0.4281	984
TRTPN			4	7.6812	0.4377	984

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG60 Parameter=PPG at 1 hour (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
REGION1	ASIA (EXCLUDING JAPAN)			-0.4343	0.4301	984
REGION1	EUROPE			-0.5447	0.3037	984
REGION1	JAPAN			0.3801	0.3424	984
REGION1	NORTH AMERICA			0	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.008207	0.2651	984
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0	.	.
BASE				-0.6109	0.02831	984

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
TRTPN			2	14.81	<.0001	0.05
TRTPN			3	20.20	<.0001	0.05
TRTPN			4	17.55	<.0001	0.05
REGION1	ASIA (EXCLUDING JAPAN)			-1.01	0.3130	0.05
REGION1	EUROPE			-1.79	0.0732	0.05
REGION1	JAPAN			1.11	0.2672	0.05
REGION1	NORTH AMERICA			.	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.03	0.9753	0.05
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.	.
BASE				-21.58	<.0001	0.05

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG60 Parameter=PPG at 1 hour (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Lower	Upper
TRTPN			2	5.5898	7.2972
TRTPN			3	7.8050	9.4850
TRTPN			4	6.8222	8.5402
REGION1	ASIA (EXCLUDING JAPAN)			-1.2784	0.4099
REGION1	EUROPE			-1.1407	0.05135
REGION1	JAPAN			-0.2918	1.0521
REGION1	NORTH AMERICA			.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.5119	0.5284
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.
BASE				-0.6665	-0.5554

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	2	984	29.23	<.0001
REGION1	3	984	3.25	0.0213
BOLAD1	1	984	0.00	0.9753
BASE	1	984	465.57	<.0001

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG60 Parameter=PPG at 1 hour (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) - NovoRapid (meal)	WORK.ENDPOINT_2	-1.2377	0.2898	984	-4.27	<.0001	0.05	-1.8065	-0.6689

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (post) - NovoRapid (meal)	WORK.ENDPOINT_2	0.9638	0.2900	984	3.32	0.0009	0.05	0.3946	1.5329

Least Squares Means

Effect	Planned Treatment for Period 30 (N)	Margins	BASE	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	2	WORK.ENDPOINT_2	11.89	-0.9662	0.2038	984	-4.74	<.0001	0.05	-1.3662	-0.5662
TRTPN	3	WORK.ENDPOINT_2	11.89	1.2353	0.2039	984	6.06	<.0001	0.05	0.8351	1.6355
TRTPN	4	WORK.ENDPOINT_2	11.89	0.2715	0.2059	984	1.32	0.1877	0.05	-0.1326	0.6756

Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG60C Parameter=PPG at 1 hour (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Model Information

Data Set	WORK.ENDPOINT_2
Dependent Variable	CHG
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Dimensions

Covariance Parameters	1
Columns in X	10
Columns in Z	0
Subjects	1
Max Obs per Subject	992

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG60C Parameter=PPG at 1 hour (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Number of Observations

Number of Observations Read	992
Number of Observations Used	992
Number of Observations Not Used	0

Covariance Parameter
Estimates

Cov Parm	Estimate
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Residual	4480.73
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Fit Statistics

-2 Res Log Likelihood	11118.6
AIC (Smaller is Better)	11120.6
AICC (Smaller is Better)	11120.6
BIC (Smaller is Better)	11125.5

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			2	116.11	7.8394	984
TRTPN			3	155.78	7.7136	984
TRTPN			4	138.42	7.8879	984

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG60C Parameter=PPG at 1 hour (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
REGION1	ASIA (EXCLUDING JAPAN)			-7.8253	7.7513	984
REGION1	EUROPE			-9.8154	5.4734	984
REGION1	JAPAN			6.8495	6.1703	984
REGION1	NORTH AMERICA			0	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.1479	4.7765	984
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0	.	.
BASE				-0.6109	0.02831	984

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
TRTPN			2	14.81	<.0001	0.05
TRTPN			3	20.20	<.0001	0.05
TRTPN			4	17.55	<.0001	0.05
REGION1	ASIA (EXCLUDING JAPAN)			-1.01	0.3130	0.05
REGION1	EUROPE			-1.79	0.0732	0.05
REGION1	JAPAN			1.11	0.2672	0.05
REGION1	NORTH AMERICA			.	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.03	0.9753	0.05
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.	.
BASE				-21.58	<.0001	0.05

Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG60C Parameter=PPG at 1 hour (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Lower	Upper
TRTPN			2	100.73	131.50
TRTPN			3	140.65	170.92
TRTPN			4	122.94	153.89
REGION1	ASIA (EXCLUDING JAPAN)			-23.0362	7.3856
REGION1	EUROPE			-20.5562	0.9254
REGION1	JAPAN			-5.2590	18.9580
REGION1	NORTH AMERICA			.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-9.2253	9.5211
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.
BASE				-0.6665	-0.5554

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	2	984	29.23	<.0001
REGION1	3	984	3.25	0.0213
BOLAD1	1	984	0.00	0.9753
BASE	1	984	465.57	<.0001

Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG60C Parameter=PPG at 1 hour (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) - NovoRapid (meal)	WORK.ENDPOINT_2	-22.3034	5.2230	984	-4.27	<.0001	0.05	-32.5530	-12.0539

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (post) - NovoRapid (meal)	WORK.ENDPOINT_2	17.3674	5.2265	984	3.32	0.0009	0.05	7.1111	27.6237

Least Squares Means

Effect	Planned Treatment for Period 30 (N)	Margins	BASE	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	2	WORK.ENDPOINT_2	214.28	-17.4112	3.6733	984	-4.74	<.0001	0.05	-24.6196	-10.2028
TRTPN	3	WORK.ENDPOINT_2	214.28	22.2596	3.6749	984	6.06	<.0001	0.05	15.0481	29.4711
TRTPN	4	WORK.ENDPOINT_2	214.28	4.8922	3.7111	984	1.32	0.1877	0.05	-2.3903	12.1747

11: Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG120 Parameter=PPG at 2 hours (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Model Information

Data Set	WORK.ENDPOINT_2
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Dimensions

Covariance Parameters	1
Columns in X	10
Columns in Z	0
Subjects	1
Max Obs per Subject	980

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG120 Parameter=PPG at 2 hours (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Number of Observations

Number of Observations Read	980
Number of Observations Used	980
Number of Observations Not Used	0

Covariance Parameter
Estimates

Cov Parm	Estimate
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Residual	20.2591
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Fit Statistics

-2 Res Log Likelihood	5730.4
AIC (Smaller is Better)	5732.4
AICC (Smaller is Better)	5732.4
BIC (Smaller is Better)	5737.3

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			2	6.7912	0.4879	972
TRTPN			3	7.7357	0.4785	972
TRTPN			4	7.4561	0.4892	972

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG120 Parameter=PPG at 2 hours (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
REGION1	ASIA (EXCLUDING JAPAN)			-0.6594	0.5264	972
REGION1	EUROPE			-0.9122	0.3720	972
REGION1	JAPAN			0.4119	0.4202	972
REGION1	NORTH AMERICA			0	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.2335	0.3240	972
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0	.	.
BASE				0.4389	0.02824	972

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
TRTPN			2	13.92	<.0001	0.05
TRTPN			3	16.17	<.0001	0.05
TRTPN			4	15.24	<.0001	0.05
REGION1	ASIA (EXCLUDING JAPAN)			-1.25	0.2106	0.05
REGION1	EUROPE			-2.45	0.0144	0.05
REGION1	JAPAN			0.98	0.3273	0.05
REGION1	NORTH AMERICA			.	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.72	0.4712	0.05
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.	.
BASE				15.54	<.0001	0.05

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG120 Parameter=PPG at 2 hours (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Lower	Upper
TRTPN			2	5.8338	7.7486
TRTPN			3	6.7966	8.6747
TRTPN			4	6.4961	8.4160
REGION1	ASIA (EXCLUDING JAPAN)			-1.6925	0.3737
REGION1	EUROPE			-1.6422	-0.1821
REGION1	JAPAN			-0.4128	1.2366
REGION1	NORTH AMERICA			.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.4022	0.8692
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.
BASE				0.3835	0.4943

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	2	972	3.80	0.0226
REGION1	3	972	4.62	0.0032
BOLAD1	1	972	0.52	0.4712
BASE	1	972	241.60	<.0001

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG120 Parameter=PPG at 2 hours (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) - NovoRapid (meal)	WORK.ENDPOINT_2	-0.6649	0.3543	972	-1.88	0.0609	0.05	-1.3602	0.03039

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (post) - NovoRapid (meal)	WORK.ENDPOINT_2	0.2796	0.3532	972	0.79	0.4288	0.05	-0.4135	0.9727

Least Squares Means

Effect	Planned Treatment for Period 30 (N)	Margins	BASE	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	2	WORK.ENDPOINT_2	12.40	12.0727	0.2489	972	48.50	<.0001	0.05	11.5842	12.5612
TRTPN	3	WORK.ENDPOINT_2	12.40	13.0172	0.2474	972	52.62	<.0001	0.05	12.5317	13.5027
TRTPN	4	WORK.ENDPOINT_2	12.40	12.7376	0.2519	972	50.57	<.0001	0.05	12.2434	13.2319

Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG120C Parameter=PPG at 2 hours (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Model Information

Data Set	WORK.ENDPOINT_2
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Dimensions

Covariance Parameters	1
Columns in X	10
Columns in Z	0
Subjects	1
Max Obs per Subject	980

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG120C Parameter=PPG at 2 hours (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Number of Observations

Number of Observations Read	980
Number of Observations Used	980
Number of Observations Not Used	0

Covariance Parameter
Estimates

Cov Parm	Estimate
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Residual	6578.54
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Fit Statistics

-2 Res Log Likelihood	11357.3
AIC (Smaller is Better)	11359.3
AICC (Smaller is Better)	11359.3
BIC (Smaller is Better)	11364.1

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			2	122.38	8.7914	972
TRTPN			3	139.40	8.6231	972
TRTPN			4	134.36	8.8151	972

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG120C Parameter=PPG at 2 hours (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
REGION1	ASIA (EXCLUDING JAPAN)			-11.8830	9.4866	972
REGION1	EUROPE			-16.4373	6.7040	972
REGION1	JAPAN			7.4220	7.5729	972
REGION1	NORTH AMERICA			0	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		4.2079	5.8377	972
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0	.	.
BASE				0.4389	0.02824	972

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
TRTPN			2	13.92	<.0001	0.05
TRTPN			3	16.17	<.0001	0.05
TRTPN			4	15.24	<.0001	0.05
REGION1	ASIA (EXCLUDING JAPAN)			-1.25	0.2106	0.05
REGION1	EUROPE			-2.45	0.0144	0.05
REGION1	JAPAN			0.98	0.3273	0.05
REGION1	NORTH AMERICA			.	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.72	0.4712	0.05
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.	.
BASE				15.54	<.0001	0.05

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG120C Parameter=PPG at 2 hours (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Lower	Upper
TRTPN			2	105.12	139.63
TRTPN			3	122.47	156.32
TRTPN			4	117.06	151.66
REGION1	ASIA (EXCLUDING JAPAN)			-30.4995	6.7335
REGION1	EUROPE			-29.5932	-3.2813
REGION1	JAPAN			-7.4390	22.2831
REGION1	NORTH AMERICA			.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-7.2480	15.6638
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.
BASE				0.3835	0.4943

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	2	972	3.80	0.0226
REGION1	3	972	4.62	0.0032
BOLAD1	1	972	0.52	0.4712
BASE	1	972	241.60	<.0001

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG120C Parameter=PPG at 2 hours (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) - NovoRapid (meal)	WORK.ENDPOINT_2	-11.9816	6.3846	972	-1.88	0.0609	0.05	-24.5108	0.5476

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (post) - NovoRapid (meal)	WORK.ENDPOINT_2	5.0382	6.3647	972	0.79	0.4288	0.05	-7.4519	17.5284

Least Squares Means

Effect	Planned Treatment for Period 30 (N)	Margins	BASE	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	2	WORK.ENDPOINT_2	223.49	217.55	4.4857	972	48.50	<.0001	0.05	208.75	226.35
TRTPN	3	WORK.ENDPOINT_2	223.49	234.57	4.4581	972	52.62	<.0001	0.05	225.82	243.32
TRTPN	4	WORK.ENDPOINT_2	223.49	229.53	4.5386	972	50.57	<.0001	0.05	220.63	238.44

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG180 Parameter=PPG at 3 hours (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Model Information

Data Set	WORK.ENDPOINT_2
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Dimensions

Covariance Parameters	1
Columns in X	10
Columns in Z	0
Subjects	1
Max Obs per Subject	978

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG180 Parameter=PPG at 3 hours (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Number of Observations

Number of Observations Read	978
Number of Observations Used	978
Number of Observations Not Used	0

Covariance Parameter
Estimates

Cov Parm	Estimate
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Residual	20.0759
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Fit Statistics

-2 Res Log Likelihood	5709.9
AIC (Smaller is Better)	5711.9
AICC (Smaller is Better)	5711.9
BIC (Smaller is Better)	5716.8

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			2	5.7469	0.4518	970
TRTPN			3	6.5761	0.4463	970
TRTPN			4	6.2629	0.4543	970

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG180 Parameter=PPG at 3 hours (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
REGION1	ASIA (EXCLUDING JAPAN)			-0.1345	0.5275	970
REGION1	EUROPE			-0.9672	0.3711	970
REGION1	JAPAN			0.5183	0.4238	970
REGION1	NORTH AMERICA			0	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.07464	0.3227	970
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0	.	.
BASE				0.4944	0.02817	970

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
TRTPN			2	12.72	<.0001	0.05
TRTPN			3	14.73	<.0001	0.05
TRTPN			4	13.79	<.0001	0.05
REGION1	ASIA (EXCLUDING JAPAN)			-0.25	0.7988	0.05
REGION1	EUROPE			-2.61	0.0093	0.05
REGION1	JAPAN			1.22	0.2216	0.05
REGION1	NORTH AMERICA			.	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.23	0.8171	0.05
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.	.
BASE				17.55	<.0001	0.05

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG180 Parameter=PPG at 3 hours (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Lower	Upper
TRTPN			2	4.8604	6.6335
TRTPN			3	5.7003	7.4519
TRTPN			4	5.3714	7.1545
REGION1	ASIA (EXCLUDING JAPAN)			-1.1695	0.9006
REGION1	EUROPE			-1.6955	-0.2389
REGION1	JAPAN			-0.3134	1.3500
REGION1	NORTH AMERICA			.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.5586	0.7078
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.
BASE				0.4391	0.5497

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	2	970	2.85	0.0581
REGION1	3	970	5.20	0.0014
BOLAD1	1	970	0.05	0.8171
BASE	1	970	307.96	<.0001

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG180 Parameter=PPG at 3 hours (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) - NovoRapid (meal)	WORK.ENDPOINT_2	-0.5160	0.3517	970	-1.47	0.1427	0.05	-1.2062	0.1742

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (post) - NovoRapid (meal)	WORK.ENDPOINT_2	0.3131	0.3528	970	0.89	0.3750	0.05	-0.3792	1.0055

Least Squares Means

Effect	Planned Treatment for Period 30 (N)	Margins	BASE	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	2	WORK.ENDPOINT_2	11.11	11.0630	0.2467	970	44.84	<.0001	0.05	10.5788	11.5472
TRTPN	3	WORK.ENDPOINT_2	11.11	11.8921	0.2485	970	47.85	<.0001	0.05	11.4044	12.3798
TRTPN	4	WORK.ENDPOINT_2	11.11	11.5790	0.2503	970	46.26	<.0001	0.05	11.0877	12.0702

Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG180C Parameter=PPG at 3 hours (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Model Information

Data Set	WORK.ENDPOINT_2
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Dimensions

Covariance Parameters	1
Columns in X	10
Columns in Z	0
Subjects	1
Max Obs per Subject	978

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG180C Parameter=PPG at 3 hours (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Number of Observations

Number of Observations Read	978
Number of Observations Used	978
Number of Observations Not Used	0

Covariance Parameter
Estimates

Cov Parm	Estimate
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Residual	6519.05
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Fit Statistics

-2 Res Log Likelihood	11325.2
AIC (Smaller is Better)	11327.2
AICC (Smaller is Better)	11327.2
BIC (Smaller is Better)	11332.1

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			2	103.56	8.1411	970
TRTPN			3	118.50	8.0422	970
TRTPN			4	112.86	8.1869	970

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG180C Parameter=PPG at 3 hours (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
REGION1	ASIA (EXCLUDING JAPAN)			-2.4229	9.5048	970
REGION1	EUROPE			-17.4294	6.6875	970
REGION1	JAPAN			9.3404	7.6372	970
REGION1	NORTH AMERICA			0	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		1.3450	5.8144	970
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0	.	.
BASE				0.4944	0.02817	970

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
TRTPN			2	12.72	<.0001	0.05
TRTPN			3	14.73	<.0001	0.05
TRTPN			4	13.79	<.0001	0.05
REGION1	ASIA (EXCLUDING JAPAN)			-0.25	0.7988	0.05
REGION1	EUROPE			-2.61	0.0093	0.05
REGION1	JAPAN			1.22	0.2216	0.05
REGION1	NORTH AMERICA			.	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.23	0.8171	0.05
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.	.
BASE				17.55	<.0001	0.05

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG180C Parameter=PPG at 3 hours (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Lower	Upper
TRTPN			2	87.5837	119.54
TRTPN			3	102.72	134.28
TRTPN			4	96.7920	128.92
REGION1	ASIA (EXCLUDING JAPAN)			-21.0753	16.2294
REGION1	EUROPE			-30.5530	-4.3057
REGION1	JAPAN			-5.6470	24.3279
REGION1	NORTH AMERICA			.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-10.0652	12.7552
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.
BASE				0.4391	0.5497

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	2	970	2.85	0.0581
REGION1	3	970	5.20	0.0014
BOLAD1	1	970	0.05	0.8171
BASE	1	970	307.96	<.0001

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG180C Parameter=PPG at 3 hours (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) - NovoRapid (meal)	WORK.ENDPOINT_2	-9.2983	6.3380	970	-1.47	0.1427	0.05	-21.7360	3.1395

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (post) - NovoRapid (meal)	WORK.ENDPOINT_2	5.6427	6.3579	970	0.89	0.3750	0.05	-6.8341	18.1194

Least Squares Means

Effect	Planned Treatment for Period 30 (N)	Margins	BASE	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	2	WORK.ENDPOINT_2	200.15	199.35	4.4462	970	44.84	<.0001	0.05	190.63	208.08
TRTPN	3	WORK.ENDPOINT_2	200.15	214.30	4.4783	970	47.85	<.0001	0.05	205.51	223.08
TRTPN	4	WORK.ENDPOINT_2	200.15	208.65	4.5107	970	46.26	<.0001	0.05	199.80	217.50

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG240 Parameter=PPG at 4 hours (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Model Information

Data Set	WORK.ENDPOINT_2
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Dimensions

Covariance Parameters	1
Columns in X	10
Columns in Z	0
Subjects	1
Max Obs per Subject	978

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG240 Parameter=PPG at 4 hours (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Number of Observations

Number of Observations Read	978
Number of Observations Used	978
Number of Observations Not Used	0

Covariance Parameter
Estimates

Cov Parm	Estimate
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Residual	16.2459
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Fit Statistics

-2 Res Log Likelihood	5504.4
AIC (Smaller is Better)	5506.4
AICC (Smaller is Better)	5506.4
BIC (Smaller is Better)	5511.2

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			2	4.4960	0.3899	970
TRTPN			3	5.2506	0.3875	970
TRTPN			4	4.9525	0.3922	970

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG240 Parameter=PPG at 4 hours (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
REGION1	ASIA (EXCLUDING JAPAN)			0.2358	0.4774	970
REGION1	EUROPE			-0.6032	0.3324	970
REGION1	JAPAN			0.4770	0.3808	970
REGION1	NORTH AMERICA			0	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.06171	0.2897	970
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0	.	.
BASE				0.5227	0.02822	970

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
TRTPN			2	11.53	<.0001	0.05
TRTPN			3	13.55	<.0001	0.05
TRTPN			4	12.63	<.0001	0.05
REGION1	ASIA (EXCLUDING JAPAN)			0.49	0.6215	0.05
REGION1	EUROPE			-1.81	0.0699	0.05
REGION1	JAPAN			1.25	0.2106	0.05
REGION1	NORTH AMERICA			.	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.21	0.8314	0.05
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.	.
BASE				18.52	<.0001	0.05

Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG240 Parameter=PPG at 4 hours (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Lower	Upper
TRTPN			2	3.7309	5.2612
TRTPN			3	4.4901	6.0111
TRTPN			4	4.1828	5.7221
REGION1	ASIA (EXCLUDING JAPAN)			-0.7011	1.1727
REGION1	EUROPE			-1.2555	0.04910
REGION1	JAPAN			-0.2702	1.2242
REGION1	NORTH AMERICA			.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.5068	0.6302
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.
BASE				0.4673	0.5780

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	2	970	2.90	0.0553
REGION1	3	970	3.39	0.0175
BOLAD1	1	970	0.05	0.8314
BASE	1	970	342.95	<.0001

Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG240 Parameter=PPG at 4 hours (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) - NovoRapid (meal)	WORK.ENDPOINT_2	-0.4564	0.3164	970	-1.44	0.1495	0.05	-1.0774	0.1645

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (post) - NovoRapid (meal)	WORK.ENDPOINT_2	0.2982	0.3168	970	0.94	0.3468	0.05	-0.3235	0.9198

Least Squares Means

Effect	Planned Treatment for Period 30 (N)	Margins	BASE	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	2	WORK.ENDPOINT_2	9.32	9.3468	0.2225	970	42.01	<.0001	0.05	8.9102	9.7835
TRTPN	3	WORK.ENDPOINT_2	9.32	10.1014	0.2231	970	45.27	<.0001	0.05	9.6635	10.5393
TRTPN	4	WORK.ENDPOINT_2	9.32	9.8032	0.2248	970	43.62	<.0001	0.05	9.3622	10.2443

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG240C Parameter=PPG at 4 hours (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Model Information

Data Set	WORK.ENDPOINT_2
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Dimensions

Covariance Parameters	1
Columns in X	10
Columns in Z	0
Subjects	1
Max Obs per Subject	978

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG240C Parameter=PPG at 4 hours (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Number of Observations

Number of Observations Read	978
Number of Observations Used	978
Number of Observations Not Used	0

Covariance Parameter
Estimates

Cov Parm	Estimate
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Residual	5275.36
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Fit Statistics

-2 Res Log Likelihood	11119.6
AIC (Smaller is Better)	11121.6
AICC (Smaller is Better)	11121.6
BIC (Smaller is Better)	11126.5

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			2	81.0188	7.0258	970
TRTPN			3	94.6161	6.9831	970
TRTPN			4	89.2434	7.0670	970

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG240C Parameter=PPG at 4 hours (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
REGION1	ASIA (EXCLUDING JAPAN)			4.2493	8.6033	970
REGION1	EUROPE			-10.8701	5.9900	970
REGION1	JAPAN			8.5951	6.8613	970
REGION1	NORTH AMERICA			0	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		1.1119	5.2205	970
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0	.	.
BASE				0.5227	0.02822	970

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
TRTPN			2	11.53	<.0001	0.05
TRTPN			3	13.55	<.0001	0.05
TRTPN			4	12.63	<.0001	0.05
REGION1	ASIA (EXCLUDING JAPAN)			0.49	0.6215	0.05
REGION1	EUROPE			-1.81	0.0699	0.05
REGION1	JAPAN			1.25	0.2106	0.05
REGION1	NORTH AMERICA			.	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.21	0.8314	0.05
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.	.
BASE				18.52	<.0001	0.05

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG240C Parameter=PPG at 4 hours (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Lower	Upper
TRTPN			2	67.2313	94.8063
TRTPN			3	80.9123	108.32
TRTPN			4	75.3749	103.11
REGION1	ASIA (EXCLUDING JAPAN)			-12.6340	21.1326
REGION1	EUROPE			-22.6249	0.8847
REGION1	JAPAN			-4.8697	22.0598
REGION1	NORTH AMERICA			.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-9.1328	11.3567
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.
BASE				0.4673	0.5780

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	2	970	2.90	0.0553
REGION1	3	970	3.39	0.0175
BOLAD1	1	970	0.05	0.8314
BASE	1	970	342.95	<.0001

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG240C Parameter=PPG at 4 hours (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) - NovoRapid (meal)	WORK.ENDPOINT_2	-8.2246	5.7019	970	-1.44	0.1495	0.05	-19.4141	2.9650

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (post) - NovoRapid (meal)	WORK.ENDPOINT_2	5.3727	5.7083	970	0.94	0.3468	0.05	-5.8293	16.5748

Least Squares Means

Effect	Planned Treatment for Period 30 (N)	Margins	BASE	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	2	WORK.ENDPOINT_2	168.01	168.43	4.0097	970	42.01	<.0001	0.05	160.56	176.30
TRTPN	3	WORK.ENDPOINT_2	168.01	182.03	4.0209	970	45.27	<.0001	0.05	174.14	189.92
TRTPN	4	WORK.ENDPOINT_2	168.01	176.65	4.0503	970	43.62	<.0001	0.05	168.71	184.60

Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG30 Parameter=PPG at 30 min (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Model Information

Data Set	WORK.ENDPOINT_2
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Dimensions

Covariance Parameters	1
Columns in X	10
Columns in Z	0
Subjects	1
Max Obs per Subject	985

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG30 Parameter=PPG at 30 min (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Number of Observations

Number of Observations Read	985
Number of Observations Used	985
Number of Observations Not Used	0

Covariance Parameter
Estimates

Cov Parm	Estimate
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Residual	8.9426
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Fit Statistics

-2 Res Log Likelihood	4959.8
AIC (Smaller is Better)	4961.8
AICC (Smaller is Better)	4961.8
BIC (Smaller is Better)	4966.6

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			2	6.0551	0.3806	977
TRTPN			3	7.7822	0.3783	977
TRTPN			4	6.8831	0.3874	977

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG30 Parameter=PPG at 30 min (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
REGION1	ASIA (EXCLUDING JAPAN)			-0.2191	0.3479	977
REGION1	EUROPE			0.06324	0.2457	977
REGION1	JAPAN			0.7540	0.2780	977
REGION1	NORTH AMERICA			0	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.2197	0.2144	977
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0	.	.
BASE				0.3547	0.03052	977

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
TRTPN			2	15.91	<.0001	0.05
TRTPN			3	20.57	<.0001	0.05
TRTPN			4	17.77	<.0001	0.05
REGION1	ASIA (EXCLUDING JAPAN)			-0.63	0.5289	0.05
REGION1	EUROPE			0.26	0.7970	0.05
REGION1	JAPAN			2.71	0.0068	0.05
REGION1	NORTH AMERICA			.	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-1.02	0.3058	0.05
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.	.
BASE				11.62	<.0001	0.05

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG30 Parameter=PPG at 30 min (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Lower	Upper
TRTPN			2	5.3083	6.8020
TRTPN			3	7.0399	8.5245
TRTPN			4	6.1229	7.6434
REGION1	ASIA (EXCLUDING JAPAN)			-0.9019	0.4636
REGION1	EUROPE			-0.4190	0.5455
REGION1	JAPAN			0.2084	1.2996
REGION1	NORTH AMERICA			.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.6403	0.2010
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.
BASE				0.2948	0.4146

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	2	977	27.50	<.0001
REGION1	3	977	4.10	0.0066
BOLAD1	1	977	1.05	0.3058
BASE	1	977	135.08	<.0001

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG30 Parameter=PPG at 30 min (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) - NovoRapid (meal)	WORK.ENDPOINT_2	-0.8280	0.2342	977	-3.54	0.0004	0.05	-1.2875	-0.3685

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (post) - NovoRapid (meal)	WORK.ENDPOINT_2	0.8990	0.2345	977	3.83	0.0001	0.05	0.4388	1.3593

Least Squares Means

Effect	Planned Treatment for Period 30 (N)	Margins	BASE	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	2	WORK.ENDPOINT_2	10.25	9.7376	0.1643	977	59.25	<.0001	0.05	9.4151	10.0601
TRTPN	3	WORK.ENDPOINT_2	10.25	11.4646	0.1648	977	69.55	<.0001	0.05	11.1411	11.7881
TRTPN	4	WORK.ENDPOINT_2	10.25	10.5656	0.1666	977	63.42	<.0001	0.05	10.2387	10.8926

Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG30C Parameter=PPG at 30 min (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Model Information

Data Set	WORK.ENDPOINT_2
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Dimensions

Covariance Parameters	1
Columns in X	10
Columns in Z	0
Subjects	1
Max Obs per Subject	985

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG30C Parameter=PPG at 30 min (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Number of Observations

Number of Observations Read	985
Number of Observations Used	985
Number of Observations Not Used	0

Covariance Parameter
Estimates

Cov Parm	Estimate
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Residual	2903.83
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Fit Statistics

-2 Res Log Likelihood	10615.5
AIC (Smaller is Better)	10617.5
AICC (Smaller is Better)	10617.5
BIC (Smaller is Better)	10622.4

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			2	109.11	6.8580	977
TRTPN			3	140.23	6.8162	977
TRTPN			4	124.03	6.9813	977

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG30C Parameter=PPG at 30 min (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
REGION1	ASIA (EXCLUDING JAPAN)			-3.9490	6.2693	977
REGION1	EUROPE			1.1396	4.4283	977
REGION1	JAPAN			13.5871	5.0097	977
REGION1	NORTH AMERICA			0	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-3.9583	3.8630	977
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0	.	.
BASE				0.3547	0.03052	977

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
TRTPN			2	15.91	<.0001	0.05
TRTPN			3	20.57	<.0001	0.05
TRTPN			4	17.77	<.0001	0.05
REGION1	ASIA (EXCLUDING JAPAN)			-0.63	0.5289	0.05
REGION1	EUROPE			0.26	0.7970	0.05
REGION1	JAPAN			2.71	0.0068	0.05
REGION1	NORTH AMERICA			.	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-1.02	0.3058	0.05
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.	.
BASE				11.62	<.0001	0.05

Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG30C Parameter=PPG at 30 min (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Lower	Upper
TRTPN			2	95.6556	122.57
TRTPN			3	126.86	153.61
TRTPN			4	110.33	137.73
REGION1	ASIA (EXCLUDING JAPAN)			-16.2518	8.3538
REGION1	EUROPE			-7.5504	9.8296
REGION1	JAPAN			3.7560	23.4181
REGION1	NORTH AMERICA			.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-11.5390	3.6223
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.
BASE				0.2948	0.4146

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	2	977	27.50	<.0001
REGION1	3	977	4.10	0.0066
BOLAD1	1	977	1.05	0.3058
BASE	1	977	135.08	<.0001

Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG30C Parameter=PPG at 30 min (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) - NovoRapid (meal)	WORK.ENDPOINT_2	-14.9206	4.2197	977	-3.54	0.0004	0.05	-23.2013	-6.6399

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (post) - NovoRapid (meal)	WORK.ENDPOINT_2	16.2004	4.2263	977	3.83	0.0001	0.05	7.9068	24.4939

Least Squares Means

Effect	Planned Treatment for Period 30 (N)	Margins	BASE	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	2	WORK.ENDPOINT_2	184.78	175.47	2.9614	977	59.25	<.0001	0.05	169.66	181.28
TRTPN	3	WORK.ENDPOINT_2	184.78	206.59	2.9705	977	69.55	<.0001	0.05	200.76	212.42
TRTPN	4	WORK.ENDPOINT_2	184.78	190.39	3.0023	977	63.42	<.0001	0.05	184.50	196.28

Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG60 Parameter=PPG at 1 hour (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Model Information

Data Set	WORK.ENDPOINT_2
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Dimensions

Covariance Parameters	1
Columns in X	10
Columns in Z	0
Subjects	1
Max Obs per Subject	987

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG60 Parameter=PPG at 1 hour (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Number of Observations

Number of Observations Read	987
Number of Observations Used	987
Number of Observations Not Used	0

Covariance Parameter
Estimates

Cov Parm	Estimate
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Residual	13.7309
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Fit Statistics

-2 Res Log Likelihood	5390.2
AIC (Smaller is Better)	5392.2
AICC (Smaller is Better)	5392.2
BIC (Smaller is Better)	5397.1

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			2	6.4461	0.4371	979
TRTPN			3	8.6407	0.4288	979
TRTPN			4	7.6883	0.4397	979

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG60 Parameter=PPG at 1 hour (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
REGION1	ASIA (EXCLUDING JAPAN)			-0.4375	0.4303	979
REGION1	EUROPE			-0.5682	0.3041	979
REGION1	JAPAN			0.3566	0.3427	979
REGION1	NORTH AMERICA			0	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.008920	0.2653	979
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0	.	.
BASE				0.3891	0.02837	979

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
TRTPN			2	14.75	<.0001	0.05
TRTPN			3	20.15	<.0001	0.05
TRTPN			4	17.48	<.0001	0.05
REGION1	ASIA (EXCLUDING JAPAN)			-1.02	0.3096	0.05
REGION1	EUROPE			-1.87	0.0620	0.05
REGION1	JAPAN			1.04	0.2984	0.05
REGION1	NORTH AMERICA			.	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.03	0.9732	0.05
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.	.
BASE				13.72	<.0001	0.05

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG60 Parameter=PPG at 1 hour (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Lower	Upper
TRTPN			2	5.5884	7.3038
TRTPN			3	7.7992	9.4823
TRTPN			4	6.8254	8.5512
REGION1	ASIA (EXCLUDING JAPAN)			-1.2819	0.4070
REGION1	EUROPE			-1.1650	0.02868
REGION1	JAPAN			-0.3160	1.0292
REGION1	NORTH AMERICA			.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.5117	0.5295
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.
BASE				0.3334	0.4448

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	2	979	29.12	<.0001
REGION1	3	979	3.27	0.0207
BOLAD1	1	979	0.00	0.9732
BASE	1	979	188.10	<.0001

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG60 Parameter=PPG at 1 hour (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) - NovoRapid (meal)	WORK.ENDPOINT_2	-1.2422	0.2901	979	-4.28	<.0001	0.05	-1.8114	-0.6730

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (post) - NovoRapid (meal)	WORK.ENDPOINT_2	0.9524	0.2902	979	3.28	0.0011	0.05	0.3829	1.5219

Least Squares Means

Effect	Planned Treatment for Period 30 (N)	Margins	BASE	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	2	WORK.ENDPOINT_2	11.90	10.9184	0.2037	979	53.61	<.0001	0.05	10.5187	11.3181
TRTPN	3	WORK.ENDPOINT_2	11.90	13.1130	0.2037	979	64.36	<.0001	0.05	12.7132	13.5128
TRTPN	4	WORK.ENDPOINT_2	11.90	12.1606	0.2064	979	58.92	<.0001	0.05	11.7556	12.5656

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG60C Parameter=PPG at 1 hour (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Model Information

Data Set	WORK.ENDPOINT_2
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Dimensions

Covariance Parameters	1
Columns in X	10
Columns in Z	0
Subjects	1
Max Obs per Subject	987

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG60C Parameter=PPG at 1 hour (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Number of Observations

Number of Observations Read	987
Number of Observations Used	987
Number of Observations Not Used	0

Covariance Parameter
Estimates

Cov Parm	Estimate
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Residual	4458.69
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Fit Statistics

-2 Res Log Likelihood	11057.5
AIC (Smaller is Better)	11059.5
AICC (Smaller is Better)	11059.5
BIC (Smaller is Better)	11064.4

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			2	116.16	7.8762	979
TRTPN			3	155.71	7.7275	979
TRTPN			4	138.54	7.9236	979

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG60C Parameter=PPG at 1 hour (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
REGION1	ASIA (EXCLUDING JAPAN)			-7.8830	7.7545	979
REGION1	EUROPE			-10.2381	5.4805	979
REGION1	JAPAN			6.4259	6.1759	979
REGION1	NORTH AMERICA			0	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.1607	4.7806	979
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0	.	.
BASE				0.3891	0.02837	979

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
TRTPN			2	14.75	<.0001	0.05
TRTPN			3	20.15	<.0001	0.05
TRTPN			4	17.48	<.0001	0.05
REGION1	ASIA (EXCLUDING JAPAN)			-1.02	0.3096	0.05
REGION1	EUROPE			-1.87	0.0620	0.05
REGION1	JAPAN			1.04	0.2984	0.05
REGION1	NORTH AMERICA			.	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.03	0.9732	0.05
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.	.
BASE				13.72	<.0001	0.05

Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG60C Parameter=PPG at 1 hour (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Lower	Upper
TRTPN			2	100.70	131.62
TRTPN			3	140.54	170.87
TRTPN			4	122.99	154.09
REGION1	ASIA (EXCLUDING JAPAN)			-23.1004	7.3344
REGION1	EUROPE			-20.9929	0.5168
REGION1	JAPAN			-5.6935	18.5454
REGION1	NORTH AMERICA			.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-9.2208	9.5422
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.
BASE				0.3334	0.4448

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	2	979	29.12	<.0001
REGION1	3	979	3.27	0.0207
BOLAD1	1	979	0.00	0.9732
BASE	1	979	188.10	<.0001

Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG60C Parameter=PPG at 1 hour (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) - NovoRapid (meal)	WORK.ENDPOINT_2	-22.3844	5.2272	979	-4.28	<.0001	0.05	-32.6422	-12.1266

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (post) - NovoRapid (meal)	WORK.ENDPOINT_2	17.1628	5.2295	979	3.28	0.0011	0.05	6.9004	27.4251

Least Squares Means

Effect	Planned Treatment for Period 30 (N)	Margins	BASE	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	2	WORK.ENDPOINT_2	214.49	196.75	3.6702	979	53.61	<.0001	0.05	189.55	203.95
TRTPN	3	WORK.ENDPOINT_2	214.49	236.30	3.6713	979	64.36	<.0001	0.05	229.09	243.50
TRTPN	4	WORK.ENDPOINT_2	214.49	219.13	3.7193	979	58.92	<.0001	0.05	211.84	226.43

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG120 Parameter=PPG at 2 hours (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Model Information

Data Set	WORK.ENDPOINT_2
Dependent Variable	CHG
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Dimensions

Covariance Parameters	1
Columns in X	10
Columns in Z	0
Subjects	1
Max Obs per Subject	980

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG120 Parameter=PPG at 2 hours (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Number of Observations

Number of Observations Read	980
Number of Observations Used	980
Number of Observations Not Used	0

Covariance Parameter
Estimates

Cov Parm	Estimate
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Residual	20.2591
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Fit Statistics

-2 Res Log Likelihood	5730.4
AIC (Smaller is Better)	5732.4
AICC (Smaller is Better)	5732.4
BIC (Smaller is Better)	5737.3

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			2	6.7912	0.4879	972
TRTPN			3	7.7357	0.4785	972
TRTPN			4	7.4561	0.4892	972

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG120 Parameter=PPG at 2 hours (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
REGION1	ASIA (EXCLUDING JAPAN)			-0.6594	0.5264	972
REGION1	EUROPE			-0.9122	0.3720	972
REGION1	JAPAN			0.4119	0.4202	972
REGION1	NORTH AMERICA			0	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.2335	0.3240	972
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0	.	.
BASE				-0.5611	0.02824	972

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
TRTPN			2	13.92	<.0001	0.05
TRTPN			3	16.17	<.0001	0.05
TRTPN			4	15.24	<.0001	0.05
REGION1	ASIA (EXCLUDING JAPAN)			-1.25	0.2106	0.05
REGION1	EUROPE			-2.45	0.0144	0.05
REGION1	JAPAN			0.98	0.3273	0.05
REGION1	NORTH AMERICA			.	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.72	0.4712	0.05
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.	.
BASE				-19.87	<.0001	0.05

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG120 Parameter=PPG at 2 hours (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Lower	Upper
TRTPN			2	5.8338	7.7486
TRTPN			3	6.7966	8.6747
TRTPN			4	6.4961	8.4160
REGION1	ASIA (EXCLUDING JAPAN)			-1.6925	0.3737
REGION1	EUROPE			-1.6422	-0.1821
REGION1	JAPAN			-0.4128	1.2366
REGION1	NORTH AMERICA			.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.4022	0.8692
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.
BASE				-0.6165	-0.5057

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	2	972	3.80	0.0226
REGION1	3	972	4.62	0.0032
BOLAD1	1	972	0.52	0.4712
BASE	1	972	394.92	<.0001

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG120 Parameter=PPG at 2 hours (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) - NovoRapid (meal)	WORK.ENDPOINT_2	-0.6649	0.3543	972	-1.88	0.0609	0.05	-1.3602	0.03039

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (post) - NovoRapid (meal)	WORK.ENDPOINT_2	0.2796	0.3532	972	0.79	0.4288	0.05	-0.4135	0.9727

Least Squares Means

Effect	Planned Treatment for Period (N)	Margins	BASE	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	2	WORK.ENDPOINT_2	12.40	-0.3298	0.2489	972	-1.33	0.1855	0.05	-0.8183	0.1587
TRTPN	3	WORK.ENDPOINT_2	12.40	0.6147	0.2474	972	2.48	0.0131	0.05	0.1292	1.1002
TRTPN	4	WORK.ENDPOINT_2	12.40	0.3351	0.2519	972	1.33	0.1837	0.05	-0.1592	0.8293

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG120C Parameter=PPG at 2 hours (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Model Information

Data Set	WORK.ENDPOINT_2
Dependent Variable	CHG
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Dimensions

Covariance Parameters	1
Columns in X	10
Columns in Z	0
Subjects	1
Max Obs per Subject	980

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG120C Parameter=PPG at 2 hours (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Number of Observations

Number of Observations Read	980
Number of Observations Used	980
Number of Observations Not Used	0

Covariance Parameter
Estimates

Cov Parm	Estimate
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Residual	6578.54
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Fit Statistics

-2 Res Log Likelihood	11357.3
AIC (Smaller is Better)	11359.3
AICC (Smaller is Better)	11359.3
BIC (Smaller is Better)	11364.1

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			2	122.38	8.7914	972
TRTPN			3	139.40	8.6231	972
TRTPN			4	134.36	8.8151	972

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG120C Parameter=PPG at 2 hours (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
REGION1	ASIA (EXCLUDING JAPAN)			-11.8830	9.4866	972
REGION1	EUROPE			-16.4373	6.7040	972
REGION1	JAPAN			7.4220	7.5729	972
REGION1	NORTH AMERICA			0	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		4.2079	5.8377	972
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0	.	.
BASE				-0.5611	0.02824	972

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
TRTPN			2	13.92	<.0001	0.05
TRTPN			3	16.17	<.0001	0.05
TRTPN			4	15.24	<.0001	0.05
REGION1	ASIA (EXCLUDING JAPAN)			-1.25	0.2106	0.05
REGION1	EUROPE			-2.45	0.0144	0.05
REGION1	JAPAN			0.98	0.3273	0.05
REGION1	NORTH AMERICA			.	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.72	0.4712	0.05
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.	.
BASE				-19.87	<.0001	0.05

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG120C Parameter=PPG at 2 hours (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Lower	Upper
TRTPN			2	105.12	139.63
TRTPN			3	122.47	156.32
TRTPN			4	117.06	151.66
REGION1	ASIA (EXCLUDING JAPAN)			-30.4995	6.7335
REGION1	EUROPE			-29.5932	-3.2813
REGION1	JAPAN			-7.4390	22.2831
REGION1	NORTH AMERICA			.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-7.2480	15.6638
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.
BASE				-0.6165	-0.5057

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	2	972	3.80	0.0226
REGION1	3	972	4.62	0.0032
BOLAD1	1	972	0.52	0.4712
BASE	1	972	394.92	<.0001

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG120C Parameter=PPG at 2 hours (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) - NovoRapid (meal)	WORK.ENDPOINT_2	-11.9816	6.3846	972	-1.88	0.0609	0.05	-24.5108	0.5476

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (post) - NovoRapid (meal)	WORK.ENDPOINT_2	5.0382	6.3647	972	0.79	0.4288	0.05	-7.4519	17.5284

Least Squares Means

Effect	Planned Treatment for Period 30 (N)	Margins	BASE	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	2	WORK.ENDPOINT_2	223.49	-5.9437	4.4857	972	-1.33	0.1855	0.05	-14.7464	2.8590
TRTPN	3	WORK.ENDPOINT_2	223.49	11.0761	4.4581	972	2.48	0.0131	0.05	2.3275	19.8247
TRTPN	4	WORK.ENDPOINT_2	223.49	6.0379	4.5386	972	1.33	0.1837	0.05	-2.8687	14.9444

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG180 Parameter=PPG at 3 hours (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Model Information

Data Set	WORK.ENDPOINT_2
Dependent Variable	CHG
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Dimensions

Covariance Parameters	1
Columns in X	10
Columns in Z	0
Subjects	1
Max Obs per Subject	978

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG180 Parameter=PPG at 3 hours (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Number of Observations

Number of Observations Read	978
Number of Observations Used	978
Number of Observations Not Used	0

Covariance Parameter
Estimates

Cov Parm	Estimate
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Residual	20.0759
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Fit Statistics

-2 Res Log Likelihood	5709.9
AIC (Smaller is Better)	5711.9
AICC (Smaller is Better)	5711.9
BIC (Smaller is Better)	5716.8

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			2	5.7469	0.4518	970
TRTPN			3	6.5761	0.4463	970
TRTPN			4	6.2629	0.4543	970

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG180 Parameter=PPG at 3 hours (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
REGION1	ASIA (EXCLUDING JAPAN)			-0.1345	0.5275	970
REGION1	EUROPE			-0.9672	0.3711	970
REGION1	JAPAN			0.5183	0.4238	970
REGION1	NORTH AMERICA			0	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.07464	0.3227	970
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0	.	.
BASE				-0.5056	0.02817	970

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
TRTPN			2	12.72	<.0001	0.05
TRTPN			3	14.73	<.0001	0.05
TRTPN			4	13.79	<.0001	0.05
REGION1	ASIA (EXCLUDING JAPAN)			-0.25	0.7988	0.05
REGION1	EUROPE			-2.61	0.0093	0.05
REGION1	JAPAN			1.22	0.2216	0.05
REGION1	NORTH AMERICA			.	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.23	0.8171	0.05
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.	.
BASE				-17.94	<.0001	0.05

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG180 Parameter=PPG at 3 hours (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Lower	Upper
TRTPN			2	4.8604	6.6335
TRTPN			3	5.7003	7.4519
TRTPN			4	5.3714	7.1545
REGION1	ASIA (EXCLUDING JAPAN)			-1.1695	0.9006
REGION1	EUROPE			-1.6955	-0.2389
REGION1	JAPAN			-0.3134	1.3500
REGION1	NORTH AMERICA			.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.5586	0.7078
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.
BASE				-0.5609	-0.4503

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	2	970	2.85	0.0581
REGION1	3	970	5.20	0.0014
BOLAD1	1	970	0.05	0.8171
BASE	1	970	321.99	<.0001

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG180 Parameter=PPG at 3 hours (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) - NovoRapid (meal)	WORK.ENDPOINT_2	-0.5160	0.3517	970	-1.47	0.1427	0.05	-1.2062	0.1742

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (post) - NovoRapid (meal)	WORK.ENDPOINT_2	0.3131	0.3528	970	0.89	0.3750	0.05	-0.3792	1.0055

Least Squares Means

Effect	Planned Treatment for Period 30 (N)	Margins	BASE	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	2	WORK.ENDPOINT_2	11.11	-0.04420	0.2467	970	-0.18	0.8579	0.05	-0.5284	0.4400
TRTPN	3	WORK.ENDPOINT_2	11.11	0.7849	0.2485	970	3.16	0.0016	0.05	0.2972	1.2726
TRTPN	4	WORK.ENDPOINT_2	11.11	0.4718	0.2503	970	1.88	0.0598	0.05	-0.01944	0.9630

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 839 of 4425	Novo Nordisk
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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG180C Parameter=PPG at 3 hours (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Model Information

Data Set	WORK.ENDPOINT_2
Dependent Variable	CHG
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Dimensions

Covariance Parameters	1
Columns in X	10
Columns in Z	0
Subjects	1
Max Obs per Subject	978

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG180C Parameter=PPG at 3 hours (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Number of Observations

Number of Observations Read	978
Number of Observations Used	978
Number of Observations Not Used	0

Covariance Parameter
Estimates

Cov Parm	Estimate
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Residual	6519.05
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Fit Statistics

-2 Res Log Likelihood	11325.2
AIC (Smaller is Better)	11327.2
AICC (Smaller is Better)	11327.2
BIC (Smaller is Better)	11332.1

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			2	103.56	8.1411	970
TRTPN			3	118.50	8.0422	970
TRTPN			4	112.86	8.1869	970

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG180C Parameter=PPG at 3 hours (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
REGION1	ASIA (EXCLUDING JAPAN)			-2.4229	9.5048	970
REGION1	EUROPE			-17.4294	6.6875	970
REGION1	JAPAN			9.3404	7.6372	970
REGION1	NORTH AMERICA			0	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		1.3450	5.8144	970
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0	.	.
BASE				-0.5056	0.02817	970

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
TRTPN			2	12.72	<.0001	0.05
TRTPN			3	14.73	<.0001	0.05
TRTPN			4	13.79	<.0001	0.05
REGION1	ASIA (EXCLUDING JAPAN)			-0.25	0.7988	0.05
REGION1	EUROPE			-2.61	0.0093	0.05
REGION1	JAPAN			1.22	0.2216	0.05
REGION1	NORTH AMERICA			.	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.23	0.8171	0.05
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.	.
BASE				-17.94	<.0001	0.05

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 842 of 4425	Novo Nordisk
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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG180C Parameter=PPG at 3 hours (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Lower	Upper
TRTPN			2	87.5837	119.54
TRTPN			3	102.72	134.28
TRTPN			4	96.7920	128.92
REGION1	ASIA (EXCLUDING JAPAN)			-21.0753	16.2294
REGION1	EUROPE			-30.5530	-4.3057
REGION1	JAPAN			-5.6470	24.3279
REGION1	NORTH AMERICA			.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-10.0652	12.7552
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.
BASE				-0.5609	-0.4503

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	2	970	2.85	0.0581
REGION1	3	970	5.20	0.0014
BOLAD1	1	970	0.05	0.8171
BASE	1	970	321.99	<.0001

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG180C Parameter=PPG at 3 hours (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) - NovoRapid (meal)	WORK.ENDPOINT_2	-9.2983	6.3380	970	-1.47	0.1427	0.05	-21.7360	3.1395

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (post) - NovoRapid (meal)	WORK.ENDPOINT_2	5.6427	6.3579	970	0.89	0.3750	0.05	-6.8341	18.1194

Least Squares Means

Effect	Planned Treatment for Period 30 (N)	Margins	BASE	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	2	WORK.ENDPOINT_2	200.15	-0.7966	4.4462	970	-0.18	0.8579	0.05	-9.5218	7.9287
TRTPN	3	WORK.ENDPOINT_2	200.15	14.1444	4.4783	970	3.16	0.0016	0.05	5.3560	22.9327
TRTPN	4	WORK.ENDPOINT_2	200.15	8.5017	4.5107	970	1.88	0.0598	0.05	-0.3502	17.3537

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 844 of 4425	Novo Nordisk
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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG240 Parameter=PPG at 4 hours (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Model Information

Data Set	WORK.ENDPOINT_2
Dependent Variable	CHG
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Dimensions

Covariance Parameters	1
Columns in X	10
Columns in Z	0
Subjects	1
Max Obs per Subject	978

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG240 Parameter=PPG at 4 hours (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Number of Observations

Number of Observations Read	978
Number of Observations Used	978
Number of Observations Not Used	0

Covariance Parameter
Estimates

Cov Parm	Estimate
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Residual	16.2459
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Fit Statistics

-2 Res Log Likelihood	5504.4
AIC (Smaller is Better)	5506.4
AICC (Smaller is Better)	5506.4
BIC (Smaller is Better)	5511.2

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			2	4.4960	0.3899	970
TRTPN			3	5.2506	0.3875	970
TRTPN			4	4.9525	0.3922	970

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG240 Parameter=PPG at 4 hours (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
REGION1	ASIA (EXCLUDING JAPAN)			0.2358	0.4774	970
REGION1	EUROPE			-0.6032	0.3324	970
REGION1	JAPAN			0.4770	0.3808	970
REGION1	NORTH AMERICA			0	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.06171	0.2897	970
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0	.	.
BASE				-0.4773	0.02822	970

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
TRTPN			2	11.53	<.0001	0.05
TRTPN			3	13.55	<.0001	0.05
TRTPN			4	12.63	<.0001	0.05
REGION1	ASIA (EXCLUDING JAPAN)			0.49	0.6215	0.05
REGION1	EUROPE			-1.81	0.0699	0.05
REGION1	JAPAN			1.25	0.2106	0.05
REGION1	NORTH AMERICA			.	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.21	0.8314	0.05
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.	.
BASE				-16.91	<.0001	0.05

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG240 Parameter=PPG at 4 hours (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Lower	Upper
TRTPN			2	3.7309	5.2612
TRTPN			3	4.4901	6.0111
TRTPN			4	4.1828	5.7221
REGION1	ASIA (EXCLUDING JAPAN)			-0.7011	1.1727
REGION1	EUROPE			-1.2555	0.04910
REGION1	JAPAN			-0.2702	1.2242
REGION1	NORTH AMERICA			.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.5068	0.6302
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.
BASE				-0.5327	-0.4220

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	2	970	2.90	0.0553
REGION1	3	970	3.39	0.0175
BOLAD1	1	970	0.05	0.8314
BASE	1	970	286.06	<.0001

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG240 Parameter=PPG at 4 hours (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) - NovoRapid (meal)	WORK.ENDPOINT_2	-0.4564	0.3164	970	-1.44	0.1495	0.05	-1.0774	0.1645

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (post) - NovoRapid (meal)	WORK.ENDPOINT_2	0.2982	0.3168	970	0.94	0.3468	0.05	-0.3235	0.9198

Least Squares Means

Effect	Planned Treatment for Period 30 (N)	Margins	BASE	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	2	WORK.ENDPOINT_2	9.32	0.02351	0.2225	970	0.11	0.9159	0.05	-0.4132	0.4602
TRTPN	3	WORK.ENDPOINT_2	9.32	0.7781	0.2231	970	3.49	0.0005	0.05	0.3402	1.2160
TRTPN	4	WORK.ENDPOINT_2	9.32	0.4799	0.2248	970	2.14	0.0330	0.05	0.03884	0.9210

Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG240C Parameter=PPG at 4 hours (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Model Information

Data Set	WORK.ENDPOINT_2
Dependent Variable	CHG
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Dimensions

Covariance Parameters	1
Columns in X	10
Columns in Z	0
Subjects	1
Max Obs per Subject	978

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG240C Parameter=PPG at 4 hours (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Number of Observations

Number of Observations Read	978
Number of Observations Used	978
Number of Observations Not Used	0

Covariance Parameter
Estimates

Cov Parm	Estimate
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Residual	5275.36
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Fit Statistics

-2 Res Log Likelihood	11119.6
AIC (Smaller is Better)	11121.6
AICC (Smaller is Better)	11121.6
BIC (Smaller is Better)	11126.5

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			2	81.0188	7.0258	970
TRTPN			3	94.6161	6.9831	970
TRTPN			4	89.2434	7.0670	970

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG240C Parameter=PPG at 4 hours (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
REGION1	ASIA (EXCLUDING JAPAN)			4.2493	8.6033	970
REGION1	EUROPE			-10.8701	5.9900	970
REGION1	JAPAN			8.5951	6.8613	970
REGION1	NORTH AMERICA			0	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		1.1119	5.2205	970
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0	.	.
BASE				-0.4773	0.02822	970

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
TRTPN			2	11.53	<.0001	0.05
TRTPN			3	13.55	<.0001	0.05
TRTPN			4	12.63	<.0001	0.05
REGION1	ASIA (EXCLUDING JAPAN)			0.49	0.6215	0.05
REGION1	EUROPE			-1.81	0.0699	0.05
REGION1	JAPAN			1.25	0.2106	0.05
REGION1	NORTH AMERICA			.	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.21	0.8314	0.05
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.	.
BASE				-16.91	<.0001	0.05

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG240C Parameter=PPG at 4 hours (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Lower	Upper
TRTPN			2	67.2313	94.8063
TRTPN			3	80.9123	108.32
TRTPN			4	75.3749	103.11
REGION1	ASIA (EXCLUDING JAPAN)			-12.6340	21.1326
REGION1	EUROPE			-22.6249	0.8847
REGION1	JAPAN			-4.8697	22.0598
REGION1	NORTH AMERICA			.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-9.1328	11.3567
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.
BASE				-0.5327	-0.4220

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	2	970	2.90	0.0553
REGION1	3	970	3.39	0.0175
BOLAD1	1	970	0.05	0.8314
BASE	1	970	286.06	<.0001

nn1218/nn1218-4131/ctr_20180214_er
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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG240C Parameter=PPG at 4 hours (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) - NovoRapid (meal)	WORK.ENDPOINT_2	-8.2246	5.7019	970	-1.44	0.1495	0.05	-19.4141	2.9650

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (post) - NovoRapid (meal)	WORK.ENDPOINT_2	5.3727	5.7083	970	0.94	0.3468	0.05	-5.8293	16.5748

Least Squares Means

Effect	Planned Treatment for Period (N)	Margins	BASE	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	2	WORK.ENDPOINT_2	168.01	0.4236	4.0097	970	0.11	0.9159	0.05	-7.4450	8.2923
TRTPN	3	WORK.ENDPOINT_2	168.01	14.0209	4.0209	970	3.49	0.0005	0.05	6.1302	21.9116
TRTPN	4	WORK.ENDPOINT_2	168.01	8.6482	4.0503	970	2.14	0.0330	0.05	0.6999	16.5965

Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG30 Parameter=PPG at 30 min (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Model Information

Data Set	WORK.ENDPOINT_2
Dependent Variable	CHG
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Dimensions

Covariance Parameters	1
Columns in X	10
Columns in Z	0
Subjects	1
Max Obs per Subject	985

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG30 Parameter=PPG at 30 min (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Number of Observations

Number of Observations Read	985
Number of Observations Used	985
Number of Observations Not Used	0

Covariance Parameter
Estimates

Cov Parm	Estimate
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Residual	8.9426
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Fit Statistics

-2 Res Log Likelihood	4959.8
AIC (Smaller is Better)	4961.8
AICC (Smaller is Better)	4961.8
BIC (Smaller is Better)	4966.6

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			2	6.0551	0.3806	977
TRTPN			3	7.7822	0.3783	977
TRTPN			4	6.8831	0.3874	977

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG30 Parameter=PPG at 30 min (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
REGION1	ASIA (EXCLUDING JAPAN)			-0.2191	0.3479	977
REGION1	EUROPE			0.06324	0.2457	977
REGION1	JAPAN			0.7540	0.2780	977
REGION1	NORTH AMERICA			0	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.2197	0.2144	977
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0	.	.
BASE				-0.6453	0.03052	977

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
TRTPN			2	15.91	<.0001	0.05
TRTPN			3	20.57	<.0001	0.05
TRTPN			4	17.77	<.0001	0.05
REGION1	ASIA (EXCLUDING JAPAN)			-0.63	0.5289	0.05
REGION1	EUROPE			0.26	0.7970	0.05
REGION1	JAPAN			2.71	0.0068	0.05
REGION1	NORTH AMERICA			.	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-1.02	0.3058	0.05
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.	.
BASE				-21.15	<.0001	0.05

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG30 Parameter=PPG at 30 min (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Lower	Upper
TRTPN			2	5.3083	6.8020
TRTPN			3	7.0399	8.5245
TRTPN			4	6.1229	7.6434
REGION1	ASIA (EXCLUDING JAPAN)			-0.9019	0.4636
REGION1	EUROPE			-0.4190	0.5455
REGION1	JAPAN			0.2084	1.2996
REGION1	NORTH AMERICA			.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.6403	0.2010
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.
BASE				-0.7052	-0.5854

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	2	977	27.50	<.0001
REGION1	3	977	4.10	0.0066
BOLAD1	1	977	1.05	0.3058
BASE	1	977	447.12	<.0001

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG30 Parameter=PPG at 30 min (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) - NovoRapid (meal)	WORK.ENDPOINT_2	-0.8280	0.2342	977	-3.54	0.0004	0.05	-1.2875	-0.3685

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (post) - NovoRapid (meal)	WORK.ENDPOINT_2	0.8990	0.2345	977	3.83	0.0001	0.05	0.4388	1.3593

Least Squares Means

Effect	Planned Treatment for Period 30 (N)	Margins	BASE	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	2	WORK.ENDPOINT_2	10.25	-0.5164	0.1643	977	-3.14	0.0017	0.05	-0.8389	-0.1939
TRTPN	3	WORK.ENDPOINT_2	10.25	1.2106	0.1648	977	7.34	<.0001	0.05	0.8871	1.5341
TRTPN	4	WORK.ENDPOINT_2	10.25	0.3116	0.1666	977	1.87	0.0618	0.05	-0.01535	0.6385

Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG30C Parameter=PPG at 30 min (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Model Information

Data Set	WORK.ENDPOINT_2
Dependent Variable	CHG
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Dimensions

Covariance Parameters	1
Columns in X	10
Columns in Z	0
Subjects	1
Max Obs per Subject	985

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG30C Parameter=PPG at 30 min (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Number of Observations

Number of Observations Read	985
Number of Observations Used	985
Number of Observations Not Used	0

Covariance Parameter
Estimates

Cov Parm	Estimate
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Residual	2903.83
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Fit Statistics

-2 Res Log Likelihood	10615.5
AIC (Smaller is Better)	10617.5
AICC (Smaller is Better)	10617.5
BIC (Smaller is Better)	10622.4

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			2	109.11	6.8580	977
TRTPN			3	140.23	6.8162	977
TRTPN			4	124.03	6.9813	977

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG30C Parameter=PPG at 30 min (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
REGION1	ASIA (EXCLUDING JAPAN)			-3.9490	6.2693	977
REGION1	EUROPE			1.1396	4.4283	977
REGION1	JAPAN			13.5871	5.0097	977
REGION1	NORTH AMERICA			0	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-3.9583	3.8630	977
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0	.	.
BASE				-0.6453	0.03052	977

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
TRTPN			2	15.91	<.0001	0.05
TRTPN			3	20.57	<.0001	0.05
TRTPN			4	17.77	<.0001	0.05
REGION1	ASIA (EXCLUDING JAPAN)			-0.63	0.5289	0.05
REGION1	EUROPE			0.26	0.7970	0.05
REGION1	JAPAN			2.71	0.0068	0.05
REGION1	NORTH AMERICA			.	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-1.02	0.3058	0.05
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.	.
BASE				-21.15	<.0001	0.05

Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG30C Parameter=PPG at 30 min (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Lower	Upper
TRTPN			2	95.6556	122.57
TRTPN			3	126.86	153.61
TRTPN			4	110.33	137.73
REGION1	ASIA (EXCLUDING JAPAN)			-16.2518	8.3538
REGION1	EUROPE			-7.5504	9.8296
REGION1	JAPAN			3.7560	23.4181
REGION1	NORTH AMERICA			.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-11.5390	3.6223
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.
BASE				-0.7052	-0.5854

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	2	977	27.50	<.0001
REGION1	3	977	4.10	0.0066
BOLAD1	1	977	1.05	0.3058
BASE	1	977	447.12	<.0001

Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG30C Parameter=PPG at 30 min (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) - NovoRapid (meal)	WORK.ENDPOINT_2	-14.9206	4.2197	977	-3.54	0.0004	0.05	-23.2013	-6.6399

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (post) - NovoRapid (meal)	WORK.ENDPOINT_2	16.2004	4.2263	977	3.83	0.0001	0.05	7.9068	24.4939

Least Squares Means

Effect	Planned Treatment for Period 30 (N)	Margins	BASE	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	2	WORK.ENDPOINT_2	184.78	-9.3057	2.9614	977	-3.14	0.0017	0.05	-15.1172	-3.4942
TRTPN	3	WORK.ENDPOINT_2	184.78	21.8153	2.9705	977	7.34	<.0001	0.05	15.9859	27.6447
TRTPN	4	WORK.ENDPOINT_2	184.78	5.6149	3.0023	977	1.87	0.0618	0.05	-0.2767	11.5065

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG60 Parameter=PPG at 1 hour (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Model Information

Data Set	WORK.ENDPOINT_2
Dependent Variable	CHG
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Dimensions

Covariance Parameters	1
Columns in X	10
Columns in Z	0
Subjects	1
Max Obs per Subject	987

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG60 Parameter=PPG at 1 hour (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Number of Observations

Number of Observations Read	987
Number of Observations Used	987
Number of Observations Not Used	0

Covariance Parameter
Estimates

Cov Parm	Estimate
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Residual	13.7309
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Fit Statistics

-2 Res Log Likelihood	5390.2
AIC (Smaller is Better)	5392.2
AICC (Smaller is Better)	5392.2
BIC (Smaller is Better)	5397.1

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			2	6.4461	0.4371	979
TRTPN			3	8.6407	0.4288	979
TRTPN			4	7.6883	0.4397	979

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG60 Parameter=PPG at 1 hour (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
REGION1	ASIA (EXCLUDING JAPAN)			-0.4375	0.4303	979
REGION1	EUROPE			-0.5682	0.3041	979
REGION1	JAPAN			0.3566	0.3427	979
REGION1	NORTH AMERICA			0	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.008920	0.2653	979
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0	.	.
BASE				-0.6109	0.02837	979

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
TRTPN			2	14.75	<.0001	0.05
TRTPN			3	20.15	<.0001	0.05
TRTPN			4	17.48	<.0001	0.05
REGION1	ASIA (EXCLUDING JAPAN)			-1.02	0.3096	0.05
REGION1	EUROPE			-1.87	0.0620	0.05
REGION1	JAPAN			1.04	0.2984	0.05
REGION1	NORTH AMERICA			.	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.03	0.9732	0.05
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.	.
BASE				-21.53	<.0001	0.05

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG60 Parameter=PPG at 1 hour (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Lower	Upper
TRTPN			2	5.5884	7.3038
TRTPN			3	7.7992	9.4823
TRTPN			4	6.8254	8.5512
REGION1	ASIA (EXCLUDING JAPAN)			-1.2819	0.4070
REGION1	EUROPE			-1.1650	0.02868
REGION1	JAPAN			-0.3160	1.0292
REGION1	NORTH AMERICA			.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.5117	0.5295
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.
BASE				-0.6666	-0.5552

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	2	979	29.12	<.0001
REGION1	3	979	3.27	0.0207
BOLAD1	1	979	0.00	0.9732
BASE	1	979	463.65	<.0001

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG60 Parameter=PPG at 1 hour (mmol/L) Study Identifier=NN1218-4131

The Mixed Procedure

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) - NovoRapid (meal)	WORK.ENDPOINT_2	-1.2422	0.2901	979	-4.28	<.0001	0.05	-1.8114	-0.6730

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (post) - NovoRapid (meal)	WORK.ENDPOINT_2	0.9524	0.2902	979	3.28	0.0011	0.05	0.3829	1.5219

Least Squares Means

Effect	Planned Treatment for Period 30 (N)	Margins	BASE	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	2	WORK.ENDPOINT_2	11.90	-0.9847	0.2037	979	-4.83	<.0001	0.05	-1.3844	-0.5851
TRTPN	3	WORK.ENDPOINT_2	11.90	1.2099	0.2037	979	5.94	<.0001	0.05	0.8101	1.6097
TRTPN	4	WORK.ENDPOINT_2	11.90	0.2574	0.2064	979	1.25	0.2126	0.05	-0.1476	0.6625

Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG60C Parameter=PPG at 1 hour (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Model Information

Data Set	WORK.ENDPOINT_2
Dependent Variable	CHG
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Dimensions

Covariance Parameters	1
Columns in X	10
Columns in Z	0
Subjects	1
Max Obs per Subject	987

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG60C Parameter=PPG at 1 hour (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Number of Observations

Number of Observations Read	987
Number of Observations Used	987
Number of Observations Not Used	0

Covariance Parameter
Estimates

Cov Parm	Estimate
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Residual	4458.69
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Fit Statistics

-2 Res Log Likelihood	11057.5
AIC (Smaller is Better)	11059.5
AICC (Smaller is Better)	11059.5
BIC (Smaller is Better)	11064.4

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			2	116.16	7.8762	979
TRTPN			3	155.71	7.7275	979
TRTPN			4	138.54	7.9236	979

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG60C Parameter=PPG at 1 hour (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
REGION1	ASIA (EXCLUDING JAPAN)			-7.8830	7.7545	979
REGION1	EUROPE			-10.2381	5.4805	979
REGION1	JAPAN			6.4259	6.1759	979
REGION1	NORTH AMERICA			0	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.1607	4.7806	979
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0	.	.
BASE				-0.6109	0.02837	979

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
TRTPN			2	14.75	<.0001	0.05
TRTPN			3	20.15	<.0001	0.05
TRTPN			4	17.48	<.0001	0.05
REGION1	ASIA (EXCLUDING JAPAN)			-1.02	0.3096	0.05
REGION1	EUROPE			-1.87	0.0620	0.05
REGION1	JAPAN			1.04	0.2984	0.05
REGION1	NORTH AMERICA			.	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.03	0.9732	0.05
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.	.
BASE				-21.53	<.0001	0.05

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Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 872 of 4425	Novo Nordisk
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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG60C Parameter=PPG at 1 hour (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Lower	Upper
TRTPN			2	100.70	131.62
TRTPN			3	140.54	170.87
TRTPN			4	122.99	154.09
REGION1	ASIA (EXCLUDING JAPAN)			-23.1004	7.3344
REGION1	EUROPE			-20.9929	0.5168
REGION1	JAPAN			-5.6935	18.5454
REGION1	NORTH AMERICA			.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-9.2208	9.5422
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.
BASE				-0.6666	-0.5552

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	2	979	29.12	<.0001
REGION1	3	979	3.27	0.0207
BOLAD1	1	979	0.00	0.9732
BASE	1	979	463.65	<.0001

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Postprandial glucose (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG60C Parameter=PPG at 1 hour (mg/dL) Study Identifier=NN1218-4131

The Mixed Procedure

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) - NovoRapid (meal)	WORK.ENDPOINT_2	-22.3844	5.2272	979	-4.28	<.0001	0.05	-32.6422	-12.1266

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (post) - NovoRapid (meal)	WORK.ENDPOINT_2	17.1628	5.2295	979	3.28	0.0011	0.05	6.9004	27.4251

Least Squares Means

Effect	Planned Treatment for Period 30 (N)	Margins	BASE	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	2	WORK.ENDPOINT_2	214.49	-17.7451	3.6702	979	-4.83	<.0001	0.05	-24.9475	-10.5427
TRTPN	3	WORK.ENDPOINT_2	214.49	21.8020	3.6713	979	5.94	<.0001	0.05	14.5975	29.0065
TRTPN	4	WORK.ENDPOINT_2	214.49	4.6392	3.7193	979	1.25	0.2126	0.05	-2.6594	11.9379

12: Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 1 hour (mg/dL) Parameter Code=MTIC60C Study Identifier=NN1218-4131

The Mixed Procedure

Model Information

Data Set	WORK.ENDPOINT_2
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Dimensions

Covariance Parameters	1
Columns in X	10
Columns in Z	0
Subjects	1
Max Obs per Subject	990

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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 1 hour (mg/dL) Parameter Code=MTIC60C Study Identifier=NN1218-4131

The Mixed Procedure

Number of Observations

Number of Observations Read	990
Number of Observations Used	990
Number of Observations Not Used	0

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	2852.76

Fit Statistics

-2 Res Log Likelihood	10652.4
AIC (Smaller is Better)	10654.4
AICC (Smaller is Better)	10654.4
BIC (Smaller is Better)	10659.3

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			2	46.9668	4.7674	982
TRTPN			3	81.4682	4.7045	982

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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 1 hour (mg/dL) Parameter Code=MTIC60C Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			4	63.2039	4.8135	982
REGION1	ASIA (EXCLUDING JAPAN)			-2.0132	6.1820	982
REGION1	EUROPE			-13.4006	4.3742	982
REGION1	JAPAN			2.2730	4.9131	982
REGION1	NORTH AMERICA			0	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.8981	3.8152	982
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0	.	.
BASE				0.3307	0.02685	982

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
TRTPN			2	9.85	<.0001	0.05
TRTPN			3	17.32	<.0001	0.05
TRTPN			4	13.13	<.0001	0.05
REGION1	ASIA (EXCLUDING JAPAN)			-0.33	0.7448	0.05
REGION1	EUROPE			-3.06	0.0022	0.05
REGION1	JAPAN			0.46	0.6437	0.05
REGION1	NORTH AMERICA			.	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.24	0.8140	0.05

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 1 hour (mg/dL) Parameter Code=MTIC60C Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
BOLAD1 BASE		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		12.32	<.0001	0.05

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Lower	Upper
TRTPN			2	37.6113	56.3223
TRTPN			3	72.2362	90.7002
TRTPN			4	53.7580	72.6498
REGION1	ASIA (EXCLUDING JAPAN)			-14.1445	10.1182
REGION1	EUROPE			-21.9844	-4.8168
REGION1	JAPAN			-7.3684	11.9145
REGION1	NORTH AMERICA			.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-6.5888	8.3849
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.
BASE				0.2780	0.3834

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 1 hour (mg/dL) Parameter Code=MTIC60C Study Identifier=NN1218-4131

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	2	982	34.47	<.0001
REGION1	3	982	5.10	0.0017
BOLAD1	1	982	0.06	0.8140
BASE	1	982	151.72	<.0001

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) - NovoRapid (meal)	WORK.ENDPOINT_2	-16.2371	4.1707	982	-3.89	0.0001	0.05	-24.4215	-8.0526

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (post) - NovoRapid (meal)	WORK.ENDPOINT_2	18.2643	4.1731	982	4.38	<.0001	0.05	10.0751	26.4535

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 1 hour (mg/dL) Parameter Code=MTIC60C Study Identifier=NN1218-4131

The Mixed Procedure

Least Squares Means

Effect	Planned Treatment for Period 30 (N)	Margins	BASE	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	2	WORK.ENDPOINT_2	92.03	73.6946	2.9356	982	25.10	<.0001	0.05	67.9337	79.4554
TRTPN	3	WORK.ENDPOINT_2	92.03	108.20	2.9368	982	36.84	<.0001	0.05	102.43	113.96
TRTPN	4	WORK.ENDPOINT_2	92.03	89.9316	2.9609	982	30.37	<.0001	0.05	84.1211	95.7422

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 1 hour (mmol/L) Parameter Code=MTIC60 Study Identifier=NN1218-4131

The Mixed Procedure

Model Information

Data Set	WORK.ENDPOINT_2
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Dimensions

Covariance Parameters	1
Columns in X	10
Columns in Z	0
Subjects	1
Max Obs per Subject	990

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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 1 hour (mmol/L) Parameter Code=MTIC60 Study Identifier=NN1218-4131

The Mixed Procedure

Number of Observations

Number of Observations Read	990
Number of Observations Used	990
Number of Observations Not Used	0

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	8.7853

Fit Statistics

-2 Res Log Likelihood	4967.8
AIC (Smaller is Better)	4969.8
AICC (Smaller is Better)	4969.8
BIC (Smaller is Better)	4974.6

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			2	2.6064	0.2646	982
TRTPN			3	4.5210	0.2611	982

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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 1 hour (mmol/L) Parameter Code=MTIC60 Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			4	3.5074	0.2671	982
REGION1	ASIA (EXCLUDING JAPAN)			-0.1117	0.3431	982
REGION1	EUROPE			-0.7437	0.2427	982
REGION1	JAPAN			0.1261	0.2726	982
REGION1	NORTH AMERICA			0	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.04984	0.2117	982
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0	.	.
BASE				0.3307	0.02685	982

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
TRTPN			2	9.85	<.0001	0.05
TRTPN			3	17.32	<.0001	0.05
TRTPN			4	13.13	<.0001	0.05
REGION1	ASIA (EXCLUDING JAPAN)			-0.33	0.7448	0.05
REGION1	EUROPE			-3.06	0.0022	0.05
REGION1	JAPAN			0.46	0.6437	0.05
REGION1	NORTH AMERICA			.	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.24	0.8140	0.05

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 1 hour (mmol/L) Parameter Code=MTIC60 Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
BOLAD1 BASE		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		12.32	<.0001	0.05

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Lower	Upper
TRTPN			2	2.0872	3.1255
TRTPN			3	4.0087	5.0333
TRTPN			4	2.9832	4.0316
REGION1	ASIA (EXCLUDING JAPAN)			-0.7849	0.5615
REGION1	EUROPE			-1.2200	-0.2673
REGION1	JAPAN			-0.4089	0.6612
REGION1	NORTH AMERICA			.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.3656	0.4653
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.
BASE				0.2780	0.3834

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 1 hour (mmol/L) Parameter Code=MTIC60 Study Identifier=NN1218-4131

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	2	982	34.47	<.0001
REGION1	3	982	5.10	0.0017
BOLAD1	1	982	0.06	0.8140
BASE	1	982	151.72	<.0001

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) - NovoRapid (meal)	WORK.ENDPOINT_2	-0.9011	0.2314	982	-3.89	0.0001	0.05	-1.3552	-0.4469

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (post) - NovoRapid (meal)	WORK.ENDPOINT_2	1.0136	0.2316	982	4.38	<.0001	0.05	0.5591	1.4680

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 1 hour (mmol/L) Parameter Code=MTIC60 Study Identifier=NN1218-4131

The Mixed Procedure

Least Squares Means

Effect	Planned Treatment for Period 30 (N)	Margins	BASE	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	2	WORK.ENDPOINT_2	5.11	4.0896	0.1629	982	25.10	<.0001	0.05	3.7699	4.4093
TRTPN	3	WORK.ENDPOINT_2	5.11	6.0042	0.1630	982	36.84	<.0001	0.05	5.6844	6.3240
TRTPN	4	WORK.ENDPOINT_2	5.11	4.9907	0.1643	982	30.37	<.0001	0.05	4.6682	5.3131

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 2 hours (mg/dL) Parameter Code=MTIC120C Study Identifier=NN1218-4131

The Mixed Procedure

Model Information

Data Set	WORK.ENDPOINT_2
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Dimensions

Covariance Parameters	1
Columns in X	10
Columns in Z	0
Subjects	1
Max Obs per Subject	982

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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 2 hours (mg/dL) Parameter Code=MTIC120C Study Identifier=NN1218-4131

The Mixed Procedure

Number of Observations

Number of Observations Read	982
Number of Observations Used	982
Number of Observations Not Used	0

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	5306.23

Fit Statistics

-2 Res Log Likelihood	11171.0
AIC (Smaller is Better)	11173.0
AICC (Smaller is Better)	11173.0
BIC (Smaller is Better)	11177.9

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			2	58.8340	6.2493	974
TRTPN			3	70.1993	6.1864	974

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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 2 hours (mg/dL) Parameter Code=MTIC120C Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			4	65.2130	6.3001	974
REGION1	ASIA (EXCLUDING JAPAN)			-5.3985	8.4855	974
REGION1	EUROPE			-20.0183	6.0104	974
REGION1	JAPAN			4.5861	6.7609	974
REGION1	NORTH AMERICA			0	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		5.5127	5.2330	974
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0	.	.
BASE				0.3866	0.02757	974

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
TRTPN			2	9.41	<.0001	0.05
TRTPN			3	11.35	<.0001	0.05
TRTPN			4	10.35	<.0001	0.05
REGION1	ASIA (EXCLUDING JAPAN)			-0.64	0.5248	0.05
REGION1	EUROPE			-3.33	0.0009	0.05
REGION1	JAPAN			0.68	0.4977	0.05
REGION1	NORTH AMERICA			.	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		1.05	0.2924	0.05

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 2 hours (mg/dL) Parameter Code=MTIC120C Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
BOLAD1 BASE		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		14.02	<.0001	0.05

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Lower	Upper
TRTPN			2	46.5704	71.0976
TRTPN			3	58.0592	82.3395
TRTPN			4	52.8496	77.5764
REGION1	ASIA (EXCLUDING JAPAN)			-22.0505	11.2536
REGION1	EUROPE			-31.8130	-8.2235
REGION1	JAPAN			-8.6814	17.8536
REGION1	NORTH AMERICA				
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-4.7566	15.7821
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY			
BASE				0.3325	0.4407

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 2 hours (mg/dL) Parameter Code=MTIC120C Study Identifier=NN1218-4131

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	2	974	2.00	0.1353
REGION1	3	974	6.29	0.0003
BOLAD1	1	974	1.11	0.2924
BASE	1	974	196.64	<.0001

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) - NovoRapid (meal)	WORK.ENDPOINT_2	-6.3790	5.7193	974	-1.12	0.2650	0.05	-17.6027	4.8446

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (post) - NovoRapid (meal)	WORK.ENDPOINT_2	4.9863	5.7065	974	0.87	0.3824	0.05	-6.2121	16.1848

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 2 hours (mg/dL) Parameter Code=MTIC120C Study Identifier=NN1218-4131

The Mixed Procedure

Least Squares Means

Effect	Planned Treatment for Period 30 (N)	Margins	BASE	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	2	WORK.ENDPOINT_2	101.04	94.7646	4.0281	974	23.53	<.0001	0.05	86.8597	102.67
TRTPN	3	WORK.ENDPOINT_2	101.04	106.13	4.0098	974	26.47	<.0001	0.05	98.2610	114.00
TRTPN	4	WORK.ENDPOINT_2	101.04	101.14	4.0567	974	24.93	<.0001	0.05	93.1827	109.10

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 2 hours (mmol/L) Parameter Code=MTIC120 Study Identifier=NN1218-4131

The Mixed Procedure

Model Information

Data Set	WORK.ENDPOINT_2
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Dimensions

Covariance Parameters	1
Columns in X	10
Columns in Z	0
Subjects	1
Max Obs per Subject	982

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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 2 hours (mmol/L) Parameter Code=MTIC120 Study Identifier=NN1218-4131

The Mixed Procedure

Number of Observations

Number of Observations Read	982
Number of Observations Used	982
Number of Observations Not Used	0

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	16.3409

Fit Statistics

-2 Res Log Likelihood	5532.6
AIC (Smaller is Better)	5534.6
AICC (Smaller is Better)	5534.6
BIC (Smaller is Better)	5539.5

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			2	3.2649	0.3468	974
TRTPN			3	3.8956	0.3433	974

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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 2 hours (mmol/L) Parameter Code=MTIC120 Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			4	3.6189	0.3496	974
REGION1	ASIA (EXCLUDING JAPAN)			-0.2996	0.4709	974
REGION1	EUROPE			-1.1109	0.3335	974
REGION1	JAPAN			0.2545	0.3752	974
REGION1	NORTH AMERICA			0	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.3059	0.2904	974
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0	.	.
BASE				0.3866	0.02757	974

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
TRTPN			2	9.41	<.0001	0.05
TRTPN			3	11.35	<.0001	0.05
TRTPN			4	10.35	<.0001	0.05
REGION1	ASIA (EXCLUDING JAPAN)			-0.64	0.5248	0.05
REGION1	EUROPE			-3.33	0.0009	0.05
REGION1	JAPAN			0.68	0.4977	0.05
REGION1	NORTH AMERICA			.	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		1.05	0.2924	0.05

Fast-acting insulin aspart
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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 2 hours (mmol/L) Parameter Code=MTIC120 Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
BOLAD1 BASE		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		14.02	<.0001	0.05

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Lower	Upper
TRTPN			2	2.5844	3.9455
TRTPN			3	3.2219	4.5693
TRTPN			4	2.9328	4.3050
REGION1	ASIA (EXCLUDING JAPAN)			-1.2237	0.6245
REGION1	EUROPE			-1.7654	-0.4564
REGION1	JAPAN			-0.4818	0.9908
REGION1	NORTH AMERICA			.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.2640	0.8758
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.
BASE				0.3325	0.4407

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 2 hours (mmol/L) Parameter Code=MTIC120 Study Identifier=NN1218-4131

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	2	974	2.00	0.1353
REGION1	3	974	6.29	0.0003
BOLAD1	1	974	1.11	0.2924
BASE	1	974	196.64	<.0001

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) - NovoRapid (meal)	WORK.ENDPOINT_2	-0.3540	0.3174	974	-1.12	0.2650	0.05	-0.9768	0.2688

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (post) - NovoRapid (meal)	WORK.ENDPOINT_2	0.2767	0.3167	974	0.87	0.3824	0.05	-0.3447	0.8982

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 2 hours (mmol/L) Parameter Code=MTIC120 Study Identifier=NN1218-4131

The Mixed Procedure

Least Squares Means

Effect	Planned Treatment for Period 30 (N)	Margins	BASE	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	2	WORK.ENDPOINT_2	5.61	5.2589	0.2235	974	23.53	<.0001	0.05	4.8202	5.6975
TRTPN	3	WORK.ENDPOINT_2	5.61	5.8896	0.2225	974	26.47	<.0001	0.05	5.4529	6.3262
TRTPN	4	WORK.ENDPOINT_2	5.61	5.6129	0.2251	974	24.93	<.0001	0.05	5.1711	6.0546

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 3 hours (mg/dL) Parameter Code=MTIC180C Study Identifier=NN1218-4131

The Mixed Procedure

Model Information

Data Set	WORK.ENDPOINT_2
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Dimensions

Covariance Parameters	1
Columns in X	10
Columns in Z	0
Subjects	1
Max Obs per Subject	981

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 3 hours (mg/dL) Parameter Code=MTIC180C Study Identifier=NN1218-4131

The Mixed Procedure

Number of Observations	
Number of Observations Read	981
Number of Observations Used	981
Number of Observations Not Used	0

Covariance Parameter
Estimates

Cov Parm	Estimate
Residual	5840.68

Fit Statistics	
-2 Res Log Likelihood	11253.0
AIC (Smaller is Better)	11255.0
AICC (Smaller is Better)	11255.0
BIC (Smaller is Better)	11259.9

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			2	45.1211	6.1934	973
TRTPN			3	54.1562	6.2164	973

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 3 hours (mg/dL) Parameter Code=MTIC180C Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			4	48.0741	6.2890	973
REGION1	ASIA (EXCLUDING JAPAN)			5.9809	8.9503	973
REGION1	EUROPE			-21.0724	6.3158	973
REGION1	JAPAN			8.4858	7.1752	973
REGION1	NORTH AMERICA			0	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		3.3883	5.4908	973
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0	.	.
BASE				0.4336	0.02816	973

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
TRTPN			2	7.29	<.0001	0.05
TRTPN			3	8.71	<.0001	0.05
TRTPN			4	7.64	<.0001	0.05
REGION1	ASIA (EXCLUDING JAPAN)			0.67	0.5041	0.05
REGION1	EUROPE			-3.34	0.0009	0.05
REGION1	JAPAN			1.18	0.2372	0.05
REGION1	NORTH AMERICA			.	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.62	0.5373	0.05

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 3 hours (mg/dL) Parameter Code=MTIC180C Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
BOLAD1 BASE		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		15.39	<.0001	0.05

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Lower	Upper
TRTPN			2	32.9672	57.2751
TRTPN			3	41.9571	66.3553
TRTPN			4	35.7326	60.4156
REGION1	ASIA (EXCLUDING JAPAN)			-11.5832	23.5449
REGION1	EUROPE			-33.4666	-8.6782
REGION1	JAPAN			-5.5949	22.5664
REGION1	NORTH AMERICA			.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-7.3869	14.1635
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.
BASE				0.3783	0.4889

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 3 hours (mg/dL) Parameter Code=MTIC180C Study Identifier=NN1218-4131

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	2	973	1.18	0.3062
REGION1	3	973	8.15	<.0001
BOLAD1	1	973	0.38	0.5373
BASE	1	973	237.00	<.0001

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) - NovoRapid (meal)	WORK.ENDPOINT_2	-2.9530	5.9841	973	-0.49	0.6218	0.05	-14.6963	8.7903

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (post) - NovoRapid (meal)	WORK.ENDPOINT_2	6.0821	6.0038	973	1.01	0.3113	0.05	-5.6999	17.8640

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 3 hours (mg/dL) Parameter Code=MTIC180C Study Identifier=NN1218-4131

The Mixed Procedure

Least Squares Means

Effect	Planned Treatment for Period 30 (N)	Margins	BASE	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	2	WORK.ENDPOINT_2	77.86	76.6273	4.2083	973	18.21	<.0001	0.05	68.3690	84.8856
TRTPN	3	WORK.ENDPOINT_2	77.86	85.6623	4.2391	973	20.21	<.0001	0.05	77.3436	93.9811
TRTPN	4	WORK.ENDPOINT_2	77.86	79.5803	4.2494	973	18.73	<.0001	0.05	71.2411	87.9194

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 3 hours (mmol/L) Parameter Code=MTIC180 Study Identifier=NN1218-4131

The Mixed Procedure

Model Information

Data Set	WORK.ENDPOINT_2
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Dimensions

Covariance Parameters	1
Columns in X	10
Columns in Z	0
Subjects	1
Max Obs per Subject	981

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 3 hours (mmol/L) Parameter Code=MTIC180 Study Identifier=NN1218-4131

The Mixed Procedure

Number of Observations

Number of Observations Read	981
Number of Observations Used	981
Number of Observations Not Used	0

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	17.9868

Fit Statistics

-2 Res Log Likelihood	5620.4
AIC (Smaller is Better)	5622.4
AICC (Smaller is Better)	5622.4
BIC (Smaller is Better)	5627.3

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			2	2.5039	0.3437	973
TRTPN			3	3.0053	0.3450	973

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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 3 hours (mmol/L) Parameter Code=MTIC180 Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			4	2.6678	0.3490	973
REGION1	ASIA (EXCLUDING JAPAN)			0.3319	0.4967	973
REGION1	EUROPE			-1.1694	0.3505	973
REGION1	JAPAN			0.4709	0.3982	973
REGION1	NORTH AMERICA			0	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.1880	0.3047	973
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0	.	.
BASE				0.4336	0.02816	973

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
TRTPN			2	7.29	<.0001	0.05
TRTPN			3	8.71	<.0001	0.05
TRTPN			4	7.64	<.0001	0.05
REGION1	ASIA (EXCLUDING JAPAN)			0.67	0.5041	0.05
REGION1	EUROPE			-3.34	0.0009	0.05
REGION1	JAPAN			1.18	0.2372	0.05
REGION1	NORTH AMERICA			.	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.62	0.5373	0.05

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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 3 hours (mmol/L) Parameter Code=MTIC180 Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
BOLAD1 BASE		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		15.39	<.0001	0.05

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Lower	Upper
TRTPN			2	1.8295	3.1784
TRTPN			3	2.3284	3.6823
TRTPN			4	1.9829	3.3527
REGION1	ASIA (EXCLUDING JAPAN)			-0.6428	1.3066
REGION1	EUROPE			-1.8572	-0.4816
REGION1	JAPAN			-0.3105	1.2523
REGION1	NORTH AMERICA				
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.4099	0.7860
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY			
BASE				0.3783	0.4889

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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 3 hours (mmol/L) Parameter Code=MTIC180 Study Identifier=NN1218-4131

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	2	973	1.18	0.3062
REGION1	3	973	8.15	<.0001
BOLAD1	1	973	0.38	0.5373
BASE	1	973	237.00	<.0001

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) - NovoRapid (meal)	WORK.ENDPOINT_2	-0.1639	0.3321	973	-0.49	0.6218	0.05	-0.8156	0.4878

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (post) - NovoRapid (meal)	WORK.ENDPOINT_2	0.3375	0.3332	973	1.01	0.3113	0.05	-0.3163	0.9913

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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 3 hours (mmol/L) Parameter Code=MTIC180 Study Identifier=NN1218-4131

The Mixed Procedure

Least Squares Means

Effect	Planned Treatment for Period 30 (N)	Margins	BASE	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	2	WORK.ENDPOINT_2	4.32	4.2523	0.2335	973	18.21	<.0001	0.05	3.7941	4.7106
TRTPN	3	WORK.ENDPOINT_2	4.32	4.7537	0.2352	973	20.21	<.0001	0.05	4.2921	5.2154
TRTPN	4	WORK.ENDPOINT_2	4.32	4.4162	0.2358	973	18.73	<.0001	0.05	3.9534	4.8790

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 30 min (mg/dL) Parameter Code=MTIC30C Study Identifier=NN1218-4131

The Mixed Procedure

Model Information

Data Set	WORK.ENDPOINT_2
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Dimensions

Covariance Parameters	1
Columns in X	10
Columns in Z	0
Subjects	1
Max Obs per Subject	988

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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 30 min (mg/dL) Parameter Code=MTIC30C Study Identifier=NN1218-4131

The Mixed Procedure

Number of Observations

Number of Observations Read	988
Number of Observations Used	988
Number of Observations Not Used	0

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	1365.04

Fit Statistics

-2 Res Log Likelihood	9907.6
AIC (Smaller is Better)	9909.6
AICC (Smaller is Better)	9909.6
BIC (Smaller is Better)	9914.4

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			2	32.9604	3.3229	980
TRTPN			3	58.9969	3.3225	980

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Parameter=PPG inc. at 30 min (mg/dL) Parameter Code=MTIC30C Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			4	42.2894	3.4093	980
REGION1	ASIA (EXCLUDING JAPAN)			1.0319	4.2800	980
REGION1	EUROPE			-2.5984	3.0295	980
REGION1	JAPAN			8.0719	3.4171	980
REGION1	NORTH AMERICA			0	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-3.0884	2.6419	980
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0	.	.
BASE				0.3201	0.02912	980

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
TRTPN			2	9.92	<.0001	0.05
TRTPN			3	17.76	<.0001	0.05
TRTPN			4	12.40	<.0001	0.05
REGION1	ASIA (EXCLUDING JAPAN)			0.24	0.8095	0.05
REGION1	EUROPE			-0.86	0.3913	0.05
REGION1	JAPAN			2.36	0.0184	0.05
REGION1	NORTH AMERICA			.	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-1.17	0.2427	0.05

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 30 min (mg/dL) Parameter Code=MTIC30C Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
BOLAD1 BASE		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		10.99	<.0001	0.05

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Lower	Upper
TRTPN			2	26.4396	39.4812
TRTPN			3	52.4769	65.5169
TRTPN			4	35.5991	48.9798
REGION1	ASIA (EXCLUDING JAPAN)			-7.3671	9.4308
REGION1	EUROPE			-8.5435	3.3468
REGION1	JAPAN			1.3663	14.7776
REGION1	NORTH AMERICA			.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-8.2728	2.0960
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.
BASE				0.2630	0.3772

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 30 min (mg/dL) Parameter Code=MTIC30C Study Identifier=NN1218-4131

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	2	980	41.98	<.0001
REGION1	3	980	3.83	0.0097
BOLAD1	1	980	1.37	0.2427
BASE	1	980	120.87	<.0001

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) - NovoRapid (meal)	WORK.ENDPOINT_2	-9.3290	2.8860	980	-3.23	0.0013	0.05	-14.9925	-3.6656

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (post) - NovoRapid (meal)	WORK.ENDPOINT_2	16.7074	2.8913	980	5.78	<.0001	0.05	11.0336	22.3813

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 30 min (mg/dL) Parameter Code=MTIC30C Study Identifier=NN1218-4131

The Mixed Procedure

Least Squares Means

Effect	Planned Treatment for Period 30 (N)	Margins	BASE	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	2	WORK.ENDPOINT_2	62.71	52.4372	2.0302	980	25.83	<.0001	0.05	48.4531	56.4212
TRTPN	3	WORK.ENDPOINT_2	62.71	78.4736	2.0368	980	38.53	<.0001	0.05	74.4766	82.4707
TRTPN	4	WORK.ENDPOINT_2	62.71	61.7662	2.0490	980	30.15	<.0001	0.05	57.7453	65.7871

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 30 min (mmol/L) Parameter Code=MTIC30 Study Identifier=NN1218-4131

The Mixed Procedure

Model Information

Data Set	WORK.ENDPOINT_2
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Dimensions

Covariance Parameters	1
Columns in X	10
Columns in Z	0
Subjects	1
Max Obs per Subject	988

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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 30 min (mmol/L) Parameter Code=MTIC30 Study Identifier=NN1218-4131

The Mixed Procedure

Number of Observations

Number of Observations Read	988
Number of Observations Used	988
Number of Observations Not Used	0

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	4.2037

Fit Statistics

-2 Res Log Likelihood	4234.5
AIC (Smaller is Better)	4236.5
AICC (Smaller is Better)	4236.5
BIC (Smaller is Better)	4241.4

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			2	1.8291	0.1844	980
TRTPN			3	3.2740	0.1844	980

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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 30 min (mmol/L) Parameter Code=MTIC30 Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			4	2.3468	0.1892	980
REGION1	ASIA (EXCLUDING JAPAN)			0.05726	0.2375	980
REGION1	EUROPE			-0.1442	0.1681	980
REGION1	JAPAN			0.4479	0.1896	980
REGION1	NORTH AMERICA			0	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.1714	0.1466	980
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0	.	.
BASE				0.3201	0.02912	980

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
TRTPN			2	9.92	<.0001	0.05
TRTPN			3	17.76	<.0001	0.05
TRTPN			4	12.40	<.0001	0.05
REGION1	ASIA (EXCLUDING JAPAN)			0.24	0.8095	0.05
REGION1	EUROPE			-0.86	0.3913	0.05
REGION1	JAPAN			2.36	0.0184	0.05
REGION1	NORTH AMERICA			.	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-1.17	0.2427	0.05

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 30 min (mmol/L) Parameter Code=MTIC30 Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
BOLAD1 BASE		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		10.99	<.0001	0.05

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Lower	Upper
TRTPN			2	1.4672	2.1910
TRTPN			3	2.9121	3.6358
TRTPN			4	1.9755	2.7181
REGION1	ASIA (EXCLUDING JAPAN)			-0.4088	0.5234
REGION1	EUROPE			-0.4741	0.1857
REGION1	JAPAN			0.07582	0.8201
REGION1	NORTH AMERICA				
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.4591	0.1163
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY			
BASE				0.2630	0.3772

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 30 min (mmol/L) Parameter Code=MTIC30 Study Identifier=NN1218-4131

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	2	980	41.98	<.0001
REGION1	3	980	3.83	0.0097
BOLAD1	1	980	1.37	0.2427
BASE	1	980	120.87	<.0001

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) - NovoRapid (meal)	WORK.ENDPOINT_2	-0.5177	0.1602	980	-3.23	0.0013	0.05	-0.8320	-0.2034

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (post) - NovoRapid (meal)	WORK.ENDPOINT_2	0.9272	0.1604	980	5.78	<.0001	0.05	0.6123	1.2420

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 30 min (mmol/L) Parameter Code=MTIC30 Study Identifier=NN1218-4131

The Mixed Procedure

Least Squares Means

Effect	Planned Treatment for Period 30 (N)	Margins	BASE	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	2	WORK.ENDPOINT_2	3.48	2.9099	0.1127	980	25.83	<.0001	0.05	2.6888	3.1310
TRTPN	3	WORK.ENDPOINT_2	3.48	4.3548	0.1130	980	38.53	<.0001	0.05	4.1330	4.5766
TRTPN	4	WORK.ENDPOINT_2	3.48	3.4276	0.1137	980	30.15	<.0001	0.05	3.2045	3.6508

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 4 hours (mg/dL) Parameter Code=MTIC240C Study Identifier=NN1218-4131

The Mixed Procedure

Model Information

Data Set	WORK.ENDPOINT_2
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Dimensions

Covariance Parameters	1
Columns in X	10
Columns in Z	0
Subjects	1
Max Obs per Subject	981

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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 4 hours (mg/dL) Parameter Code=MTIC240C Study Identifier=NN1218-4131

The Mixed Procedure

Number of Observations

Number of Observations Read	981
Number of Observations Used	981
Number of Observations Not Used	0

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	4838.61

Fit Statistics

-2 Res Log Likelihood	11069.7
AIC (Smaller is Better)	11071.7
AICC (Smaller is Better)	11071.7
BIC (Smaller is Better)	11076.6

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			2	24.0690	5.4531	973
TRTPN			3	32.2472	5.4805	973

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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 4 hours (mg/dL) Parameter Code=MTIC240C Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			4	26.6625	5.5335	973
REGION1	ASIA (EXCLUDING JAPAN)			12.0393	8.1924	973
REGION1	EUROPE			-14.8815	5.7238	973
REGION1	JAPAN			6.4205	6.5144	973
REGION1	NORTH AMERICA			0	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		2.8729	4.9882	973
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0	.	.
BASE				0.4693	0.02817	973

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
TRTPN			2	4.41	<.0001	0.05
TRTPN			3	5.88	<.0001	0.05
TRTPN			4	4.82	<.0001	0.05
REGION1	ASIA (EXCLUDING JAPAN)			1.47	0.1420	0.05
REGION1	EUROPE			-2.60	0.0095	0.05
REGION1	JAPAN			0.99	0.3246	0.05
REGION1	NORTH AMERICA			.	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.58	0.5648	0.05

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 4 hours (mg/dL) Parameter Code=MTIC240C Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
BOLAD1 BASE		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		16.66	<.0001	0.05

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Lower	Upper
TRTPN			2	13.3679	34.7702
TRTPN			3	21.4922	43.0022
TRTPN			4	15.8034	37.5215
REGION1	ASIA (EXCLUDING JAPAN)			-4.0375	28.1161
REGION1	EUROPE			-26.1138	-3.6491
REGION1	JAPAN			-6.3635	19.2045
REGION1	NORTH AMERICA				
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-6.9161	12.6618
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY			
BASE				0.4140	0.5245

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 4 hours (mg/dL) Parameter Code=MTIC240C Study Identifier=NN1218-4131

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	2	973	1.18	0.3083
REGION1	3	973	6.27	0.0003
BOLAD1	1	973	0.33	0.5648
BASE	1	973	277.57	<.0001

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) - NovoRapid (meal)	WORK.ENDPOINT_2	-2.5934	5.4475	973	-0.48	0.6341	0.05	-13.2836	8.0968

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (post) - NovoRapid (meal)	WORK.ENDPOINT_2	5.5847	5.4547	973	1.02	0.3062	0.05	-5.1195	16.2890

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 4 hours (mg/dL) Parameter Code=MTIC240C Study Identifier=NN1218-4131

The Mixed Procedure

Least Squares Means

Effect	Planned Treatment for Period 30 (N)	Margins	BASE	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	2	WORK.ENDPOINT_2	45.92	45.4086	3.8399	973	11.83	<.0001	0.05	37.8732	52.9439
TRTPN	3	WORK.ENDPOINT_2	45.92	53.5867	3.8511	973	13.91	<.0001	0.05	46.0294	61.1441
TRTPN	4	WORK.ENDPOINT_2	45.92	48.0020	3.8610	973	12.43	<.0001	0.05	40.4251	55.5789

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 4 hours (mmol/L) Parameter Code=MTIC240 Study Identifier=NN1218-4131

The Mixed Procedure

Model Information

Data Set	WORK.ENDPOINT_2
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Dimensions

Covariance Parameters	1
Columns in X	10
Columns in Z	0
Subjects	1
Max Obs per Subject	981

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 4 hours (mmol/L) Parameter Code=MTIC240 Study Identifier=NN1218-4131

The Mixed Procedure

Number of Observations

Number of Observations Read	981
Number of Observations Used	981
Number of Observations Not Used	0

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	14.9009

Fit Statistics

-2 Res Log Likelihood	5437.1
AIC (Smaller is Better)	5439.1
AICC (Smaller is Better)	5439.1
BIC (Smaller is Better)	5444.0

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			2	1.3357	0.3026	973
TRTPN			3	1.7895	0.3041	973

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 4 hours (mmol/L) Parameter Code=MTIC240 Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			4	1.4796	0.3071	973
REGION1	ASIA (EXCLUDING JAPAN)			0.6681	0.4546	973
REGION1	EUROPE			-0.8258	0.3176	973
REGION1	JAPAN			0.3563	0.3615	973
REGION1	NORTH AMERICA			0	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.1594	0.2768	973
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0	.	.
BASE				0.4693	0.02817	973

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
TRTPN			2	4.41	<.0001	0.05
TRTPN			3	5.88	<.0001	0.05
TRTPN			4	4.82	<.0001	0.05
REGION1	ASIA (EXCLUDING JAPAN)			1.47	0.1420	0.05
REGION1	EUROPE			-2.60	0.0095	0.05
REGION1	JAPAN			0.99	0.3246	0.05
REGION1	NORTH AMERICA			.	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.58	0.5648	0.05

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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 4 hours (mmol/L) Parameter Code=MTIC240 Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
BOLAD1 BASE		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		16.66	<.0001	0.05

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Lower	Upper
TRTPN			2	0.7418	1.9295
TRTPN			3	1.1927	2.3864
TRTPN			4	0.8770	2.0822
REGION1	ASIA (EXCLUDING JAPAN)			-0.2241	1.5603
REGION1	EUROPE			-1.4492	-0.2025
REGION1	JAPAN			-0.3531	1.0657
REGION1	NORTH AMERICA			.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.3838	0.7027
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.
BASE				0.4140	0.5245

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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 4 hours (mmol/L) Parameter Code=MTIC240 Study Identifier=NN1218-4131

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	2	973	1.18	0.3083
REGION1	3	973	6.27	0.0003
BOLAD1	1	973	0.33	0.5648
BASE	1	973	277.57	<.0001

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) - NovoRapid (meal)	WORK.ENDPOINT_2	-0.1439	0.3023	973	-0.48	0.6341	0.05	-0.7372	0.4493

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (post) - NovoRapid (meal)	WORK.ENDPOINT_2	0.3099	0.3027	973	1.02	0.3062	0.05	-0.2841	0.9039

Fast-acting insulin aspart
NN1218-4131

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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 4 hours (mmol/L) Parameter Code=MTIC240 Study Identifier=NN1218-4131

The Mixed Procedure

Least Squares Means

Effect	Planned Treatment for Period 30 (N)	Margins	BASE	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	2	WORK.ENDPOINT_2	2.55	2.5199	0.2131	973	11.83	<.0001	0.05	2.1017	2.9381
TRTPN	3	WORK.ENDPOINT_2	2.55	2.9737	0.2137	973	13.91	<.0001	0.05	2.5543	3.3931
TRTPN	4	WORK.ENDPOINT_2	2.55	2.6638	0.2143	973	12.43	<.0001	0.05	2.2433	3.0843

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 1 hour (mg/dL) Parameter Code=MTIC60C Study Identifier=NN1218-4131

The Mixed Procedure

Model Information

Data Set	WORK.ENDPOINT_2
Dependent Variable	CHG
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Dimensions

Covariance Parameters	1
Columns in X	10
Columns in Z	0
Subjects	1
Max Obs per Subject	990

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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 1 hour (mg/dL) Parameter Code=MTIC60C Study Identifier=NN1218-4131

The Mixed Procedure

Number of Observations

Number of Observations Read	990
Number of Observations Used	990
Number of Observations Not Used	0

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	2852.76

Fit Statistics

-2 Res Log Likelihood	10652.4
AIC (Smaller is Better)	10654.4
AICC (Smaller is Better)	10654.4
BIC (Smaller is Better)	10659.3

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			2	46.9668	4.7674	982
TRTPN			3	81.4682	4.7045	982

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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 1 hour (mg/dL) Parameter Code=MTIC60C Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			4	63.2039	4.8135	982
REGION1	ASIA (EXCLUDING JAPAN)			-2.0132	6.1820	982
REGION1	EUROPE			-13.4006	4.3742	982
REGION1	JAPAN			2.2730	4.9131	982
REGION1	NORTH AMERICA			0	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.8981	3.8152	982
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0	.	.
BASE				-0.6693	0.02685	982

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
TRTPN			2	9.85	<.0001	0.05
TRTPN			3	17.32	<.0001	0.05
TRTPN			4	13.13	<.0001	0.05
REGION1	ASIA (EXCLUDING JAPAN)			-0.33	0.7448	0.05
REGION1	EUROPE			-3.06	0.0022	0.05
REGION1	JAPAN			0.46	0.6437	0.05
REGION1	NORTH AMERICA			.	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.24	0.8140	0.05

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 1 hour (mg/dL) Parameter Code=MTIC60C Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
BOLAD1 BASE		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		-24.93	<.0001	0.05

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Lower	Upper
TRTPN			2	37.6113	56.3223
TRTPN			3	72.2362	90.7002
TRTPN			4	53.7580	72.6498
REGION1	ASIA (EXCLUDING JAPAN)			-14.1445	10.1182
REGION1	EUROPE			-21.9844	-4.8168
REGION1	JAPAN			-7.3684	11.9145
REGION1	NORTH AMERICA			.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-6.5888	8.3849
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.
BASE				-0.7220	-0.6166

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 1 hour (mg/dL) Parameter Code=MTIC60C Study Identifier=NN1218-4131

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	2	982	34.47	<.0001
REGION1	3	982	5.10	0.0017
BOLAD1	1	982	0.06	0.8140
BASE	1	982	621.50	<.0001

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) - NovoRapid (meal)	WORK.ENDPOINT_2	-16.2371	4.1707	982	-3.89	0.0001	0.05	-24.4215	-8.0526

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (post) - NovoRapid (meal)	WORK.ENDPOINT_2	18.2643	4.1731	982	4.38	<.0001	0.05	10.0751	26.4535

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 1 hour (mg/dL) Parameter Code=MTIC60C Study Identifier=NN1218-4131

The Mixed Procedure

Least Squares Means

Effect	Planned Treatment for Period 30 (N)	Margins	BASE	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	2	WORK.ENDPOINT_2	92.03	-18.3385	2.9356	982	-6.25	<.0001	0.05	-24.0993	-12.5777
TRTPN	3	WORK.ENDPOINT_2	92.03	16.1629	2.9368	982	5.50	<.0001	0.05	10.3998	21.9260
TRTPN	4	WORK.ENDPOINT_2	92.03	-2.1014	2.9609	982	-0.71	0.4781	0.05	-7.9119	3.7091

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 1 hour (mmol/L) Parameter Code=MTIC60 Study Identifier=NN1218-4131

The Mixed Procedure

Model Information

Data Set	WORK.ENDPOINT_2
Dependent Variable	CHG
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Dimensions

Covariance Parameters	1
Columns in X	10
Columns in Z	0
Subjects	1
Max Obs per Subject	990

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 1 hour (mmol/L) Parameter Code=MTIC60 Study Identifier=NN1218-4131

The Mixed Procedure

Number of Observations

Number of Observations Read	990
Number of Observations Used	990
Number of Observations Not Used	0

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	8.7853

Fit Statistics

-2 Res Log Likelihood	4967.8
AIC (Smaller is Better)	4969.8
AICC (Smaller is Better)	4969.8
BIC (Smaller is Better)	4974.6

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			2	2.6064	0.2646	982
TRTPN			3	4.5210	0.2611	982

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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 1 hour (mmol/L) Parameter Code=MTIC60 Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			4	3.5074	0.2671	982
REGION1	ASIA (EXCLUDING JAPAN)			-0.1117	0.3431	982
REGION1	EUROPE			-0.7437	0.2427	982
REGION1	JAPAN			0.1261	0.2726	982
REGION1	NORTH AMERICA			0	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.04984	0.2117	982
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0	.	.
BASE				-0.6693	0.02685	982

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
TRTPN			2	9.85	<.0001	0.05
TRTPN			3	17.32	<.0001	0.05
TRTPN			4	13.13	<.0001	0.05
REGION1	ASIA (EXCLUDING JAPAN)			-0.33	0.7448	0.05
REGION1	EUROPE			-3.06	0.0022	0.05
REGION1	JAPAN			0.46	0.6437	0.05
REGION1	NORTH AMERICA			.	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.24	0.8140	0.05

Fast-acting insulin aspart
NN1218-4131

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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 1 hour (mmol/L) Parameter Code=MTIC60 Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
BOLAD1 BASE		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		-24.93	<.0001	0.05

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Lower	Upper
TRTPN			2	2.0872	3.1255
TRTPN			3	4.0087	5.0333
TRTPN			4	2.9832	4.0316
REGION1	ASIA (EXCLUDING JAPAN)			-0.7849	0.5615
REGION1	EUROPE			-1.2200	-0.2673
REGION1	JAPAN			-0.4089	0.6612
REGION1	NORTH AMERICA			.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.3656	0.4653
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.
BASE				-0.7220	-0.6166

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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 1 hour (mmol/L) Parameter Code=MTIC60 Study Identifier=NN1218-4131

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	2	982	34.47	<.0001
REGION1	3	982	5.10	0.0017
BOLAD1	1	982	0.06	0.8140
BASE	1	982	621.50	<.0001

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) - NovoRapid (meal)	WORK.ENDPOINT_2	-0.9011	0.2314	982	-3.89	0.0001	0.05	-1.3552	-0.4469

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (post) - NovoRapid (meal)	WORK.ENDPOINT_2	1.0136	0.2316	982	4.38	<.0001	0.05	0.5591	1.4680

Fast-acting insulin aspart
NN1218-4131

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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 1 hour (mmol/L) Parameter Code=MTIC60 Study Identifier=NN1218-4131

The Mixed Procedure

Least Squares Means

Effect	Planned Treatment for Period 30 (N)	Margins	BASE	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	2	WORK.ENDPOINT_2	5.11	-1.0177	0.1629	982	-6.25	<.0001	0.05	-1.3374	-0.6980
TRTPN	3	WORK.ENDPOINT_2	5.11	0.8969	0.1630	982	5.50	<.0001	0.05	0.5771	1.2168
TRTPN	4	WORK.ENDPOINT_2	5.11	-0.1166	0.1643	982	-0.71	0.4781	0.05	-0.4391	0.2058

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 2 hours (mg/dL) Parameter Code=MTIC120C Study Identifier=NN1218-4131

The Mixed Procedure

Model Information

Data Set	WORK.ENDPOINT_2
Dependent Variable	CHG
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Dimensions

Covariance Parameters	1
Columns in X	10
Columns in Z	0
Subjects	1
Max Obs per Subject	982

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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 2 hours (mg/dL) Parameter Code=MTIC120C Study Identifier=NN1218-4131

The Mixed Procedure

Number of Observations

Number of Observations Read	982
Number of Observations Used	982
Number of Observations Not Used	0

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	5306.23

Fit Statistics

-2 Res Log Likelihood	11171.0
AIC (Smaller is Better)	11173.0
AICC (Smaller is Better)	11173.0
BIC (Smaller is Better)	11177.9

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			2	58.8340	6.2493	974
TRTPN			3	70.1993	6.1864	974

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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 2 hours (mg/dL) Parameter Code=MTIC120C Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			4	65.2130	6.3001	974
REGION1	ASIA (EXCLUDING JAPAN)			-5.3985	8.4855	974
REGION1	EUROPE			-20.0183	6.0104	974
REGION1	JAPAN			4.5861	6.7609	974
REGION1	NORTH AMERICA			0	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		5.5127	5.2330	974
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0	.	.
BASE				-0.6134	0.02757	974

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
TRTPN			2	9.41	<.0001	0.05
TRTPN			3	11.35	<.0001	0.05
TRTPN			4	10.35	<.0001	0.05
REGION1	ASIA (EXCLUDING JAPAN)			-0.64	0.5248	0.05
REGION1	EUROPE			-3.33	0.0009	0.05
REGION1	JAPAN			0.68	0.4977	0.05
REGION1	NORTH AMERICA			.	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		1.05	0.2924	0.05

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 2 hours (mg/dL) Parameter Code=MTIC120C Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
BOLAD1 BASE		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		-22.25	<.0001	0.05

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Lower	Upper
TRTPN			2	46.5704	71.0976
TRTPN			3	58.0592	82.3395
TRTPN			4	52.8496	77.5764
REGION1	ASIA (EXCLUDING JAPAN)			-22.0505	11.2536
REGION1	EUROPE			-31.8130	-8.2235
REGION1	JAPAN			-8.6814	17.8536
REGION1	NORTH AMERICA				
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-4.7566	15.7821
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY			
BASE				-0.6675	-0.5593

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 2 hours (mg/dL) Parameter Code=MTIC120C Study Identifier=NN1218-4131

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	2	974	2.00	0.1353
REGION1	3	974	6.29	0.0003
BOLAD1	1	974	1.11	0.2924
BASE	1	974	494.90	<.0001

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) - NovoRapid (meal)	WORK.ENDPOINT_2	-6.3790	5.7193	974	-1.12	0.2650	0.05	-17.6027	4.8446

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (post) - NovoRapid (meal)	WORK.ENDPOINT_2	4.9863	5.7065	974	0.87	0.3824	0.05	-6.2121	16.1848

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 2 hours (mg/dL) Parameter Code=MTIC120C Study Identifier=NN1218-4131

The Mixed Procedure

Least Squares Means

Effect	Planned Treatment for Period 30 (N)	Margins	BASE	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	2	WORK.ENDPOINT_2	101.04	-6.2759	4.0281	974	-1.56	0.1196	0.05	-14.1807	1.6289
TRTPN	3	WORK.ENDPOINT_2	101.04	5.0895	4.0098	974	1.27	0.2047	0.05	-2.7795	12.9584
TRTPN	4	WORK.ENDPOINT_2	101.04	0.1031	4.0567	974	0.03	0.9797	0.05	-7.8578	8.0640

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 2 hours (mmol/L) Parameter Code=MTIC120 Study Identifier=NN1218-4131

The Mixed Procedure

Model Information

Data Set	WORK.ENDPOINT_2
Dependent Variable	CHG
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Dimensions

Covariance Parameters	1
Columns in X	10
Columns in Z	0
Subjects	1
Max Obs per Subject	982

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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 2 hours (mmol/L) Parameter Code=MTIC120 Study Identifier=NN1218-4131

The Mixed Procedure

Number of Observations

Number of Observations Read	982
Number of Observations Used	982
Number of Observations Not Used	0

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	16.3409

Fit Statistics

-2 Res Log Likelihood	5532.6
AIC (Smaller is Better)	5534.6
AICC (Smaller is Better)	5534.6
BIC (Smaller is Better)	5539.5

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			2	3.2649	0.3468	974
TRTPN			3	3.8956	0.3433	974

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Parameter=PPG inc. at 2 hours (mmol/L) Parameter Code=MTIC120 Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			4	3.6189	0.3496	974
REGION1	ASIA (EXCLUDING JAPAN)			-0.2996	0.4709	974
REGION1	EUROPE			-1.1109	0.3335	974
REGION1	JAPAN			0.2545	0.3752	974
REGION1	NORTH AMERICA			0	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.3059	0.2904	974
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0	.	.
BASE				-0.6134	0.02757	974

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
TRTPN			2	9.41	<.0001	0.05
TRTPN			3	11.35	<.0001	0.05
TRTPN			4	10.35	<.0001	0.05
REGION1	ASIA (EXCLUDING JAPAN)			-0.64	0.5248	0.05
REGION1	EUROPE			-3.33	0.0009	0.05
REGION1	JAPAN			0.68	0.4977	0.05
REGION1	NORTH AMERICA			.	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		1.05	0.2924	0.05

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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 2 hours (mmol/L) Parameter Code=MTIC120 Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
BOLAD1 BASE		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		-22.25	<.0001	0.05

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Lower	Upper
TRTPN			2	2.5844	3.9455
TRTPN			3	3.2219	4.5693
TRTPN			4	2.9328	4.3050
REGION1	ASIA (EXCLUDING JAPAN)			-1.2237	0.6245
REGION1	EUROPE			-1.7654	-0.4564
REGION1	JAPAN			-0.4818	0.9908
REGION1	NORTH AMERICA			.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.2640	0.8758
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.
BASE				-0.6675	-0.5593

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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 2 hours (mmol/L) Parameter Code=MTIC120 Study Identifier=NN1218-4131

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	2	974	2.00	0.1353
REGION1	3	974	6.29	0.0003
BOLAD1	1	974	1.11	0.2924
BASE	1	974	494.90	<.0001

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) - NovoRapid (meal)	WORK.ENDPOINT_2	-0.3540	0.3174	974	-1.12	0.2650	0.05	-0.9768	0.2688

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (post) - NovoRapid (meal)	WORK.ENDPOINT_2	0.2767	0.3167	974	0.87	0.3824	0.05	-0.3447	0.8982

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 2 hours (mmol/L) Parameter Code=MTIC120 Study Identifier=NN1218-4131

The Mixed Procedure

Least Squares Means

Effect	Planned Treatment for Period 30 (N)	Margins	BASE	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	2	WORK.ENDPOINT_2	5.61	-0.3483	0.2235	974	-1.56	0.1196	0.05	-0.7869	0.09040
TRTPN	3	WORK.ENDPOINT_2	5.61	0.2824	0.2225	974	1.27	0.2047	0.05	-0.1542	0.7191
TRTPN	4	WORK.ENDPOINT_2	5.61	0.005723	0.2251	974	0.03	0.9797	0.05	-0.4361	0.4475

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 3 hours (mg/dL) Parameter Code=MTIC180C Study Identifier=NN1218-4131

The Mixed Procedure

Model Information

Data Set	WORK.ENDPOINT_2
Dependent Variable	CHG
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Dimensions

Covariance Parameters	1
Columns in X	10
Columns in Z	0
Subjects	1
Max Obs per Subject	981

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 3 hours (mg/dL) Parameter Code=MTIC180C Study Identifier=NN1218-4131

The Mixed Procedure

Number of Observations

Number of Observations Read	981
Number of Observations Used	981
Number of Observations Not Used	0

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	5840.68

Fit Statistics

-2 Res Log Likelihood	11253.0
AIC (Smaller is Better)	11255.0
AICC (Smaller is Better)	11255.0
BIC (Smaller is Better)	11259.9

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			2	45.1211	6.1934	973
TRTPN			3	54.1562	6.2164	973

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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 3 hours (mg/dL) Parameter Code=MTIC180C Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			4	48.0741	6.2890	973
REGION1	ASIA (EXCLUDING JAPAN)			5.9809	8.9503	973
REGION1	EUROPE			-21.0724	6.3158	973
REGION1	JAPAN			8.4858	7.1752	973
REGION1	NORTH AMERICA			0	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		3.3883	5.4908	973
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0	.	.
BASE				-0.5664	0.02816	973

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
TRTPN			2	7.29	<.0001	0.05
TRTPN			3	8.71	<.0001	0.05
TRTPN			4	7.64	<.0001	0.05
REGION1	ASIA (EXCLUDING JAPAN)			0.67	0.5041	0.05
REGION1	EUROPE			-3.34	0.0009	0.05
REGION1	JAPAN			1.18	0.2372	0.05
REGION1	NORTH AMERICA			.	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.62	0.5373	0.05

Fast-acting insulin aspart
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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 3 hours (mg/dL) Parameter Code=MTIC180C Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
BOLAD1 BASE		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		-20.11	<.0001	0.05

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Lower	Upper
TRTPN			2	32.9672	57.2751
TRTPN			3	41.9571	66.3553
TRTPN			4	35.7326	60.4156
REGION1	ASIA (EXCLUDING JAPAN)			-11.5832	23.5449
REGION1	EUROPE			-33.4666	-8.6782
REGION1	JAPAN			-5.5949	22.5664
REGION1	NORTH AMERICA			.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-7.3869	14.1635
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.
BASE				-0.6217	-0.5111

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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 3 hours (mg/dL) Parameter Code=MTIC180C Study Identifier=NN1218-4131

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	2	973	1.18	0.3062
REGION1	3	973	8.15	<.0001
BOLAD1	1	973	0.38	0.5373
BASE	1	973	404.46	<.0001

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) - NovoRapid (meal)	WORK.ENDPOINT_2	-2.9530	5.9841	973	-0.49	0.6218	0.05	-14.6963	8.7903

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (post) - NovoRapid (meal)	WORK.ENDPOINT_2	6.0821	6.0038	973	1.01	0.3113	0.05	-5.6999	17.8640

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 3 hours (mg/dL) Parameter Code=MTIC180C Study Identifier=NN1218-4131

The Mixed Procedure

Least Squares Means

Effect	Planned Treatment for Period 30 (N)	Margins	BASE	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	2	WORK.ENDPOINT_2	77.86	-1.2353	4.2083	973	-0.29	0.7692	0.05	-9.4936	7.0230
TRTPN	3	WORK.ENDPOINT_2	77.86	7.7998	4.2391	973	1.84	0.0661	0.05	-0.5190	16.1185
TRTPN	4	WORK.ENDPOINT_2	77.86	1.7177	4.2494	973	0.40	0.6861	0.05	-6.6214	10.0568

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 3 hours (mmol/L) Parameter Code=MTIC180 Study Identifier=NN1218-4131

The Mixed Procedure

Model Information

Data Set	WORK.ENDPOINT_2
Dependent Variable	CHG
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Dimensions

Covariance Parameters	1
Columns in X	10
Columns in Z	0
Subjects	1
Max Obs per Subject	981

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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 3 hours (mmol/L) Parameter Code=MTIC180 Study Identifier=NN1218-4131

The Mixed Procedure

Number of Observations

Number of Observations Read	981
Number of Observations Used	981
Number of Observations Not Used	0

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	17.9868

Fit Statistics

-2 Res Log Likelihood	5620.4
AIC (Smaller is Better)	5622.4
AICC (Smaller is Better)	5622.4
BIC (Smaller is Better)	5627.3

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			2	2.5039	0.3437	973
TRTPN			3	3.0053	0.3450	973

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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 3 hours (mmol/L) Parameter Code=MTIC180 Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			4	2.6678	0.3490	973
REGION1	ASIA (EXCLUDING JAPAN)			0.3319	0.4967	973
REGION1	EUROPE			-1.1694	0.3505	973
REGION1	JAPAN			0.4709	0.3982	973
REGION1	NORTH AMERICA			0	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.1880	0.3047	973
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0	.	.
BASE				-0.5664	0.02816	973

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
TRTPN			2	7.29	<.0001	0.05
TRTPN			3	8.71	<.0001	0.05
TRTPN			4	7.64	<.0001	0.05
REGION1	ASIA (EXCLUDING JAPAN)			0.67	0.5041	0.05
REGION1	EUROPE			-3.34	0.0009	0.05
REGION1	JAPAN			1.18	0.2372	0.05
REGION1	NORTH AMERICA			.	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.62	0.5373	0.05

Fast-acting insulin aspart
NN1218-4131

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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 3 hours (mmol/L) Parameter Code=MTIC180 Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
BOLAD1 BASE		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		-20.11	<.0001	0.05

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Lower	Upper
TRTPN			2	1.8295	3.1784
TRTPN			3	2.3284	3.6823
TRTPN			4	1.9829	3.3527
REGION1	ASIA (EXCLUDING JAPAN)			-0.6428	1.3066
REGION1	EUROPE			-1.8572	-0.4816
REGION1	JAPAN			-0.3105	1.2523
REGION1	NORTH AMERICA				
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.4099	0.7860
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY			
BASE				-0.6217	-0.5111

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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 3 hours (mmol/L) Parameter Code=MTIC180 Study Identifier=NN1218-4131

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	2	973	1.18	0.3062
REGION1	3	973	8.15	<.0001
BOLAD1	1	973	0.38	0.5373
BASE	1	973	404.46	<.0001

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) - NovoRapid (meal)	WORK.ENDPOINT_2	-0.1639	0.3321	973	-0.49	0.6218	0.05	-0.8156	0.4878

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (post) - NovoRapid (meal)	WORK.ENDPOINT_2	0.3375	0.3332	973	1.01	0.3113	0.05	-0.3163	0.9913

Fast-acting insulin aspart
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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 3 hours (mmol/L) Parameter Code=MTIC180 Study Identifier=NN1218-4131

The Mixed Procedure

Least Squares Means

Effect	Planned Treatment for Period 30 (N)	Margins	BASE	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	2	WORK.ENDPOINT_2	4.32	-0.06855	0.2335	973	-0.29	0.7692	0.05	-0.5268	0.3897
TRTPN	3	WORK.ENDPOINT_2	4.32	0.4328	0.2352	973	1.84	0.0661	0.05	-0.02880	0.8945
TRTPN	4	WORK.ENDPOINT_2	4.32	0.09532	0.2358	973	0.40	0.6861	0.05	-0.3674	0.5581

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 30 min (mg/dL) Parameter Code=MTIC30C Study Identifier=NN1218-4131

The Mixed Procedure

Model Information

Data Set	WORK.ENDPOINT_2
Dependent Variable	CHG
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Dimensions

Covariance Parameters	1
Columns in X	10
Columns in Z	0
Subjects	1
Max Obs per Subject	988

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 30 min (mg/dL) Parameter Code=MTIC30C Study Identifier=NN1218-4131

The Mixed Procedure

Number of Observations

Number of Observations Read	988
Number of Observations Used	988
Number of Observations Not Used	0

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	1365.04

Fit Statistics

-2 Res Log Likelihood	9907.6
AIC (Smaller is Better)	9909.6
AICC (Smaller is Better)	9909.6
BIC (Smaller is Better)	9914.4

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			2	32.9604	3.3229	980
TRTPN			3	58.9969	3.3225	980

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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 30 min (mg/dL) Parameter Code=MTIC30C Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			4	42.2894	3.4093	980
REGION1	ASIA (EXCLUDING JAPAN)			1.0319	4.2800	980
REGION1	EUROPE			-2.5984	3.0295	980
REGION1	JAPAN			8.0719	3.4171	980
REGION1	NORTH AMERICA			0	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-3.0884	2.6419	980
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0	.	.
BASE				-0.6799	0.02912	980

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
TRTPN			2	9.92	<.0001	0.05
TRTPN			3	17.76	<.0001	0.05
TRTPN			4	12.40	<.0001	0.05
REGION1	ASIA (EXCLUDING JAPAN)			0.24	0.8095	0.05
REGION1	EUROPE			-0.86	0.3913	0.05
REGION1	JAPAN			2.36	0.0184	0.05
REGION1	NORTH AMERICA			.	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-1.17	0.2427	0.05

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 30 min (mg/dL) Parameter Code=MTIC30C Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
BOLAD1 BASE		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		-23.35	<.0001	0.05

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Lower	Upper
TRTPN			2	26.4396	39.4812
TRTPN			3	52.4769	65.5169
TRTPN			4	35.5991	48.9798
REGION1	ASIA (EXCLUDING JAPAN)			-7.3671	9.4308
REGION1	EUROPE			-8.5435	3.3468
REGION1	JAPAN			1.3663	14.7776
REGION1	NORTH AMERICA			.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-8.2728	2.0960
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.
BASE				-0.7370	-0.6228

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 30 min (mg/dL) Parameter Code=MTIC30C Study Identifier=NN1218-4131

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	2	980	41.98	<.0001
REGION1	3	980	3.83	0.0097
BOLAD1	1	980	1.37	0.2427
BASE	1	980	545.24	<.0001

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) - NovoRapid (meal)	WORK.ENDPOINT_2	-9.3290	2.8860	980	-3.23	0.0013	0.05	-14.9925	-3.6656

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (post) - NovoRapid (meal)	WORK.ENDPOINT_2	16.7074	2.8913	980	5.78	<.0001	0.05	11.0336	22.3813

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 30 min (mg/dL) Parameter Code=MTIC30C Study Identifier=NN1218-4131

The Mixed Procedure

Least Squares Means

Effect	Planned Treatment for Period 30 (N)	Margins	BASE	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	2	WORK.ENDPOINT_2	62.71	-10.2735	2.0302	980	-5.06	<.0001	0.05	-14.2576	-6.2895
TRTPN	3	WORK.ENDPOINT_2	62.71	15.7629	2.0368	980	7.74	<.0001	0.05	11.7659	19.7600
TRTPN	4	WORK.ENDPOINT_2	62.71	-0.9445	2.0490	980	-0.46	0.6449	0.05	-4.9654	3.0764

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 30 min (mmol/L) Parameter Code=MTIC30 Study Identifier=NN1218-4131

The Mixed Procedure

Model Information

Data Set	WORK.ENDPOINT_2
Dependent Variable	CHG
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Dimensions

Covariance Parameters	1
Columns in X	10
Columns in Z	0
Subjects	1
Max Obs per Subject	988

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 30 min (mmol/L) Parameter Code=MTIC30 Study Identifier=NN1218-4131

The Mixed Procedure

Number of Observations	
Number of Observations Read	988
Number of Observations Used	988
Number of Observations Not Used	0

Covariance Parameter
Estimates

Cov Parm	Estimate
Residual	4.2037

Fit Statistics	
-2 Res Log Likelihood	4234.5
AIC (Smaller is Better)	4236.5
AICC (Smaller is Better)	4236.5
BIC (Smaller is Better)	4241.4

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			2	1.8291	0.1844	980
TRTPN			3	3.2740	0.1844	980

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 30 min (mmol/L) Parameter Code=MTIC30 Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			4	2.3468	0.1892	980
REGION1	ASIA (EXCLUDING JAPAN)			0.05726	0.2375	980
REGION1	EUROPE			-0.1442	0.1681	980
REGION1	JAPAN			0.4479	0.1896	980
REGION1	NORTH AMERICA			0	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.1714	0.1466	980
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0	.	.
BASE				-0.6799	0.02912	980

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
TRTPN			2	9.92	<.0001	0.05
TRTPN			3	17.76	<.0001	0.05
TRTPN			4	12.40	<.0001	0.05
REGION1	ASIA (EXCLUDING JAPAN)			0.24	0.8095	0.05
REGION1	EUROPE			-0.86	0.3913	0.05
REGION1	JAPAN			2.36	0.0184	0.05
REGION1	NORTH AMERICA			.	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-1.17	0.2427	0.05

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 30 min (mmol/L) Parameter Code=MTIC30 Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
BOLAD1 BASE		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		-23.35	<.0001	0.05

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Lower	Upper
TRTPN			2	1.4672	2.1910
TRTPN			3	2.9121	3.6358
TRTPN			4	1.9755	2.7181
REGION1	ASIA (EXCLUDING JAPAN)			-0.4088	0.5234
REGION1	EUROPE			-0.4741	0.1857
REGION1	JAPAN			0.07582	0.8201
REGION1	NORTH AMERICA				
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.4591	0.1163
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY			
BASE				-0.7370	-0.6228

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 30 min (mmol/L) Parameter Code=MTIC30 Study Identifier=NN1218-4131

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	2	980	41.98	<.0001
REGION1	3	980	3.83	0.0097
BOLAD1	1	980	1.37	0.2427
BASE	1	980	545.24	<.0001

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) - NovoRapid (meal)	WORK.ENDPOINT_2	-0.5177	0.1602	980	-3.23	0.0013	0.05	-0.8320	-0.2034

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (post) - NovoRapid (meal)	WORK.ENDPOINT_2	0.9272	0.1604	980	5.78	<.0001	0.05	0.6123	1.2420

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 30 min (mmol/L) Parameter Code=MTIC30 Study Identifier=NN1218-4131

The Mixed Procedure

Least Squares Means

Effect	Planned Treatment for Period 30 (N)	Margins	BASE	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	2	WORK.ENDPOINT_2	3.48	-0.5701	0.1127	980	-5.06	<.0001	0.05	-0.7912	-0.3490
TRTPN	3	WORK.ENDPOINT_2	3.48	0.8747	0.1130	980	7.74	<.0001	0.05	0.6529	1.0966
TRTPN	4	WORK.ENDPOINT_2	3.48	-0.05241	0.1137	980	-0.46	0.6449	0.05	-0.2755	0.1707

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 4 hours (mg/dL) Parameter Code=MTIC240C Study Identifier=NN1218-4131

The Mixed Procedure

Model Information

Data Set	WORK.ENDPOINT_2
Dependent Variable	CHG
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Dimensions

Covariance Parameters	1
Columns in X	10
Columns in Z	0
Subjects	1
Max Obs per Subject	981

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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 4 hours (mg/dL) Parameter Code=MTIC240C Study Identifier=NN1218-4131

The Mixed Procedure

Number of Observations

Number of Observations Read	981
Number of Observations Used	981
Number of Observations Not Used	0

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	4838.61

Fit Statistics

-2 Res Log Likelihood	11069.7
AIC (Smaller is Better)	11071.7
AICC (Smaller is Better)	11071.7
BIC (Smaller is Better)	11076.6

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			2	24.0690	5.4531	973
TRTPN			3	32.2472	5.4805	973

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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 4 hours (mg/dL) Parameter Code=MTIC240C Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			4	26.6625	5.5335	973
REGION1	ASIA (EXCLUDING JAPAN)			12.0393	8.1924	973
REGION1	EUROPE			-14.8815	5.7238	973
REGION1	JAPAN			6.4205	6.5144	973
REGION1	NORTH AMERICA			0	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		2.8729	4.9882	973
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0	.	.
BASE				-0.5307	0.02817	973

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
TRTPN			2	4.41	<.0001	0.05
TRTPN			3	5.88	<.0001	0.05
TRTPN			4	4.82	<.0001	0.05
REGION1	ASIA (EXCLUDING JAPAN)			1.47	0.1420	0.05
REGION1	EUROPE			-2.60	0.0095	0.05
REGION1	JAPAN			0.99	0.3246	0.05
REGION1	NORTH AMERICA			.	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.58	0.5648	0.05

Fast-acting insulin aspart
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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 4 hours (mg/dL) Parameter Code=MTIC240C Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
BOLAD1 BASE		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		-18.84	<.0001	0.05

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Lower	Upper
TRTPN			2	13.3679	34.7702
TRTPN			3	21.4922	43.0022
TRTPN			4	15.8034	37.5215
REGION1	ASIA (EXCLUDING JAPAN)			-4.0375	28.1161
REGION1	EUROPE			-26.1138	-3.6491
REGION1	JAPAN			-6.3635	19.2045
REGION1	NORTH AMERICA				
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-6.9161	12.6618
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY			
BASE				-0.5860	-0.4755

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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 4 hours (mg/dL) Parameter Code=MTIC240C Study Identifier=NN1218-4131

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	2	973	1.18	0.3083
REGION1	3	973	6.27	0.0003
BOLAD1	1	973	0.33	0.5648
BASE	1	973	355.08	<.0001

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) - NovoRapid (meal)	WORK.ENDPOINT_2	-2.5934	5.4475	973	-0.48	0.6341	0.05	-13.2836	8.0968

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (post) - NovoRapid (meal)	WORK.ENDPOINT_2	5.5847	5.4547	973	1.02	0.3062	0.05	-5.1195	16.2890

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 4 hours (mg/dL) Parameter Code=MTIC240C Study Identifier=NN1218-4131

The Mixed Procedure

Least Squares Means

Effect	Planned Treatment for Period 30 (N)	Margins	BASE	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	2	WORK.ENDPOINT_2	45.92	-0.5121	3.8399	973	-0.13	0.8939	0.05	-8.0475	7.0232
TRTPN	3	WORK.ENDPOINT_2	45.92	7.6661	3.8511	973	1.99	0.0468	0.05	0.1087	15.2234
TRTPN	4	WORK.ENDPOINT_2	45.92	2.0813	3.8610	973	0.54	0.5900	0.05	-5.4956	9.6582

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 4 hours (mmol/L) Parameter Code=MTIC240 Study Identifier=NN1218-4131

The Mixed Procedure

Model Information

Data Set	WORK.ENDPOINT_2
Dependent Variable	CHG
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Dimensions

Covariance Parameters	1
Columns in X	10
Columns in Z	0
Subjects	1
Max Obs per Subject	981

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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 4 hours (mmol/L) Parameter Code=MTIC240 Study Identifier=NN1218-4131

The Mixed Procedure

Number of Observations

Number of Observations Read	981
Number of Observations Used	981
Number of Observations Not Used	0

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	14.9009

Fit Statistics

-2 Res Log Likelihood	5437.1
AIC (Smaller is Better)	5439.1
AICC (Smaller is Better)	5439.1
BIC (Smaller is Better)	5444.0

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			2	1.3357	0.3026	973
TRTPN			3	1.7895	0.3041	973

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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 4 hours (mmol/L) Parameter Code=MTIC240 Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			4	1.4796	0.3071	973
REGION1	ASIA (EXCLUDING JAPAN)			0.6681	0.4546	973
REGION1	EUROPE			-0.8258	0.3176	973
REGION1	JAPAN			0.3563	0.3615	973
REGION1	NORTH AMERICA			0	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.1594	0.2768	973
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0	.	.
BASE				-0.5307	0.02817	973

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
TRTPN			2	4.41	<.0001	0.05
TRTPN			3	5.88	<.0001	0.05
TRTPN			4	4.82	<.0001	0.05
REGION1	ASIA (EXCLUDING JAPAN)			1.47	0.1420	0.05
REGION1	EUROPE			-2.60	0.0095	0.05
REGION1	JAPAN			0.99	0.3246	0.05
REGION1	NORTH AMERICA			.	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.58	0.5648	0.05

Fast-acting insulin aspart
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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 4 hours (mmol/L) Parameter Code=MTIC240 Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
BOLAD1 BASE		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		-18.84	<.0001	0.05

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Lower	Upper
TRTPN			2	0.7418	1.9295
TRTPN			3	1.1927	2.3864
TRTPN			4	0.8770	2.0822
REGION1	ASIA (EXCLUDING JAPAN)			-0.2241	1.5603
REGION1	EUROPE			-1.4492	-0.2025
REGION1	JAPAN			-0.3531	1.0657
REGION1	NORTH AMERICA			.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.3838	0.7027
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.
BASE				-0.5860	-0.4755

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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 4 hours (mmol/L) Parameter Code=MTIC240 Study Identifier=NN1218-4131

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	2	973	1.18	0.3083
REGION1	3	973	6.27	0.0003
BOLAD1	1	973	0.33	0.5648
BASE	1	973	355.08	<.0001

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) - NovoRapid (meal)	WORK.ENDPOINT_2	-0.1439	0.3023	973	-0.48	0.6341	0.05	-0.7372	0.4493

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (post) - NovoRapid (meal)	WORK.ENDPOINT_2	0.3099	0.3027	973	1.02	0.3062	0.05	-0.2841	0.9039

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NN1218-4131

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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter=PPG inc. at 4 hours (mmol/L) Parameter Code=MTIC240 Study Identifier=NN1218-4131

The Mixed Procedure

Least Squares Means

Effect	Planned Treatment for Period 30 (N)	Margins	BASE	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	2	WORK.ENDPOINT_2	2.55	-0.02842	0.2131	973	-0.13	0.8939	0.05	-0.4466	0.3897
TRTPN	3	WORK.ENDPOINT_2	2.55	0.4254	0.2137	973	1.99	0.0468	0.05	0.006031	0.8448
TRTPN	4	WORK.ENDPOINT_2	2.55	0.1155	0.2143	973	0.54	0.5900	0.05	-0.3050	0.5360

13: Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 1 hour (mg/dL) Parameter Code=MTIC60C Study Identifier=NN1218-4131

The Mixed Procedure

Model Information

Data Set	WORK.ENDPOINT_2
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Dimensions

Covariance Parameters	1
Columns in X	10
Columns in Z	0
Subjects	1
Max Obs per Subject	985

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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 1 hour (mg/dL) Parameter Code=MTIC60C Study Identifier=NN1218-4131

The Mixed Procedure

Number of Observations

Number of Observations Read	985
Number of Observations Used	985
Number of Observations Not Used	0

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	2853.85

Fit Statistics

-2 Res Log Likelihood	10598.8
AIC (Smaller is Better)	10600.8
AICC (Smaller is Better)	10600.8
BIC (Smaller is Better)	10605.7

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			2	47.4120	4.8000	977
TRTPN			3	81.3962	4.7235	977

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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 1 hour (mg/dL) Parameter Code=MTIC60C Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			4	63.1434	4.8547	977
REGION1	ASIA (EXCLUDING JAPAN)			-1.6784	6.2013	977
REGION1	EUROPE			-13.2512	4.3915	977
REGION1	JAPAN			2.4576	4.9300	977
REGION1	NORTH AMERICA			0	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.5631	3.8288	977
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0	.	.
BASE				0.3297	0.02700	977

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
TRTPN			2	9.88	<.0001	0.05
TRTPN			3	17.23	<.0001	0.05
TRTPN			4	13.01	<.0001	0.05
REGION1	ASIA (EXCLUDING JAPAN)			-0.27	0.7867	0.05
REGION1	EUROPE			-3.02	0.0026	0.05
REGION1	JAPAN			0.50	0.6182	0.05
REGION1	NORTH AMERICA			.	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.15	0.8831	0.05

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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 1 hour (mg/dL) Parameter Code=MTIC60C Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
BOLAD1 BASE		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		12.21	<.0001	0.05

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Lower	Upper
TRTPN			2	37.9926	56.8314
TRTPN			3	72.1267	90.6656
TRTPN			4	53.6167	72.6702
REGION1	ASIA (EXCLUDING JAPAN)			-13.8478	10.4911
REGION1	EUROPE			-21.8691	-4.6333
REGION1	JAPAN			-7.2169	12.1322
REGION1	NORTH AMERICA				
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-6.9506	8.0767
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY			
BASE				0.2767	0.3827

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 1 hour (mg/dL) Parameter Code=MTIC60C Study Identifier=NN1218-4131

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	2	977	33.35	<.0001
REGION1	3	977	5.06	0.0018
BOLAD1	1	977	0.02	0.8831
BASE	1	977	149.07	<.0001

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) - NovoRapid (meal)	WORK.ENDPOINT_2	-15.7315	4.1849	977	-3.76	0.0002	0.05	-23.9440	-7.5189

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (post) - NovoRapid (meal)	WORK.ENDPOINT_2	18.2527	4.1870	977	4.36	<.0001	0.05	10.0361	26.4693

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 1 hour (mg/dL) Parameter Code=MTIC60C Study Identifier=NN1218-4131

The Mixed Procedure

Least Squares Means

Effect	Planned Treatment for Period 30 (N)	Margins	BASE	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	2	WORK.ENDPOINT_2	92.31	74.0738	2.9408	977	25.19	<.0001	0.05	68.3027	79.8448
TRTPN	3	WORK.ENDPOINT_2	92.31	108.06	2.9418	977	36.73	<.0001	0.05	102.29	113.83
TRTPN	4	WORK.ENDPOINT_2	92.31	89.8052	2.9755	977	30.18	<.0001	0.05	83.9662	95.6443

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 1 hour (mmol/L) Parameter Code=MTIC60 Study Identifier=NN1218-4131

The Mixed Procedure

Model Information

Data Set	WORK.ENDPOINT_2
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Dimensions

Covariance Parameters	1
Columns in X	10
Columns in Z	0
Subjects	1
Max Obs per Subject	985

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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 1 hour (mmol/L) Parameter Code=MTIC60 Study Identifier=NN1218-4131

The Mixed Procedure

Number of Observations

Number of Observations Read	985
Number of Observations Used	985
Number of Observations Not Used	0

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	8.7886

Fit Statistics

-2 Res Log Likelihood	4943.0
AIC (Smaller is Better)	4945.0
AICC (Smaller is Better)	4945.0
BIC (Smaller is Better)	4949.9

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			2	2.6311	0.2664	977
TRTPN			3	4.5170	0.2621	977

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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 1 hour (mmol/L) Parameter Code=MTIC60 Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			4	3.5041	0.2694	977
REGION1	ASIA (EXCLUDING JAPAN)			-0.09314	0.3441	977
REGION1	EUROPE			-0.7354	0.2437	977
REGION1	JAPAN			0.1364	0.2736	977
REGION1	NORTH AMERICA			0	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.03125	0.2125	977
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0	.	.
BASE				0.3297	0.02700	977

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
TRTPN			2	9.88	<.0001	0.05
TRTPN			3	17.23	<.0001	0.05
TRTPN			4	13.01	<.0001	0.05
REGION1	ASIA (EXCLUDING JAPAN)			-0.27	0.7867	0.05
REGION1	EUROPE			-3.02	0.0026	0.05
REGION1	JAPAN			0.50	0.6182	0.05
REGION1	NORTH AMERICA			.	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.15	0.8831	0.05

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 1 hour (mmol/L) Parameter Code=MTIC60 Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
BOLAD1 BASE		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		12.21	<.0001	0.05

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Lower	Upper
TRTPN			2	2.1084	3.1538
TRTPN			3	4.0026	5.0314
TRTPN			4	2.9754	4.0328
REGION1	ASIA (EXCLUDING JAPAN)			-0.7685	0.5822
REGION1	EUROPE			-1.2136	-0.2571
REGION1	JAPAN			-0.4005	0.6733
REGION1	NORTH AMERICA			.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.3857	0.4482
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.
BASE				0.2767	0.3827

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 1 hour (mmol/L) Parameter Code=MTIC60 Study Identifier=NN1218-4131

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	2	977	33.35	<.0001
REGION1	3	977	5.06	0.0018
BOLAD1	1	977	0.02	0.8831
BASE	1	977	149.07	<.0001

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) - NovoRapid (meal)	WORK.ENDPOINT_2	-0.8730	0.2322	977	-3.76	0.0002	0.05	-1.3287	-0.4173

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (post) - NovoRapid (meal)	WORK.ENDPOINT_2	1.0129	0.2324	977	4.36	<.0001	0.05	0.5569	1.4689

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 1 hour (mmol/L) Parameter Code=MTIC60 Study Identifier=NN1218-4131

The Mixed Procedure

Least Squares Means

Effect	Planned Treatment for Period 30 (N)	Margins	BASE	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	2	WORK.ENDPOINT_2	5.12	4.1106	0.1632	977	25.19	<.0001	0.05	3.7904	4.4309
TRTPN	3	WORK.ENDPOINT_2	5.12	5.9966	0.1633	977	36.73	<.0001	0.05	5.6762	6.3169
TRTPN	4	WORK.ENDPOINT_2	5.12	4.9836	0.1651	977	30.18	<.0001	0.05	4.6596	5.3077

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 2 hours (mg/dL) Parameter Code=MTIC120C Study Identifier=NN1218-4131

The Mixed Procedure

Model Information

Data Set	WORK.ENDPOINT_2
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Dimensions

Covariance Parameters	1
Columns in X	10
Columns in Z	0
Subjects	1
Max Obs per Subject	977

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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 2 hours (mg/dL) Parameter Code=MTIC120C Study Identifier=NN1218-4131

The Mixed Procedure

Number of Observations

Number of Observations Read	977
Number of Observations Used	977
Number of Observations Not Used	0

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	5292.52

Fit Statistics

-2 Res Log Likelihood	11111.4
AIC (Smaller is Better)	11113.4
AICC (Smaller is Better)	11113.4
BIC (Smaller is Better)	11118.3

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			2	59.5782	6.2774	969
TRTPN			3	70.3046	6.1984	969

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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 2 hours (mg/dL) Parameter Code=MTIC120C Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			4	65.2551	6.3401	969
REGION1	ASIA (EXCLUDING JAPAN)			-4.7139	8.4977	969
REGION1	EUROPE			-19.9727	6.0271	969
REGION1	JAPAN			4.3285	6.7732	969
REGION1	NORTH AMERICA			0	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		4.6226	5.2444	969
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0	.	.
BASE				0.3860	0.02767	969

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
TRTPN			2	9.49	<.0001	0.05
TRTPN			3	11.34	<.0001	0.05
TRTPN			4	10.29	<.0001	0.05
REGION1	ASIA (EXCLUDING JAPAN)			-0.55	0.5792	0.05
REGION1	EUROPE			-3.31	0.0010	0.05
REGION1	JAPAN			0.64	0.5229	0.05
REGION1	NORTH AMERICA			.	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.88	0.3783	0.05

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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 2 hours (mg/dL) Parameter Code=MTIC120C Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
BOLAD1 BASE		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		13.95	<.0001	0.05

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Lower	Upper
TRTPN			2	47.2592	71.8971
TRTPN			3	58.1406	82.4685
TRTPN			4	52.8133	77.6970
REGION1	ASIA (EXCLUDING JAPAN)			-21.3899	11.9622
REGION1	EUROPE			-31.8003	-8.1450
REGION1	JAPAN			-8.9633	17.6202
REGION1	NORTH AMERICA				
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-5.6690	14.9142
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY			
BASE				0.3317	0.4403

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 2 hours (mg/dL) Parameter Code=MTIC120C Study Identifier=NN1218-4131

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	2	969	1.78	0.1695
REGION1	3	969	6.18	0.0004
BOLAD1	1	969	0.78	0.3783
BASE	1	969	194.59	<.0001

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) - NovoRapid (meal)	WORK.ENDPOINT_2	-5.6770	5.7306	969	-0.99	0.3221	0.05	-16.9228	5.5688

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (post) - NovoRapid (meal)	WORK.ENDPOINT_2	5.0494	5.7170	969	0.88	0.3773	0.05	-6.1698	16.2686

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 2 hours (mg/dL) Parameter Code=MTIC120C Study Identifier=NN1218-4131

The Mixed Procedure

Least Squares Means

Effect	Planned Treatment for Period 30 (N)	Margins	BASE	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	2	WORK.ENDPOINT_2	101.45	95.1068	4.0293	969	23.60	<.0001	0.05	87.1996	103.01
TRTPN	3	WORK.ENDPOINT_2	101.45	105.83	4.0106	969	26.39	<.0001	0.05	97.9627	113.70
TRTPN	4	WORK.ENDPOINT_2	101.45	100.78	4.0707	969	24.76	<.0001	0.05	92.7953	108.77

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 2 hours (mmol/L) Parameter Code=MTIC120 Study Identifier=NN1218-4131

The Mixed Procedure

Model Information

Data Set	WORK.ENDPOINT_2
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Dimensions

Covariance Parameters	1
Columns in X	10
Columns in Z	0
Subjects	1
Max Obs per Subject	977

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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 2 hours (mmol/L) Parameter Code=MTIC120 Study Identifier=NN1218-4131

The Mixed Procedure

Number of Observations

Number of Observations Read	977
Number of Observations Used	977
Number of Observations Not Used	0

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	16.2987

Fit Statistics

-2 Res Log Likelihood	5501.9
AIC (Smaller is Better)	5503.9
AICC (Smaller is Better)	5503.9
BIC (Smaller is Better)	5508.8

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			2	3.3062	0.3484	969
TRTPN			3	3.9015	0.3440	969

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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 2 hours (mmol/L) Parameter Code=MTIC120 Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			4	3.6213	0.3518	969
REGION1	ASIA (EXCLUDING JAPAN)			-0.2616	0.4716	969
REGION1	EUROPE			-1.1084	0.3345	969
REGION1	JAPAN			0.2402	0.3759	969
REGION1	NORTH AMERICA			0	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.2565	0.2910	969
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0	.	.
BASE				0.3860	0.02767	969

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
TRTPN			2	9.49	<.0001	0.05
TRTPN			3	11.34	<.0001	0.05
TRTPN			4	10.29	<.0001	0.05
REGION1	ASIA (EXCLUDING JAPAN)			-0.55	0.5792	0.05
REGION1	EUROPE			-3.31	0.0010	0.05
REGION1	JAPAN			0.64	0.5229	0.05
REGION1	NORTH AMERICA			.	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.88	0.3783	0.05

Fast-acting insulin aspart
NN1218-4131

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Novo Nordisk

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 2 hours (mmol/L) Parameter Code=MTIC120 Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
BOLAD1 BASE		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		13.95	<.0001	0.05

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Lower	Upper
TRTPN			2	2.6226	3.9899
TRTPN			3	3.2264	4.5765
TRTPN			4	2.9308	4.3117
REGION1	ASIA (EXCLUDING JAPAN)			-1.1870	0.6638
REGION1	EUROPE			-1.7647	-0.4520
REGION1	JAPAN			-0.4974	0.9778
REGION1	NORTH AMERICA			.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.3146	0.8276
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.
BASE				0.3317	0.4403

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 2 hours (mmol/L) Parameter Code=MTIC120 Study Identifier=NN1218-4131

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	2	969	1.78	0.1695
REGION1	3	969	6.18	0.0004
BOLAD1	1	969	0.78	0.3783
BASE	1	969	194.59	<.0001

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) - NovoRapid (meal)	WORK.ENDPOINT_2	-0.3150	0.3180	969	-0.99	0.3221	0.05	-0.9391	0.3090

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (post) - NovoRapid (meal)	WORK.ENDPOINT_2	0.2802	0.3173	969	0.88	0.3773	0.05	-0.3424	0.9028

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 2 hours (mmol/L) Parameter Code=MTIC120 Study Identifier=NN1218-4131

The Mixed Procedure

Least Squares Means

Effect	Planned Treatment for Period 30 (N)	Margins	BASE	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	2	WORK.ENDPOINT_2	5.63	5.2778	0.2236	969	23.60	<.0001	0.05	4.8390	5.7166
TRTPN	3	WORK.ENDPOINT_2	5.63	5.8731	0.2226	969	26.39	<.0001	0.05	5.4363	6.3099
TRTPN	4	WORK.ENDPOINT_2	5.63	5.5929	0.2259	969	24.76	<.0001	0.05	5.1496	6.0362

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 3 hours (mg/dL) Parameter Code=MTIC180C Study Identifier=NN1218-4131

The Mixed Procedure

Model Information

Data Set	WORK.ENDPOINT_2
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Dimensions

Covariance Parameters	1
Columns in X	10
Columns in Z	0
Subjects	1
Max Obs per Subject	976

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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 3 hours (mg/dL) Parameter Code=MTIC180C Study Identifier=NN1218-4131

The Mixed Procedure

Number of Observations

Number of Observations Read	976
Number of Observations Used	976
Number of Observations Not Used	0

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	5828.86

Fit Statistics

-2 Res Log Likelihood	11193.5
AIC (Smaller is Better)	11195.5
AICC (Smaller is Better)	11195.5
BIC (Smaller is Better)	11200.4

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			2	45.4409	6.2156	968
TRTPN			3	54.0264	6.2251	968

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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 3 hours (mg/dL) Parameter Code=MTIC180C Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			4	47.5543	6.3256	968
REGION1	ASIA (EXCLUDING JAPAN)			6.8049	8.9610	968
REGION1	EUROPE			-20.7914	6.3351	968
REGION1	JAPAN			8.3852	7.1861	968
REGION1	NORTH AMERICA			0	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		2.3357	5.5044	968
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0	.	.
BASE				0.4373	0.02829	968

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
TRTPN			2	7.31	<.0001	0.05
TRTPN			3	8.68	<.0001	0.05
TRTPN			4	7.52	<.0001	0.05
REGION1	ASIA (EXCLUDING JAPAN)			0.76	0.4478	0.05
REGION1	EUROPE			-3.28	0.0011	0.05
REGION1	JAPAN			1.17	0.2436	0.05
REGION1	NORTH AMERICA			.	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.42	0.6714	0.05

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 3 hours (mg/dL) Parameter Code=MTIC180C Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
BOLAD1 BASE		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		15.46	<.0001	0.05

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Lower	Upper
TRTPN			2	33.2433	57.6385
TRTPN			3	41.8103	66.2426
TRTPN			4	35.1409	59.9677
REGION1	ASIA (EXCLUDING JAPAN)			-10.7802	24.3901
REGION1	EUROPE			-33.2235	-8.3593
REGION1	JAPAN			-5.7169	22.4873
REGION1	NORTH AMERICA			.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-8.4662	13.1375
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.
BASE				0.3817	0.4928

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 3 hours (mg/dL) Parameter Code=MTIC180C Study Identifier=NN1218-4131

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	2	968	1.11	0.3284
REGION1	3	968	8.04	<.0001
BOLAD1	1	968	0.18	0.6714
BASE	1	968	238.96	<.0001

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) - NovoRapid (meal)	WORK.ENDPOINT_2	-2.1134	5.9970	968	-0.35	0.7246	0.05	-13.8820	9.6552

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (post) - NovoRapid (meal)	WORK.ENDPOINT_2	6.4722	6.0165	968	1.08	0.2823	0.05	-5.3347	18.2791

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 3 hours (mg/dL) Parameter Code=MTIC180C Study Identifier=NN1218-4131

The Mixed Procedure

Least Squares Means

Effect	Planned Treatment for Period 30 (N)	Margins	BASE	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	2	WORK.ENDPOINT_2	78.32	76.9858	4.2103	968	18.29	<.0001	0.05	68.7235	85.2481
TRTPN	3	WORK.ENDPOINT_2	78.32	85.5714	4.2411	968	20.18	<.0001	0.05	77.2486	93.8942
TRTPN	4	WORK.ENDPOINT_2	78.32	79.0992	4.2652	968	18.55	<.0001	0.05	70.7291	87.4693

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 3 hours (mmol/L) Parameter Code=MTIC180 Study Identifier=NN1218-4131

The Mixed Procedure

Model Information

Data Set	WORK.ENDPOINT_2
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Dimensions

Covariance Parameters	1
Columns in X	10
Columns in Z	0
Subjects	1
Max Obs per Subject	976

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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 3 hours (mmol/L) Parameter Code=MTIC180 Study Identifier=NN1218-4131

The Mixed Procedure

Number of Observations

Number of Observations Read	976
Number of Observations Used	976
Number of Observations Not Used	0

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	17.9504

Fit Statistics

-2 Res Log Likelihood	5589.8
AIC (Smaller is Better)	5591.8
AICC (Smaller is Better)	5591.8
BIC (Smaller is Better)	5596.7

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			2	2.5217	0.3449	968
TRTPN			3	2.9981	0.3455	968

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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 3 hours (mmol/L) Parameter Code=MTIC180 Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			4	2.6390	0.3510	968
REGION1	ASIA (EXCLUDING JAPAN)			0.3776	0.4973	968
REGION1	EUROPE			-1.1538	0.3516	968
REGION1	JAPAN			0.4653	0.3988	968
REGION1	NORTH AMERICA			0	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.1296	0.3055	968
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0	.	.
BASE				0.4373	0.02829	968

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
TRTPN			2	7.31	<.0001	0.05
TRTPN			3	8.68	<.0001	0.05
TRTPN			4	7.52	<.0001	0.05
REGION1	ASIA (EXCLUDING JAPAN)			0.76	0.4478	0.05
REGION1	EUROPE			-3.28	0.0011	0.05
REGION1	JAPAN			1.17	0.2436	0.05
REGION1	NORTH AMERICA			.	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.42	0.6714	0.05

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 3 hours (mmol/L) Parameter Code=MTIC180 Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
BOLAD1 BASE		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		15.46	<.0001	0.05

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Lower	Upper
TRTPN			2	1.8448	3.1986
TRTPN			3	2.3202	3.6761
TRTPN			4	1.9501	3.3278
REGION1	ASIA (EXCLUDING JAPAN)			-0.5982	1.3535
REGION1	EUROPE			-1.8437	-0.4639
REGION1	JAPAN			-0.3173	1.2479
REGION1	NORTH AMERICA				
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.4698	0.7291
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY			
BASE				0.3817	0.4928

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 3 hours (mmol/L) Parameter Code=MTIC180 Study Identifier=NN1218-4131

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	2	968	1.11	0.3284
REGION1	3	968	8.04	<.0001
BOLAD1	1	968	0.18	0.6714
BASE	1	968	238.96	<.0001

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) - NovoRapid (meal)	WORK.ENDPOINT_2	-0.1173	0.3328	968	-0.35	0.7246	0.05	-0.7704	0.5358

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (post) - NovoRapid (meal)	WORK.ENDPOINT_2	0.3592	0.3339	968	1.08	0.2823	0.05	-0.2960	1.0144

Fast-acting insulin aspart
NN1218-4131

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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 3 hours (mmol/L) Parameter Code=MTIC180 Study Identifier=NN1218-4131

The Mixed Procedure

Least Squares Means

Effect	Planned Treatment for Period 30 (N)	Margins	BASE	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	2	WORK.ENDPOINT_2	4.35	4.2722	0.2336	968	18.29	<.0001	0.05	3.8137	4.7307
TRTPN	3	WORK.ENDPOINT_2	4.35	4.7487	0.2354	968	20.18	<.0001	0.05	4.2868	5.2106
TRTPN	4	WORK.ENDPOINT_2	4.35	4.3895	0.2367	968	18.55	<.0001	0.05	3.9250	4.8540

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 30 min (mg/dL) Parameter Code=MTIC30C Study Identifier=NN1218-4131

The Mixed Procedure

Model Information

Data Set	WORK.ENDPOINT_2
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Dimensions

Covariance Parameters	1
Columns in X	10
Columns in Z	0
Subjects	1
Max Obs per Subject	983

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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 30 min (mg/dL) Parameter Code=MTIC30C Study Identifier=NN1218-4131

The Mixed Procedure

Number of Observations

Number of Observations Read	983
Number of Observations Used	983
Number of Observations Not Used	0

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	1367.17

Fit Statistics

-2 Res Log Likelihood	9858.7
AIC (Smaller is Better)	9860.7
AICC (Smaller is Better)	9860.7
BIC (Smaller is Better)	9865.6

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			2	32.7669	3.3527	975
TRTPN			3	58.6289	3.3425	975

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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 30 min (mg/dL) Parameter Code=MTIC30C Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			4	41.7441	3.4489	975
REGION1	ASIA (EXCLUDING JAPAN)			1.4110	4.2953	975
REGION1	EUROPE			-2.3106	3.0432	975
REGION1	JAPAN			8.4774	3.4288	975
REGION1	NORTH AMERICA			0	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-3.2718	2.6526	975
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0	.	.
BASE				0.3232	0.02942	975

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
TRTPN			2	9.77	<.0001	0.05
TRTPN			3	17.54	<.0001	0.05
TRTPN			4	12.10	<.0001	0.05
REGION1	ASIA (EXCLUDING JAPAN)			0.33	0.7426	0.05
REGION1	EUROPE			-0.76	0.4479	0.05
REGION1	JAPAN			2.47	0.0136	0.05
REGION1	NORTH AMERICA			.	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-1.23	0.2177	0.05

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 30 min (mg/dL) Parameter Code=MTIC30C Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
BOLAD1 BASE		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		10.98	<.0001	0.05

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Lower	Upper
TRTPN			2	26.1874	39.3463
TRTPN			3	52.0697	65.1882
TRTPN			4	34.9760	48.5123
REGION1	ASIA (EXCLUDING JAPAN)			-7.0182	9.8402
REGION1	EUROPE			-8.2826	3.6614
REGION1	JAPAN			1.7488	15.2060
REGION1	NORTH AMERICA			.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-8.4773	1.9338
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.
BASE				0.2654	0.3809

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 30 min (mg/dL) Parameter Code=MTIC30C Study Identifier=NN1218-4131

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	2	975	41.40	<.0001
REGION1	3	975	3.93	0.0084
BOLAD1	1	975	1.52	0.2177
BASE	1	975	120.66	<.0001

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) - NovoRapid (meal)	WORK.ENDPOINT_2	-8.9772	2.8982	975	-3.10	0.0020	0.05	-14.6647	-3.2898

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (post) - NovoRapid (meal)	WORK.ENDPOINT_2	16.8848	2.9031	975	5.82	<.0001	0.05	11.1878	22.5819

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 30 min (mg/dL) Parameter Code=MTIC30C Study Identifier=NN1218-4131

The Mixed Procedure

Least Squares Means

Effect	Planned Treatment for Period 30 (N)	Margins	BASE	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	2	WORK.ENDPOINT_2	62.89	52.6340	2.0351	975	25.86	<.0001	0.05	48.6404	56.6276
TRTPN	3	WORK.ENDPOINT_2	62.89	78.4961	2.0415	975	38.45	<.0001	0.05	74.4898	82.5023
TRTPN	4	WORK.ENDPOINT_2	62.89	61.6112	2.0606	975	29.90	<.0001	0.05	57.5675	65.6550

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 30 min (mmol/L) Parameter Code=MTIC30 Study Identifier=NN1218-4131

The Mixed Procedure

Model Information

Data Set	WORK.ENDPOINT_2
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Dimensions

Covariance Parameters	1
Columns in X	10
Columns in Z	0
Subjects	1
Max Obs per Subject	983

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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 30 min (mmol/L) Parameter Code=MTIC30 Study Identifier=NN1218-4131

The Mixed Procedure

Number of Observations

Number of Observations Read	983
Number of Observations Used	983
Number of Observations Not Used	0

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	4.2103

Fit Statistics

-2 Res Log Likelihood	4214.6
AIC (Smaller is Better)	4216.6
AICC (Smaller is Better)	4216.6
BIC (Smaller is Better)	4221.4

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			2	1.8184	0.1861	975
TRTPN			3	3.2535	0.1855	975

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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 30 min (mmol/L) Parameter Code=MTIC30 Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			4	2.3165	0.1914	975
REGION1	ASIA (EXCLUDING JAPAN)			0.07830	0.2384	975
REGION1	EUROPE			-0.1282	0.1689	975
REGION1	JAPAN			0.4704	0.1903	975
REGION1	NORTH AMERICA			0	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.1816	0.1472	975
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0	.	.
BASE				0.3232	0.02942	975

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
TRTPN			2	9.77	<.0001	0.05
TRTPN			3	17.54	<.0001	0.05
TRTPN			4	12.10	<.0001	0.05
REGION1	ASIA (EXCLUDING JAPAN)			0.33	0.7426	0.05
REGION1	EUROPE			-0.76	0.4479	0.05
REGION1	JAPAN			2.47	0.0136	0.05
REGION1	NORTH AMERICA			.	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-1.23	0.2177	0.05

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 30 min (mmol/L) Parameter Code=MTIC30 Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
BOLAD1 BASE		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		10.98	<.0001	0.05

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Lower	Upper
TRTPN			2	1.4532	2.1835
TRTPN			3	2.8895	3.6175
TRTPN			4	1.9410	2.6921
REGION1	ASIA (EXCLUDING JAPAN)			-0.3895	0.5461
REGION1	EUROPE			-0.4596	0.2032
REGION1	JAPAN			0.09705	0.8438
REGION1	NORTH AMERICA				
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.4704	0.1073
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY			
BASE				0.2654	0.3809

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 30 min (mmol/L) Parameter Code=MTIC30 Study Identifier=NN1218-4131

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	2	975	41.40	<.0001
REGION1	3	975	3.93	0.0084
BOLAD1	1	975	1.52	0.2177
BASE	1	975	120.66	<.0001

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) - NovoRapid (meal)	WORK.ENDPOINT_2	-0.4982	0.1608	975	-3.10	0.0020	0.05	-0.8138	-0.1826

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (post) - NovoRapid (meal)	WORK.ENDPOINT_2	0.9370	0.1611	975	5.82	<.0001	0.05	0.6209	1.2532

Fast-acting insulin aspart
NN1218-4131

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Novo Nordisk

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 30 min (mmol/L) Parameter Code=MTIC30 Study Identifier=NN1218-4131

The Mixed Procedure

Least Squares Means

Effect	Planned Treatment for Period 30 (N)	Margins	BASE	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	2	WORK.ENDPOINT_2	3.49	2.9209	0.1129	975	25.86	<.0001	0.05	2.6992	3.1425
TRTPN	3	WORK.ENDPOINT_2	3.49	4.3561	0.1133	975	38.45	<.0001	0.05	4.1337	4.5784
TRTPN	4	WORK.ENDPOINT_2	3.49	3.4190	0.1144	975	29.90	<.0001	0.05	3.1946	3.6434

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 4 hours (mg/dL) Parameter Code=MTIC240C Study Identifier=NN1218-4131

The Mixed Procedure

Model Information

Data Set	WORK.ENDPOINT_2
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Dimensions

Covariance Parameters	1
Columns in X	10
Columns in Z	0
Subjects	1
Max Obs per Subject	976

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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 4 hours (mg/dL) Parameter Code=MTIC240C Study Identifier=NN1218-4131

The Mixed Procedure

Number of Observations

Number of Observations Read	976
Number of Observations Used	976
Number of Observations Not Used	0

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	4830.33

Fit Statistics

-2 Res Log Likelihood	11011.4
AIC (Smaller is Better)	11013.4
AICC (Smaller is Better)	11013.4
BIC (Smaller is Better)	11018.3

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			2	24.1353	5.4706	968
TRTPN			3	31.9493	5.4859	968

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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 4 hours (mg/dL) Parameter Code=MTIC240C Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			4	25.8676	5.5589	968
REGION1	ASIA (EXCLUDING JAPAN)			12.9749	8.2020	968
REGION1	EUROPE			-14.3422	5.7406	968
REGION1	JAPAN			6.8828	6.5257	968
REGION1	NORTH AMERICA			0	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		1.9986	5.0016	968
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0	.	.
BASE				0.4735	0.02827	968

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
TRTPN			2	4.41	<.0001	0.05
TRTPN			3	5.82	<.0001	0.05
TRTPN			4	4.65	<.0001	0.05
REGION1	ASIA (EXCLUDING JAPAN)			1.58	0.1140	0.05
REGION1	EUROPE			-2.50	0.0126	0.05
REGION1	JAPAN			1.05	0.2918	0.05
REGION1	NORTH AMERICA			.	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.40	0.6895	0.05

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 4 hours (mg/dL) Parameter Code=MTIC240C Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
BOLAD1 BASE		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		16.75	<.0001	0.05

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Lower	Upper
TRTPN			2	13.3997	34.8709
TRTPN			3	21.1836	42.7150
TRTPN			4	14.9588	36.7764
REGION1	ASIA (EXCLUDING JAPAN)			-3.1209	29.0706
REGION1	EUROPE			-25.6077	-3.0766
REGION1	JAPAN			-5.9235	19.6890
REGION1	NORTH AMERICA			.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-7.8166	11.8139
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.
BASE				0.4181	0.5290

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 4 hours (mg/dL) Parameter Code=MTIC240C Study Identifier=NN1218-4131

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	2	968	1.13	0.3222
REGION1	3	968	6.26	0.0003
BOLAD1	1	968	0.16	0.6895
BASE	1	968	280.57	<.0001

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) - NovoRapid (meal)	WORK.ENDPOINT_2	-1.7323	5.4600	968	-0.32	0.7511	0.05	-12.4471	8.9826

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (post) - NovoRapid (meal)	WORK.ENDPOINT_2	6.0817	5.4661	968	1.11	0.2661	0.05	-4.6451	16.8086

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 4 hours (mg/dL) Parameter Code=MTIC240C Study Identifier=NN1218-4131

The Mixed Procedure

Least Squares Means

Effect	Planned Treatment for Period 30 (N)	Margins	BASE	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	2	WORK.ENDPOINT_2	46.29	45.7531	3.8425	968	11.91	<.0001	0.05	38.2125	53.2937
TRTPN	3	WORK.ENDPOINT_2	46.29	53.5671	3.8533	968	13.90	<.0001	0.05	46.0054	61.1289
TRTPN	4	WORK.ENDPOINT_2	46.29	47.4854	3.8756	968	12.25	<.0001	0.05	39.8799	55.0909

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 4 hours (mmol/L) Parameter Code=MTIC240 Study Identifier=NN1218-4131

The Mixed Procedure

Model Information

Data Set	WORK.ENDPOINT_2
Dependent Variable	AVAL
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Dimensions

Covariance Parameters	1
Columns in X	10
Columns in Z	0
Subjects	1
Max Obs per Subject	976

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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 4 hours (mmol/L) Parameter Code=MTIC240 Study Identifier=NN1218-4131

The Mixed Procedure

Number of Observations

Number of Observations Read	976
Number of Observations Used	976
Number of Observations Not Used	0

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	14.8754

Fit Statistics

-2 Res Log Likelihood	5407.7
AIC (Smaller is Better)	5409.7
AICC (Smaller is Better)	5409.7
BIC (Smaller is Better)	5414.6

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			2	1.3394	0.3036	968
TRTPN			3	1.7730	0.3044	968

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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 4 hours (mmol/L) Parameter Code=MTIC240 Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			4	1.4355	0.3085	968
REGION1	ASIA (EXCLUDING JAPAN)			0.7200	0.4552	968
REGION1	EUROPE			-0.7959	0.3186	968
REGION1	JAPAN			0.3820	0.3621	968
REGION1	NORTH AMERICA			0	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.1109	0.2776	968
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0	.	.
BASE				0.4735	0.02827	968

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
TRTPN			2	4.41	<.0001	0.05
TRTPN			3	5.82	<.0001	0.05
TRTPN			4	4.65	<.0001	0.05
REGION1	ASIA (EXCLUDING JAPAN)			1.58	0.1140	0.05
REGION1	EUROPE			-2.50	0.0126	0.05
REGION1	JAPAN			1.05	0.2918	0.05
REGION1	NORTH AMERICA			.	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.40	0.6895	0.05

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 4 hours (mmol/L) Parameter Code=MTIC240 Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
BOLAD1 BASE		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		16.75	<.0001	0.05

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Lower	Upper
TRTPN			2	0.7436	1.9351
TRTPN			3	1.1756	2.3704
TRTPN			4	0.8301	2.0409
REGION1	ASIA (EXCLUDING JAPAN)			-0.1732	1.6132
REGION1	EUROPE			-1.4211	-0.1707
REGION1	JAPAN			-0.3287	1.0926
REGION1	NORTH AMERICA			.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.4338	0.6556
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.
BASE				0.4181	0.5290

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 4 hours (mmol/L) Parameter Code=MTIC240 Study Identifier=NN1218-4131

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	2	968	1.13	0.3222
REGION1	3	968	6.26	0.0003
BOLAD1	1	968	0.16	0.6895
BASE	1	968	280.57	<.0001

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) - NovoRapid (meal)	WORK.ENDPOINT_2	-0.09613	0.3030	968	-0.32	0.7511	0.05	-0.6907	0.4985

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (post) - NovoRapid (meal)	WORK.ENDPOINT_2	0.3375	0.3033	968	1.11	0.2661	0.05	-0.2578	0.9328

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 4 hours (mmol/L) Parameter Code=MTIC240 Study Identifier=NN1218-4131

The Mixed Procedure

Least Squares Means

Effect	Planned Treatment for Period 30 (N)	Margins	BASE	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	2	WORK.ENDPOINT_2	2.57	2.5390	0.2132	968	11.91	<.0001	0.05	2.1206	2.9575
TRTPN	3	WORK.ENDPOINT_2	2.57	2.9726	0.2138	968	13.90	<.0001	0.05	2.5530	3.3923
TRTPN	4	WORK.ENDPOINT_2	2.57	2.6352	0.2151	968	12.25	<.0001	0.05	2.2131	3.0572

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 1 hour (mg/dL) Parameter Code=MTIC60C Study Identifier=NN1218-4131

The Mixed Procedure

Model Information

Data Set	WORK.ENDPOINT_2
Dependent Variable	CHG
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Dimensions

Covariance Parameters	1
Columns in X	10
Columns in Z	0
Subjects	1
Max Obs per Subject	985

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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 1 hour (mg/dL) Parameter Code=MTIC60C Study Identifier=NN1218-4131

The Mixed Procedure

Number of Observations

Number of Observations Read	985
Number of Observations Used	985
Number of Observations Not Used	0

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	2853.85

Fit Statistics

-2 Res Log Likelihood	10598.8
AIC (Smaller is Better)	10600.8
AICC (Smaller is Better)	10600.8
BIC (Smaller is Better)	10605.7

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			2	47.4120	4.8000	977
TRTPN			3	81.3962	4.7235	977

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09FEB2018:20:27:35 - a_ppg_stat_diff.sas/a_ppg_inc_stat_on_fas_app.txt

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 1 hour (mg/dL) Parameter Code=MTIC60C Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			4	63.1434	4.8547	977
REGION1	ASIA (EXCLUDING JAPAN)			-1.6784	6.2013	977
REGION1	EUROPE			-13.2512	4.3915	977
REGION1	JAPAN			2.4576	4.9300	977
REGION1	NORTH AMERICA			0	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.5631	3.8288	977
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0	.	.
BASE				-0.6703	0.02700	977

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
TRTPN			2	9.88	<.0001	0.05
TRTPN			3	17.23	<.0001	0.05
TRTPN			4	13.01	<.0001	0.05
REGION1	ASIA (EXCLUDING JAPAN)			-0.27	0.7867	0.05
REGION1	EUROPE			-3.02	0.0026	0.05
REGION1	JAPAN			0.50	0.6182	0.05
REGION1	NORTH AMERICA			.	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.15	0.8831	0.05

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 1 hour (mg/dL) Parameter Code=MTIC60C Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
BOLAD1 BASE		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		-24.82	<.0001	0.05

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Lower	Upper
TRTPN			2	37.9926	56.8314
TRTPN			3	72.1267	90.6656
TRTPN			4	53.6167	72.6702
REGION1	ASIA (EXCLUDING JAPAN)			-13.8478	10.4911
REGION1	EUROPE			-21.8691	-4.6333
REGION1	JAPAN			-7.2169	12.1322
REGION1	NORTH AMERICA				
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-6.9506	8.0767
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY			
BASE				-0.7233	-0.6173

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 1 hour (mg/dL) Parameter Code=MTIC60C Study Identifier=NN1218-4131

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	2	977	33.35	<.0001
REGION1	3	977	5.06	0.0018
BOLAD1	1	977	0.02	0.8831
BASE	1	977	616.17	<.0001

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) - NovoRapid (meal)	WORK.ENDPOINT_2	-15.7315	4.1849	977	-3.76	0.0002	0.05	-23.9440	-7.5189

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (post) - NovoRapid (meal)	WORK.ENDPOINT_2	18.2527	4.1870	977	4.36	<.0001	0.05	10.0361	26.4693

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 1 hour (mg/dL) Parameter Code=MTIC60C Study Identifier=NN1218-4131

The Mixed Procedure

Least Squares Means

Effect	Planned Treatment for Period 30 (N)	Margins	BASE	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	2	WORK.ENDPOINT_2	92.31	-18.2398	2.9408	977	-6.20	<.0001	0.05	-24.0109	-12.4688
TRTPN	3	WORK.ENDPOINT_2	92.31	15.7443	2.9418	977	5.35	<.0001	0.05	9.9714	21.5173
TRTPN	4	WORK.ENDPOINT_2	92.31	-2.5084	2.9755	977	-0.84	0.3994	0.05	-8.3475	3.3307

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 1 hour (mmol/L) Parameter Code=MTIC60 Study Identifier=NN1218-4131

The Mixed Procedure

Model Information

Data Set	WORK.ENDPOINT_2
Dependent Variable	CHG
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Dimensions

Covariance Parameters	1
Columns in X	10
Columns in Z	0
Subjects	1
Max Obs per Subject	985

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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 1 hour (mmol/L) Parameter Code=MTIC60 Study Identifier=NN1218-4131

The Mixed Procedure

Number of Observations

Number of Observations Read	985
Number of Observations Used	985
Number of Observations Not Used	0

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	8.7886

Fit Statistics

-2 Res Log Likelihood	4943.0
AIC (Smaller is Better)	4945.0
AICC (Smaller is Better)	4945.0
BIC (Smaller is Better)	4949.9

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			2	2.6311	0.2664	977
TRTPN			3	4.5170	0.2621	977

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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 1 hour (mmol/L) Parameter Code=MTIC60 Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			4	3.5041	0.2694	977
REGION1	ASIA (EXCLUDING JAPAN)			-0.09314	0.3441	977
REGION1	EUROPE			-0.7354	0.2437	977
REGION1	JAPAN			0.1364	0.2736	977
REGION1	NORTH AMERICA			0	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.03125	0.2125	977
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0	.	.
BASE				-0.6703	0.02700	977

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
TRTPN			2	9.88	<.0001	0.05
TRTPN			3	17.23	<.0001	0.05
TRTPN			4	13.01	<.0001	0.05
REGION1	ASIA (EXCLUDING JAPAN)			-0.27	0.7867	0.05
REGION1	EUROPE			-3.02	0.0026	0.05
REGION1	JAPAN			0.50	0.6182	0.05
REGION1	NORTH AMERICA			.	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.15	0.8831	0.05

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 1 hour (mmol/L) Parameter Code=MTIC60 Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
BOLAD1 BASE		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		-24.82	<.0001	0.05

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Lower	Upper
TRTPN			2	2.1084	3.1538
TRTPN			3	4.0026	5.0314
TRTPN			4	2.9754	4.0328
REGION1	ASIA (EXCLUDING JAPAN)			-0.7685	0.5822
REGION1	EUROPE			-1.2136	-0.2571
REGION1	JAPAN			-0.4005	0.6733
REGION1	NORTH AMERICA			.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.3857	0.4482
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.
BASE				-0.7233	-0.6173

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 1 hour (mmol/L) Parameter Code=MTIC60 Study Identifier=NN1218-4131

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	2	977	33.35	<.0001
REGION1	3	977	5.06	0.0018
BOLAD1	1	977	0.02	0.8831
BASE	1	977	616.17	<.0001

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) - NovoRapid (meal)	WORK.ENDPOINT_2	-0.8730	0.2322	977	-3.76	0.0002	0.05	-1.3287	-0.4173

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (post) - NovoRapid (meal)	WORK.ENDPOINT_2	1.0129	0.2324	977	4.36	<.0001	0.05	0.5569	1.4689

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 1 hour (mmol/L) Parameter Code=MTIC60 Study Identifier=NN1218-4131

The Mixed Procedure

Least Squares Means

Effect	Planned Treatment for Period 30 (N)	Margins	BASE	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	2	WORK.ENDPOINT_2	5.12	-1.0122	0.1632	977	-6.20	<.0001	0.05	-1.3325	-0.6919
TRTPN	3	WORK.ENDPOINT_2	5.12	0.8737	0.1633	977	5.35	<.0001	0.05	0.5534	1.1941
TRTPN	4	WORK.ENDPOINT_2	5.12	-0.1392	0.1651	977	-0.84	0.3994	0.05	-0.4632	0.1848

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 2 hours (mg/dL) Parameter Code=MTIC120C Study Identifier=NN1218-4131

The Mixed Procedure

Model Information

Data Set	WORK.ENDPOINT_2
Dependent Variable	CHG
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Dimensions

Covariance Parameters	1
Columns in X	10
Columns in Z	0
Subjects	1
Max Obs per Subject	977

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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 2 hours (mg/dL) Parameter Code=MTIC120C Study Identifier=NN1218-4131

The Mixed Procedure

Number of Observations

Number of Observations Read	977
Number of Observations Used	977
Number of Observations Not Used	0

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	5292.52

Fit Statistics

-2 Res Log Likelihood	11111.4
AIC (Smaller is Better)	11113.4
AICC (Smaller is Better)	11113.4
BIC (Smaller is Better)	11118.3

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			2	59.5782	6.2774	969
TRTPN			3	70.3046	6.1984	969

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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 2 hours (mg/dL) Parameter Code=MTIC120C Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			4	65.2551	6.3401	969
REGION1	ASIA (EXCLUDING JAPAN)			-4.7139	8.4977	969
REGION1	EUROPE			-19.9727	6.0271	969
REGION1	JAPAN			4.3285	6.7732	969
REGION1	NORTH AMERICA			0	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		4.6226	5.2444	969
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0	.	.
BASE				-0.6140	0.02767	969

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
TRTPN			2	9.49	<.0001	0.05
TRTPN			3	11.34	<.0001	0.05
TRTPN			4	10.29	<.0001	0.05
REGION1	ASIA (EXCLUDING JAPAN)			-0.55	0.5792	0.05
REGION1	EUROPE			-3.31	0.0010	0.05
REGION1	JAPAN			0.64	0.5229	0.05
REGION1	NORTH AMERICA			.	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.88	0.3783	0.05

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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 2 hours (mg/dL) Parameter Code=MTIC120C Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
BOLAD1 BASE		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		-22.19	<.0001	0.05

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Lower	Upper
TRTPN			2	47.2592	71.8971
TRTPN			3	58.1406	82.4685
TRTPN			4	52.8133	77.6970
REGION1	ASIA (EXCLUDING JAPAN)			-21.3899	11.9622
REGION1	EUROPE			-31.8003	-8.1450
REGION1	JAPAN			-8.9633	17.6202
REGION1	NORTH AMERICA				
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-5.6690	14.9142
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY			
BASE				-0.6683	-0.5597

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 2 hours (mg/dL) Parameter Code=MTIC120C Study Identifier=NN1218-4131

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	2	969	1.78	0.1695
REGION1	3	969	6.18	0.0004
BOLAD1	1	969	0.78	0.3783
BASE	1	969	492.35	<.0001

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) - NovoRapid (meal)	WORK.ENDPOINT_2	-5.6770	5.7306	969	-0.99	0.3221	0.05	-16.9228	5.5688

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (post) - NovoRapid (meal)	WORK.ENDPOINT_2	5.0494	5.7170	969	0.88	0.3773	0.05	-6.1698	16.2686

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 2 hours (mg/dL) Parameter Code=MTIC120C Study Identifier=NN1218-4131

The Mixed Procedure

Least Squares Means

Effect	Planned Treatment for Period 30 (N)	Margins	BASE	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	2	WORK.ENDPOINT_2	101.45	-6.3383	4.0293	969	-1.57	0.1160	0.05	-14.2454	1.5689
TRTPN	3	WORK.ENDPOINT_2	101.45	4.3882	4.0106	969	1.09	0.2742	0.05	-3.4824	12.2587
TRTPN	4	WORK.ENDPOINT_2	101.45	-0.6613	4.0707	969	-0.16	0.8710	0.05	-8.6498	7.3272

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 2 hours (mmol/L) Parameter Code=MTIC120 Study Identifier=NN1218-4131

The Mixed Procedure

Model Information

Data Set	WORK.ENDPOINT_2
Dependent Variable	CHG
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Dimensions

Covariance Parameters	1
Columns in X	10
Columns in Z	0
Subjects	1
Max Obs per Subject	977

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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 2 hours (mmol/L) Parameter Code=MTIC120 Study Identifier=NN1218-4131

The Mixed Procedure

Number of Observations

Number of Observations Read	977
Number of Observations Used	977
Number of Observations Not Used	0

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	16.2987

Fit Statistics

-2 Res Log Likelihood	5501.9
AIC (Smaller is Better)	5503.9
AICC (Smaller is Better)	5503.9
BIC (Smaller is Better)	5508.8

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			2	3.3062	0.3484	969
TRTPN			3	3.9015	0.3440	969

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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 2 hours (mmol/L) Parameter Code=MTIC120 Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			4	3.6213	0.3518	969
REGION1	ASIA (EXCLUDING JAPAN)			-0.2616	0.4716	969
REGION1	EUROPE			-1.1084	0.3345	969
REGION1	JAPAN			0.2402	0.3759	969
REGION1	NORTH AMERICA			0	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.2565	0.2910	969
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0	.	.
BASE				-0.6140	0.02767	969

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
TRTPN			2	9.49	<.0001	0.05
TRTPN			3	11.34	<.0001	0.05
TRTPN			4	10.29	<.0001	0.05
REGION1	ASIA (EXCLUDING JAPAN)			-0.55	0.5792	0.05
REGION1	EUROPE			-3.31	0.0010	0.05
REGION1	JAPAN			0.64	0.5229	0.05
REGION1	NORTH AMERICA			.	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.88	0.3783	0.05

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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 2 hours (mmol/L) Parameter Code=MTIC120 Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
BOLAD1 BASE		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		-22.19	<.0001	0.05

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Lower	Upper
TRTPN			2	2.6226	3.9899
TRTPN			3	3.2264	4.5765
TRTPN			4	2.9308	4.3117
REGION1	ASIA (EXCLUDING JAPAN)			-1.1870	0.6638
REGION1	EUROPE			-1.7647	-0.4520
REGION1	JAPAN			-0.4974	0.9778
REGION1	NORTH AMERICA			.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.3146	0.8276
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.
BASE				-0.6683	-0.5597

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 2 hours (mmol/L) Parameter Code=MTIC120 Study Identifier=NN1218-4131

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	2	969	1.78	0.1695
REGION1	3	969	6.18	0.0004
BOLAD1	1	969	0.78	0.3783
BASE	1	969	492.35	<.0001

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) - NovoRapid (meal)	WORK.ENDPOINT_2	-0.3150	0.3180	969	-0.99	0.3221	0.05	-0.9391	0.3090

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (post) - NovoRapid (meal)	WORK.ENDPOINT_2	0.2802	0.3173	969	0.88	0.3773	0.05	-0.3424	0.9028

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 2 hours (mmol/L) Parameter Code=MTIC120 Study Identifier=NN1218-4131

The Mixed Procedure

Least Squares Means

Effect	Planned Treatment for Period 30 (N)	Margins	BASE	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	2	WORK.ENDPOINT_2	5.63	-0.3517	0.2236	969	-1.57	0.1160	0.05	-0.7905	0.08707
TRTPN	3	WORK.ENDPOINT_2	5.63	0.2435	0.2226	969	1.09	0.2742	0.05	-0.1932	0.6803
TRTPN	4	WORK.ENDPOINT_2	5.63	-0.03670	0.2259	969	-0.16	0.8710	0.05	-0.4800	0.4066

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 3 hours (mg/dL) Parameter Code=MTIC180C Study Identifier=NN1218-4131

The Mixed Procedure

Model Information

Data Set	WORK.ENDPOINT_2
Dependent Variable	CHG
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Dimensions

Covariance Parameters	1
Columns in X	10
Columns in Z	0
Subjects	1
Max Obs per Subject	976

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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 3 hours (mg/dL) Parameter Code=MTIC180C Study Identifier=NN1218-4131

The Mixed Procedure

Number of Observations

Number of Observations Read	976
Number of Observations Used	976
Number of Observations Not Used	0

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	5828.86

Fit Statistics

-2 Res Log Likelihood	11193.5
AIC (Smaller is Better)	11195.5
AICC (Smaller is Better)	11195.5
BIC (Smaller is Better)	11200.4

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			2	45.4409	6.2156	968
TRTPN			3	54.0264	6.2251	968

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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 3 hours (mg/dL) Parameter Code=MTIC180C Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			4	47.5543	6.3256	968
REGION1	ASIA (EXCLUDING JAPAN)			6.8049	8.9610	968
REGION1	EUROPE			-20.7914	6.3351	968
REGION1	JAPAN			8.3852	7.1861	968
REGION1	NORTH AMERICA			0	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		2.3357	5.5044	968
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0	.	.
BASE				-0.5627	0.02829	968

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
TRTPN			2	7.31	<.0001	0.05
TRTPN			3	8.68	<.0001	0.05
TRTPN			4	7.52	<.0001	0.05
REGION1	ASIA (EXCLUDING JAPAN)			0.76	0.4478	0.05
REGION1	EUROPE			-3.28	0.0011	0.05
REGION1	JAPAN			1.17	0.2436	0.05
REGION1	NORTH AMERICA			.	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.42	0.6714	0.05

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 3 hours (mg/dL) Parameter Code=MTIC180C Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
BOLAD1 BASE		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		-19.89	<.0001	0.05

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Lower	Upper
TRTPN			2	33.2433	57.6385
TRTPN			3	41.8103	66.2426
TRTPN			4	35.1409	59.9677
REGION1	ASIA (EXCLUDING JAPAN)			-10.7802	24.3901
REGION1	EUROPE			-33.2235	-8.3593
REGION1	JAPAN			-5.7169	22.4873
REGION1	NORTH AMERICA			.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-8.4662	13.1375
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.
BASE				-0.6183	-0.5072

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 3 hours (mg/dL) Parameter Code=MTIC180C Study Identifier=NN1218-4131

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	2	968	1.11	0.3284
REGION1	3	968	8.04	<.0001
BOLAD1	1	968	0.18	0.6714
BASE	1	968	395.80	<.0001

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) - NovoRapid (meal)	WORK.ENDPOINT_2	-2.1134	5.9970	968	-0.35	0.7246	0.05	-13.8820	9.6552

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (post) - NovoRapid (meal)	WORK.ENDPOINT_2	6.4722	6.0165	968	1.08	0.2823	0.05	-5.3347	18.2791

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 3 hours (mg/dL) Parameter Code=MTIC180C Study Identifier=NN1218-4131

The Mixed Procedure

Least Squares Means

Effect	Planned Treatment for Period 30 (N)	Margins	BASE	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	2	WORK.ENDPOINT_2	78.32	-1.3347	4.2103	968	-0.32	0.7513	0.05	-9.5970	6.9276
TRTPN	3	WORK.ENDPOINT_2	78.32	7.2508	4.2411	968	1.71	0.0876	0.05	-1.0720	15.5736
TRTPN	4	WORK.ENDPOINT_2	78.32	0.7787	4.2652	968	0.18	0.8552	0.05	-7.5914	9.1487

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 3 hours (mmol/L) Parameter Code=MTIC180 Study Identifier=NN1218-4131

The Mixed Procedure

Model Information

Data Set	WORK.ENDPOINT_2
Dependent Variable	CHG
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Dimensions

Covariance Parameters	1
Columns in X	10
Columns in Z	0
Subjects	1
Max Obs per Subject	976

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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 3 hours (mmol/L) Parameter Code=MTIC180 Study Identifier=NN1218-4131

The Mixed Procedure

Number of Observations

Number of Observations Read	976
Number of Observations Used	976
Number of Observations Not Used	0

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	17.9504

Fit Statistics

-2 Res Log Likelihood	5589.8
AIC (Smaller is Better)	5591.8
AICC (Smaller is Better)	5591.8
BIC (Smaller is Better)	5596.7

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			2	2.5217	0.3449	968
TRTPN			3	2.9981	0.3455	968

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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 3 hours (mmol/L) Parameter Code=MTIC180 Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			4	2.6390	0.3510	968
REGION1	ASIA (EXCLUDING JAPAN)			0.3776	0.4973	968
REGION1	EUROPE			-1.1538	0.3516	968
REGION1	JAPAN			0.4653	0.3988	968
REGION1	NORTH AMERICA			0	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.1296	0.3055	968
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0	.	.
BASE				-0.5627	0.02829	968

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
TRTPN			2	7.31	<.0001	0.05
TRTPN			3	8.68	<.0001	0.05
TRTPN			4	7.52	<.0001	0.05
REGION1	ASIA (EXCLUDING JAPAN)			0.76	0.4478	0.05
REGION1	EUROPE			-3.28	0.0011	0.05
REGION1	JAPAN			1.17	0.2436	0.05
REGION1	NORTH AMERICA			.	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.42	0.6714	0.05

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 3 hours (mmol/L) Parameter Code=MTIC180 Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
BOLAD1 BASE		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		-19.89	<.0001	0.05

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Lower	Upper
TRTPN			2	1.8448	3.1986
TRTPN			3	2.3202	3.6761
TRTPN			4	1.9501	3.3278
REGION1	ASIA (EXCLUDING JAPAN)			-0.5982	1.3535
REGION1	EUROPE			-1.8437	-0.4639
REGION1	JAPAN			-0.3173	1.2479
REGION1	NORTH AMERICA				
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.4698	0.7291
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY			
BASE				-0.6183	-0.5072

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 3 hours (mmol/L) Parameter Code=MTIC180 Study Identifier=NN1218-4131

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	2	968	1.11	0.3284
REGION1	3	968	8.04	<.0001
BOLAD1	1	968	0.18	0.6714
BASE	1	968	395.80	<.0001

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) - NovoRapid (meal)	WORK.ENDPOINT_2	-0.1173	0.3328	968	-0.35	0.7246	0.05	-0.7704	0.5358

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (post) - NovoRapid (meal)	WORK.ENDPOINT_2	0.3592	0.3339	968	1.08	0.2823	0.05	-0.2960	1.0144

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 3 hours (mmol/L) Parameter Code=MTIC180 Study Identifier=NN1218-4131

The Mixed Procedure

Least Squares Means

Effect	Planned Treatment for Period 30 (N)	Margins	BASE	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	2	WORK.ENDPOINT_2	4.35	-0.07407	0.2336	968	-0.32	0.7513	0.05	-0.5326	0.3844
TRTPN	3	WORK.ENDPOINT_2	4.35	0.4024	0.2354	968	1.71	0.0876	0.05	-0.05949	0.8642
TRTPN	4	WORK.ENDPOINT_2	4.35	0.04321	0.2367	968	0.18	0.8552	0.05	-0.4213	0.5077

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 30 min (mg/dL) Parameter Code=MTIC30C Study Identifier=NN1218-4131

The Mixed Procedure

Model Information

Data Set	WORK.ENDPOINT_2
Dependent Variable	CHG
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Dimensions

Covariance Parameters	1
Columns in X	10
Columns in Z	0
Subjects	1
Max Obs per Subject	983

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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 30 min (mg/dL) Parameter Code=MTIC30C Study Identifier=NN1218-4131

The Mixed Procedure

Number of Observations

Number of Observations Read	983
Number of Observations Used	983
Number of Observations Not Used	0

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	1367.17

Fit Statistics

-2 Res Log Likelihood	9858.7
AIC (Smaller is Better)	9860.7
AICC (Smaller is Better)	9860.7
BIC (Smaller is Better)	9865.6

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			2	32.7669	3.3527	975
TRTPN			3	58.6289	3.3425	975

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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 30 min (mg/dL) Parameter Code=MTIC30C Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			4	41.7441	3.4489	975
REGION1	ASIA (EXCLUDING JAPAN)			1.4110	4.2953	975
REGION1	EUROPE			-2.3106	3.0432	975
REGION1	JAPAN			8.4774	3.4288	975
REGION1	NORTH AMERICA			0	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-3.2718	2.6526	975
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0	.	.
BASE				-0.6768	0.02942	975

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
TRTPN			2	9.77	<.0001	0.05
TRTPN			3	17.54	<.0001	0.05
TRTPN			4	12.10	<.0001	0.05
REGION1	ASIA (EXCLUDING JAPAN)			0.33	0.7426	0.05
REGION1	EUROPE			-0.76	0.4479	0.05
REGION1	JAPAN			2.47	0.0136	0.05
REGION1	NORTH AMERICA			.	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-1.23	0.2177	0.05

Fast-acting insulin aspart
NN1218-4131

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Novo Nordisk

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 30 min (mg/dL) Parameter Code=MTIC30C Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
BOLAD1 BASE		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		-23.01	<.0001	0.05

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Lower	Upper
TRTPN			2	26.1874	39.3463
TRTPN			3	52.0697	65.1882
TRTPN			4	34.9760	48.5123
REGION1	ASIA (EXCLUDING JAPAN)			-7.0182	9.8402
REGION1	EUROPE			-8.2826	3.6614
REGION1	JAPAN			1.7488	15.2060
REGION1	NORTH AMERICA			.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-8.4773	1.9338
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.
BASE				-0.7346	-0.6191

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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 30 min (mg/dL) Parameter Code=MTIC30C Study Identifier=NN1218-4131

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	2	975	41.40	<.0001
REGION1	3	975	3.93	0.0084
BOLAD1	1	975	1.52	0.2177
BASE	1	975	529.31	<.0001

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) - NovoRapid (meal)	WORK.ENDPOINT_2	-8.9772	2.8982	975	-3.10	0.0020	0.05	-14.6647	-3.2898

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (post) - NovoRapid (meal)	WORK.ENDPOINT_2	16.8848	2.9031	975	5.82	<.0001	0.05	11.1878	22.5819

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 30 min (mg/dL) Parameter Code=MTIC30C Study Identifier=NN1218-4131

The Mixed Procedure

Least Squares Means

Effect	Planned Treatment for Period 30 (N)	Margins	BASE	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	2	WORK.ENDPOINT_2	62.89	-10.2527	2.0351	975	-5.04	<.0001	0.05	-14.2463	-6.2591
TRTPN	3	WORK.ENDPOINT_2	62.89	15.6094	2.0415	975	7.65	<.0001	0.05	11.6031	19.6156
TRTPN	4	WORK.ENDPOINT_2	62.89	-1.2754	2.0606	975	-0.62	0.5361	0.05	-5.3192	2.7683

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 30 min (mmol/L) Parameter Code=MTIC30 Study Identifier=NN1218-4131

The Mixed Procedure

Model Information

Data Set	WORK.ENDPOINT_2
Dependent Variable	CHG
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Dimensions

Covariance Parameters	1
Columns in X	10
Columns in Z	0
Subjects	1
Max Obs per Subject	983

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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 30 min (mmol/L) Parameter Code=MTIC30 Study Identifier=NN1218-4131

The Mixed Procedure

Number of Observations

Number of Observations Read	983
Number of Observations Used	983
Number of Observations Not Used	0

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	4.2103

Fit Statistics

-2 Res Log Likelihood	4214.6
AIC (Smaller is Better)	4216.6
AICC (Smaller is Better)	4216.6
BIC (Smaller is Better)	4221.4

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			2	1.8184	0.1861	975
TRTPN			3	3.2535	0.1855	975

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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 30 min (mmol/L) Parameter Code=MTIC30 Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			4	2.3165	0.1914	975
REGION1	ASIA (EXCLUDING JAPAN)			0.07830	0.2384	975
REGION1	EUROPE			-0.1282	0.1689	975
REGION1	JAPAN			0.4704	0.1903	975
REGION1	NORTH AMERICA			0	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.1816	0.1472	975
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0	.	.
BASE				-0.6768	0.02942	975

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
TRTPN			2	9.77	<.0001	0.05
TRTPN			3	17.54	<.0001	0.05
TRTPN			4	12.10	<.0001	0.05
REGION1	ASIA (EXCLUDING JAPAN)			0.33	0.7426	0.05
REGION1	EUROPE			-0.76	0.4479	0.05
REGION1	JAPAN			2.47	0.0136	0.05
REGION1	NORTH AMERICA			.	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-1.23	0.2177	0.05

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 30 min (mmol/L) Parameter Code=MTIC30 Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
BOLAD1 BASE		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		-23.01	<.0001	0.05

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Lower	Upper
TRTPN			2	1.4532	2.1835
TRTPN			3	2.8895	3.6175
TRTPN			4	1.9410	2.6921
REGION1	ASIA (EXCLUDING JAPAN)			-0.3895	0.5461
REGION1	EUROPE			-0.4596	0.2032
REGION1	JAPAN			0.09705	0.8438
REGION1	NORTH AMERICA				
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.4704	0.1073
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY			
BASE				-0.7346	-0.6191

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 30 min (mmol/L) Parameter Code=MTIC30 Study Identifier=NN1218-4131

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	2	975	41.40	<.0001
REGION1	3	975	3.93	0.0084
BOLAD1	1	975	1.52	0.2177
BASE	1	975	529.31	<.0001

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) - NovoRapid (meal)	WORK.ENDPOINT_2	-0.4982	0.1608	975	-3.10	0.0020	0.05	-0.8138	-0.1826

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (post) - NovoRapid (meal)	WORK.ENDPOINT_2	0.9370	0.1611	975	5.82	<.0001	0.05	0.6209	1.2532

Fast-acting insulin aspart
NN1218-4131

Clinical Trial Report
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1.0

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Novo Nordisk

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 30 min (mmol/L) Parameter Code=MTIC30 Study Identifier=NN1218-4131

The Mixed Procedure

Least Squares Means

Effect	Planned Treatment for Period 30 (N)	Margins	BASE	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	2	WORK.ENDPOINT_2	3.49	-0.5690	0.1129	975	-5.04	<.0001	0.05	-0.7906	-0.3473
TRTPN	3	WORK.ENDPOINT_2	3.49	0.8662	0.1133	975	7.65	<.0001	0.05	0.6439	1.0885
TRTPN	4	WORK.ENDPOINT_2	3.49	-0.07078	0.1144	975	-0.62	0.5361	0.05	-0.2952	0.1536

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 4 hours (mg/dL) Parameter Code=MTIC240C Study Identifier=NN1218-4131

The Mixed Procedure

Model Information

Data Set	WORK.ENDPOINT_2
Dependent Variable	CHG
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Dimensions

Covariance Parameters	1
Columns in X	10
Columns in Z	0
Subjects	1
Max Obs per Subject	976

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 4 hours (mg/dL) Parameter Code=MTIC240C Study Identifier=NN1218-4131

The Mixed Procedure

Number of Observations

Number of Observations Read	976
Number of Observations Used	976
Number of Observations Not Used	0

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	4830.33

Fit Statistics

-2 Res Log Likelihood	11011.4
AIC (Smaller is Better)	11013.4
AICC (Smaller is Better)	11013.4
BIC (Smaller is Better)	11018.3

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			2	24.1353	5.4706	968
TRTPN			3	31.9493	5.4859	968

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 4 hours (mg/dL) Parameter Code=MTIC240C Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			4	25.8676	5.5589	968
REGION1	ASIA (EXCLUDING JAPAN)			12.9749	8.2020	968
REGION1	EUROPE			-14.3422	5.7406	968
REGION1	JAPAN			6.8828	6.5257	968
REGION1	NORTH AMERICA			0	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		1.9986	5.0016	968
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0	.	.
BASE				-0.5265	0.02827	968

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
TRTPN			2	4.41	<.0001	0.05
TRTPN			3	5.82	<.0001	0.05
TRTPN			4	4.65	<.0001	0.05
REGION1	ASIA (EXCLUDING JAPAN)			1.58	0.1140	0.05
REGION1	EUROPE			-2.50	0.0126	0.05
REGION1	JAPAN			1.05	0.2918	0.05
REGION1	NORTH AMERICA			.	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.40	0.6895	0.05

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 4 hours (mg/dL) Parameter Code=MTIC240C Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
BOLAD1 BASE		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		-18.62	<.0001	0.05

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Lower	Upper
TRTPN			2	13.3997	34.8709
TRTPN			3	21.1836	42.7150
TRTPN			4	14.9588	36.7764
REGION1	ASIA (EXCLUDING JAPAN)			-3.1209	29.0706
REGION1	EUROPE			-25.6077	-3.0766
REGION1	JAPAN			-5.9235	19.6890
REGION1	NORTH AMERICA			.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-7.8166	11.8139
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.
BASE				-0.5819	-0.4710

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 4 hours (mg/dL) Parameter Code=MTIC240C Study Identifier=NN1218-4131

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	2	968	1.13	0.3222
REGION1	3	968	6.26	0.0003
BOLAD1	1	968	0.16	0.6895
BASE	1	968	346.79	<.0001

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) - NovoRapid (meal)	WORK.ENDPOINT_2	-1.7323	5.4600	968	-0.32	0.7511	0.05	-12.4471	8.9826

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (post) - NovoRapid (meal)	WORK.ENDPOINT_2	6.0817	5.4661	968	1.11	0.2661	0.05	-4.6451	16.8086

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 4 hours (mg/dL) Parameter Code=MTIC240C Study Identifier=NN1218-4131

The Mixed Procedure

Least Squares Means

Effect	Planned Treatment for Period 30 (N)	Margins	BASE	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	2	WORK.ENDPOINT_2	46.29	-0.5395	3.8425	968	-0.14	0.8884	0.05	-8.0801	7.0012
TRTPN	3	WORK.ENDPOINT_2	46.29	7.2746	3.8533	968	1.89	0.0593	0.05	-0.2872	14.8363
TRTPN	4	WORK.ENDPOINT_2	46.29	1.1928	3.8756	968	0.31	0.7583	0.05	-6.4127	8.7983

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 4 hours (mmol/L) Parameter Code=MTIC240 Study Identifier=NN1218-4131

The Mixed Procedure

Model Information

Data Set	WORK.ENDPOINT_2
Dependent Variable	CHG
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Dimensions

Covariance Parameters	1
Columns in X	10
Columns in Z	0
Subjects	1
Max Obs per Subject	976

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Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 4 hours (mmol/L) Parameter Code=MTIC240 Study Identifier=NN1218-4131

The Mixed Procedure

Number of Observations

Number of Observations Read	976
Number of Observations Used	976
Number of Observations Not Used	0

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	14.8754

Fit Statistics

-2 Res Log Likelihood	5407.7
AIC (Smaller is Better)	5409.7
AICC (Smaller is Better)	5409.7
BIC (Smaller is Better)	5414.6

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			2	1.3394	0.3036	968
TRTPN			3	1.7730	0.3044	968

nn1218/nn1218-4131/ctr_20180214_er
09FEB2018:20:27:35 - a_ppg_stat_diff.sas/a_ppg_inc_stat_on_fas_app.txt

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 4 hours (mmol/L) Parameter Code=MTIC240 Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Estimate	Standard Error	DF
TRTPN			4	1.4355	0.3085	968
REGION1	ASIA (EXCLUDING JAPAN)			0.7200	0.4552	968
REGION1	EUROPE			-0.7959	0.3186	968
REGION1	JAPAN			0.3820	0.3621	968
REGION1	NORTH AMERICA			0	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.1109	0.2776	968
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0	.	.
BASE				-0.5265	0.02827	968

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
TRTPN			2	4.41	<.0001	0.05
TRTPN			3	5.82	<.0001	0.05
TRTPN			4	4.65	<.0001	0.05
REGION1	ASIA (EXCLUDING JAPAN)			1.58	0.1140	0.05
REGION1	EUROPE			-2.50	0.0126	0.05
REGION1	JAPAN			1.05	0.2918	0.05
REGION1	NORTH AMERICA			.	.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.40	0.6895	0.05

nn1218/nn1218-4131/ctr_20180214_er
09FEB2018:20:27:35 - a_ppg_stat_diff.sas/a_ppg_inc_stat_on_fas_app.txt

Fast-acting insulin aspart
NN1218-4131

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Novo Nordisk

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 4 hours (mmol/L) Parameter Code=MTIC240 Study Identifier=NN1218-4131

The Mixed Procedure

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	t Value	Pr > t	Alpha
BOLAD1 BASE		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		-18.62	<.0001	0.05

Solution for Fixed Effects

Effect	Geographic Region Grouping Method 1	Bolus Adjustment Method at Timepoint 1	Planned Treatment for Period 30 (N)	Lower	Upper
TRTPN			2	0.7436	1.9351
TRTPN			3	1.1756	2.3704
TRTPN			4	0.8301	2.0409
REGION1	ASIA (EXCLUDING JAPAN)			-0.1732	1.6132
REGION1	EUROPE			-1.4211	-0.1707
REGION1	JAPAN			-0.3287	1.0926
REGION1	NORTH AMERICA			.	.
BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.4338	0.6556
BOLAD1		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		.	.
BASE				-0.5819	-0.4710

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 4 hours (mmol/L) Parameter Code=MTIC240 Study Identifier=NN1218-4131

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	2	968	1.13	0.3222
REGION1	3	968	6.26	0.0003
BOLAD1	1	968	0.16	0.6895
BASE	1	968	346.79	<.0001

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) - NovoRapid (meal)	WORK.ENDPOINT_2	-0.09613	0.3030	968	-0.32	0.7511	0.05	-0.6907	0.4985

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	Faster aspart (post) - NovoRapid (meal)	WORK.ENDPOINT_2	0.3375	0.3033	968	1.11	0.2661	0.05	-0.2578	0.9328

Postprandial glucose increments (meal test) 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter=PPG inc. at 4 hours (mmol/L) Parameter Code=MTIC240 Study Identifier=NN1218-4131

The Mixed Procedure

Least Squares Means

Effect	Planned Treatment for Period 30 (N)	Margins	BASE	Estimate	Standard Error	DF	t Value	Pr > t	Alpha	Lower	Upper
TRTPN	2	WORK.ENDPOINT_2	2.57	-0.02994	0.2132	968	-0.14	0.8884	0.05	-0.4484	0.3885
TRTPN	3	WORK.ENDPOINT_2	2.57	0.4037	0.2138	968	1.89	0.0593	0.05	-0.01594	0.8233
TRTPN	4	WORK.ENDPOINT_2	2.57	0.06620	0.2151	968	0.31	0.7583	0.05	-0.3559	0.4883

14: Fasting plasma glucose 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=FPGU Planned Treatment for Period 30 (N)=2

Obs	PARAM	Description	Value
1	FPG (mg/dL)	Data Set	WORK.ENDPOINT_PARAM
2	FPG (mg/dL)	Method	Monotone-data_MCMC
3	FPG (mg/dL)	Multiple Imputation Chain	Multiple Chains
4	FPG (mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
5	FPG (mg/dL)	Start	Starting Value
6	FPG (mg/dL)	Prior	Jeffreys
7	FPG (mg/dL)	Number of Imputations	20000
8	FPG (mg/dL)	Number of Burn-in Iterations	200
9	FPG (mg/dL)	Seed for random number generator	1234

Parameter Code=FPGU Planned Treatment for Period 30 (N)=3

Obs	PARAM	Description	Value
10	FPG (mg/dL)	Data Set	WORK.ENDPOINT_PARAM
11	FPG (mg/dL)	Method	Monotone-data_MCMC
12	FPG (mg/dL)	Multiple Imputation Chain	Multiple Chains
13	FPG (mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
14	FPG (mg/dL)	Start	Starting Value
15	FPG (mg/dL)	Prior	Jeffreys
16	FPG (mg/dL)	Number of Imputations	20000
17	FPG (mg/dL)	Number of Burn-in Iterations	200
18	FPG (mg/dL)	Seed for random number generator	1908816431

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=FPGU Planned Treatment for Period 30 (N)=4

Obs	PARAM	Description	Value
19	FPG (mg/dL)	Data Set	WORK.ENDPOINT_PARAM
20	FPG (mg/dL)	Method	Monotone-data_MCMC
21	FPG (mg/dL)	Multiple Imputation Chain	Multiple Chains
22	FPG (mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
23	FPG (mg/dL)	Start	Starting Value
24	FPG (mg/dL)	Prior	Jeffreys
25	FPG (mg/dL)	Number of Imputations	20000
26	FPG (mg/dL)	Number of Burn-in Iterations	200
27	FPG (mg/dL)	Seed for random number generator	1429674529

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with MCMC
Missing data pattern

Parameter Code=FPGU Planned Treatment for Period 30 (N)=2

Obs	PARAM	Group	BASE_ Miss_	visit2200_ Miss_	visit3600_ Miss_	Freq	Percent	BASE	visit2200	visit3600
1	FPG (mg/dL)	1	X	X	X	326	95.60	123.027957	26.626485	2.752748
2	FPG (mg/dL)	2	X	X	O	3	0.88	142.358000	3.003333	.
3	FPG (mg/dL)	3	X	.	X	10	2.93	110.642800	.	16.218000
4	FPG (mg/dL)	4	X	O	O	2	0.59	129.744000	.	.

Parameter Code=FPGU Planned Treatment for Period 30 (N)=3

Obs	PARAM	Group	BASE_ Miss_	visit2200_ Miss_	visit3600_ Miss_	Freq	Percent	BASE	visit2200	visit3600
5	FPG (mg/dL)	1	X	X	X	325	96.15	123.816806	27.928228	8.244843
6	FPG (mg/dL)	2	X	X	O	9	2.66	139.955333	-0.400444	.
7	FPG (mg/dL)	3	X	.	X	4	1.18	134.699500	.	3.604000

Parameter Code=FPGU Planned Treatment for Period 30 (N)=4

Obs	PARAM	Group	BASE_ Miss_	visit2200_ Miss_	visit3600_ Miss_	Freq	Percent	BASE	visit2200	visit3600
8	FPG (mg/dL)	1	X	X	X	322	95.27	122.418478	27.707149	10.700075
9	FPG (mg/dL)	2	X	X	O	9	2.66	130.144444	44.449333	.
10	FPG (mg/dL)	3	X	.	X	5	1.48	107.399200	.	1.802000
11	FPG (mg/dL)	4	X	O	O	2	0.59	88.298000	.	.

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=FPGU Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM	Description	Value
1	1	FPG (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	FPG (mg/dL)	Method	Monotone
3	1	FPG (mg/dL)	Number of Imputations	1
4	1	FPG (mg/dL)	Seed for random number generator	4321

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=FPGU Planned Treatment for Period 30 (N)=2

O b s	I m p u t a t i o n _	P A R A M E T E R S	G r o u p	R E G I O N 1	B O L U S I N G 1	B O L U S I N G 2	B O L U S I N G 3	B O L U S I N G 4	B O L U S I N G 5	F r e q	P e r c e n t	B A S E	v i s i t s	v i s i t s
1	1	FPG (mg/dL)	1	X	X	X	X	X		336	98.53	122.659351	26.293303	3.153500
2	1	FPG (mg/dL)	2	X	X	X	X	.		3	0.88	142.358000	3.003333	.
3	1	FPG (mg/dL)	3	X	X	X	.	.		2	0.59	129.744000	.	.

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=FPGU Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
1	1	FPG (mg/dL)	Intercept			-0.01283	0.022844
2	1	FPG (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)		-0.16334	-0.127417
3	1	FPG (mg/dL)	REGION1	EUROPE		-0.08456	-0.221404
4	1	FPG (mg/dL)	REGION1	JAPAN		0.16900	0.149507
5	1	FPG (mg/dL)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.00691	-0.054750
6	1	FPG (mg/dL)	BASE			-0.43464	-0.450579

Parameter Code=FPGU Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	FPG (mg/dL)	Intercept			0.00673	-0.018184
8	1	FPG (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)		-0.08123	-0.014278
9	1	FPG (mg/dL)	REGION1	EUROPE		-0.02534	-0.026635
10	1	FPG (mg/dL)	REGION1	JAPAN		0.10051	0.098778
11	1	FPG (mg/dL)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.09318	-0.043317
12	1	FPG (mg/dL)	BASE			-0.47412	-0.396244
13	1	FPG (mg/dL)	visit2200			0.20860	0.242431

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=FPGU Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM	Description	Value
1	1	FPG (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	FPG (mg/dL)	Method	Monotone
3	1	FPG (mg/dL)	Number of Imputations	1
4	1	FPG (mg/dL)	Seed for random number generator	4322

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=FPGU Planned Treatment for Period 30 (N)=3

O b s	I m p u t a t i o n _	P A R A M _	G r o u p	R E G I O N _	B O L _	B L A N K _	v i s i t _	v i s i t _	F r e q	P e r c e n t	B A S E	v i s i t _	v i s i t _
1	1	FPG (mg/dL)	1	X	X	X	X	X	329	97.34	123.949119	27.346666	8.188419
2	1	FPG (mg/dL)	2	X	X	X	X	.	9	2.66	139.955333	-0.400444	.

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=FPGU Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
1	1	FPG (mg/dL)	Intercept			-0.03813	0.051996
2	1	FPG (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)		-0.18186	-0.053517
3	1	FPG (mg/dL)	REGION1	EUROPE		-0.05301	-0.053887
4	1	FPG (mg/dL)	REGION1	JAPAN		0.22558	0.141823
5	1	FPG (mg/dL)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.06829	0.092116
6	1	FPG (mg/dL)	BASE			-0.51894	-0.570869
7	1	FPG (mg/dL)	visit2200			0.17017	0.081724

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=FPGU Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM	Description	Value
1	1	FPG (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	FPG (mg/dL)	Method	Monotone
3	1	FPG (mg/dL)	Number of Imputations	1
4	1	FPG (mg/dL)	Seed for random number generator	4323

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=FPGU Planned Treatment for Period 30 (N)=4

O b s	I m p u t a t i o n _	P A R A M	G r o u p	R E G I O N 1					B O L U S I N G 1					B O L U S I N G 2					B O L U S I N G 3					P e r c e n t					B A S E					v i s i t 2 0 0					v i s i t 3 6 0 0																																																																																																																																																																																																																																																																																																																																																																																																																				
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Fasting plasma glucose 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=FPGU Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
1	1	FPG (mg/dL)	Intercept			0.01667	-0.030217
2	1	FPG (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)		0.02856	0.078043
3	1	FPG (mg/dL)	REGION1	EUROPE		0.06649	-0.047367
4	1	FPG (mg/dL)	REGION1	JAPAN		0.09155	0.130229
5	1	FPG (mg/dL)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.05201	-0.050527
6	1	FPG (mg/dL)	BASE			-0.52929	-0.605619

Parameter Code=FPGU Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	FPG (mg/dL)	Intercept			0.00575	-0.051341
8	1	FPG (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)		-0.10669	-0.187366
9	1	FPG (mg/dL)	REGION1	EUROPE		0.07899	0.134376
10	1	FPG (mg/dL)	REGION1	JAPAN		0.17900	0.272509
11	1	FPG (mg/dL)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.07958	-0.051987
12	1	FPG (mg/dL)	BASE			-0.49586	-0.459925
13	1	FPG (mg/dL)	visit2200			0.17260	0.150869

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=C105585P Planned Treatment for Period 30 (N)=2

Obs	PARAM	Description	Value
1	FPG (mmol/L)	Data Set	WORK.ENDPOINT_PARAM
2	FPG (mmol/L)	Method	Monotone-data_MCMC
3	FPG (mmol/L)	Multiple Imputation Chain	Multiple Chains
4	FPG (mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
5	FPG (mmol/L)	Start	Starting Value
6	FPG (mmol/L)	Prior	Jeffreys
7	FPG (mmol/L)	Number of Imputations	20000
8	FPG (mmol/L)	Number of Burn-in Iterations	200
9	FPG (mmol/L)	Seed for random number generator	1234

Parameter Code=C105585P Planned Treatment for Period 30 (N)=3

Obs	PARAM	Description	Value
10	FPG (mmol/L)	Data Set	WORK.ENDPOINT_PARAM
11	FPG (mmol/L)	Method	Monotone-data_MCMC
12	FPG (mmol/L)	Multiple Imputation Chain	Multiple Chains
13	FPG (mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
14	FPG (mmol/L)	Start	Starting Value
15	FPG (mmol/L)	Prior	Jeffreys
16	FPG (mmol/L)	Number of Imputations	20000
17	FPG (mmol/L)	Number of Burn-in Iterations	200
18	FPG (mmol/L)	Seed for random number generator	1908816431

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=C105585P Planned Treatment for Period 30 (N)=4

Obs	PARAM	Description	Value
19	FPG (mmol/L)	Data Set	WORK.ENDPOINT_PARAM
20	FPG (mmol/L)	Method	Monotone-data_MCMC
21	FPG (mmol/L)	Multiple Imputation Chain	Multiple Chains
22	FPG (mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
23	FPG (mmol/L)	Start	Starting Value
24	FPG (mmol/L)	Prior	Jeffreys
25	FPG (mmol/L)	Number of Imputations	20000
26	FPG (mmol/L)	Number of Burn-in Iterations	200
27	FPG (mmol/L)	Seed for random number generator	1429674529

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with MCMC
Missing data pattern

Parameter Code=C105585P Planned Treatment for Period 30 (N)=2

Obs	PARAM	Group	BASE_ Miss_	visit2200_ Miss_	visit3600_ Miss_	Freq	Percent	BASE	visit2200	visit3600
1	FPG (mmol/L)	1	X	X	X	326	95.60	6.827301	1.477607	0.152761
2	FPG (mmol/L)	2	X	X	O	3	0.88	7.900000	0.166667	.
3	FPG (mmol/L)	3	X	.	X	10	2.93	6.140000	.	0.900000
4	FPG (mmol/L)	4	X	O	O	2	0.59	7.200000	.	.

Parameter Code=C105585P Planned Treatment for Period 30 (N)=3

Obs	PARAM	Group	BASE_ Miss_	visit2200_ Miss_	visit3600_ Miss_	Freq	Percent	BASE	visit2200	visit3600
5	FPG (mmol/L)	1	X	X	X	325	96.15	6.871077	1.549846	0.457538
6	FPG (mmol/L)	2	X	X	O	9	2.66	7.766667	-0.022222	.
7	FPG (mmol/L)	3	X	.	X	4	1.18	7.475000	.	0.200000

Parameter Code=C105585P Planned Treatment for Period 30 (N)=4

Obs	PARAM	Group	BASE_ Miss_	visit2200_ Miss_	visit3600_ Miss_	Freq	Percent	BASE	visit2200	visit3600
8	FPG (mmol/L)	1	X	X	X	322	95.27	6.793478	1.537578	0.593789
9	FPG (mmol/L)	2	X	X	O	9	2.66	7.222222	2.466667	.
10	FPG (mmol/L)	3	X	.	X	5	1.48	5.960000	.	0.100000
11	FPG (mmol/L)	4	X	O	O	2	0.59	4.900000	.	.

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=C105585P Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM	Description	Value
1	1	FPG (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	FPG (mmol/L)	Method	Monotone
3	1	FPG (mmol/L)	Number of Imputations	1
4	1	FPG (mmol/L)	Seed for random number generator	4321

Fast-acting insulin aspart
NN1218-4131

Clinical Trial Report
Statistical document

Date:
Version:

14 February 2018
1.0

Status:
Page:

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Novo Nordisk

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=C105585P Planned Treatment for Period 30 (N)=2

O b s	I m p u t a t i o n _	P A R A M _	G r o u p	R E G I O N 1	B O L D 1	B L A D S E	v i s i t 2	v i s i t 3	F r e q	P e r c e n t	B A S E	v i s i t 2	v i s i t 3
1	1	FPG (mmol/L)	1	X	X	X	X	X	336	98.53	6.806845	1.459118	0.175000
2	1	FPG (mmol/L)	2	X	X	X	X	.	3	0.88	7.900000	0.166667	.
3	1	FPG (mmol/L)	3	X	X	X	.	.	2	0.59	7.200000	.	.

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression Regression Information

Parameter Code=C105585P Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2200

[illegible]

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=C105585P Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

Imputed a t i o n s		P A R A M E T E R	E F F E C T	R E G I O N	B O L U S	O b s e r v e d	
7	1	FPG (mmol/L)	Intercept			0.00673	-0.018184
8	1	FPG (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)		-0.08123	-0.014278
9	1	FPG (mmol/L)	REGION1	EUROPE		-0.02534	-0.026635
10	1	FPG (mmol/L)	REGION1	JAPAN		0.10051	0.098778
11	1	FPG (mmol/L)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.09318	-0.043317
12	1	FPG (mmol/L)	BASE			-0.47412	-0.396244
13	1	FPG (mmol/L)	visit2200			0.20860	0.242431

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=C105585P Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM	Description	Value
1	1	FPG (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	FPG (mmol/L)	Method	Monotone
3	1	FPG (mmol/L)	Number of Imputations	1
4	1	FPG (mmol/L)	Seed for random number generator	4322

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=C105585P Planned Treatment for Period 30 (N)=3

O b s	I m p u t a t i o n _	P A R A M _	G r o u p	R E G I O N _			v i s i t i t _		F r e q	P e r c e n t	B A S E	v i s i t _	v i s i t _
				M	M	M	M	M					
1	1	FPG (mmol/L)	1	X	X	X	X	X	329	97.34	6.878419	1.517573	0.454407
2	1	FPG (mmol/L)	2	X	X	X	X	.	9	2.66	7.766667	-0.022222	.

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=C105585P Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

O b s	I m p u t a t i o n s	P A R A M E T E R	E F F E C T	R E G I O N	B O L U S	O b s e r v e d	I
1	1	FPG (mmol/L)	Intercept			-0.03813	0.051996
2	1	FPG (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)		-0.18186	-0.053517
3	1	FPG (mmol/L)	REGION1	EUROPE		-0.05301	-0.053887
4	1	FPG (mmol/L)	REGION1	JAPAN		0.22558	0.141823
5	1	FPG (mmol/L)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.06829	0.092116
6	1	FPG (mmol/L)	BASE			-0.51894	-0.570869
7	1	FPG (mmol/L)	visit2200			0.17017	0.081724

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=C105585P Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM	Description	Value
1	1	FPG (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	FPG (mmol/L)	Method	Monotone
3	1	FPG (mmol/L)	Number of Imputations	1
4	1	FPG (mmol/L)	Seed for random number generator	4323

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=C105585P Planned Treatment for Period 30 (N)=4

O b s	I m p u t a t i o n _	P A R A M E T E R	G r o u p	R E G I O N 1	B O L D 1	B L A N K 1	B L A N K 2	B L A N K 3	B L A N K 4	F r e q	P e r c e n t	B A S E	v i s i t 2 0	v i s i t 3 0
1	1	FPG (mmol/L)	1	X	X	X	X	X		327	96.75	6.780734	1.540982	0.586239
2	1	FPG (mmol/L)	2	X	X	X	X	.		9	2.66	7.222222	2.466667	.
3	1	FPG (mmol/L)	3	X	X	X	.	.		2	0.59	4.900000	.	.

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=C105585P Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2200

Obs	N	Imputed	P	E	R	B	O	\bar{I}
			A	f	E	O	b	
			R	e	G	L	s	
			A	c	I	A	V	
			M	t	N	D	a	
					1	1	1	
1	1	FPG (mmol/L)	Intercept				0.01667	-0.030217
2	1	FPG (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)			0.02856	0.078043
3	1	FPG (mmol/L)	REGION1	EUROPE			0.06649	-0.047367
4	1	FPG (mmol/L)	REGION1	JAPAN			0.09155	0.130229
5	1	FPG (mmol/L)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.05201	-0.050527
6	1	FPG (mmol/L)	BASE				-0.52929	-0.605619

```
nn1218/nn1218-4131/ctr_20180214_er
09FEB2018:20:27:20 - a lab stat diff.sas/a fpg stat in_fas app.txt
```

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure Model Information

Parameter Code=C105585P Parameter=FPG (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Data Set	WORK.IMPUTE
2	1	NN1218-4131	Dependent Variable	eotVisit
3	1	NN1218-4131	Covariance Structure	Diagonal
4	1	NN1218-4131	Estimation Method	REML
5	1	NN1218-4131	Residual Variance Method	Profile
6	1	NN1218-4131	Fixed Effects SE Method	Model-Based
7	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=FPGU Parameter=FPG (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
8	1	NN1218-4131	Data Set	WORK.IMPUTE
9	1	NN1218-4131	Dependent Variable	eotVisit
10	1	NN1218-4131	Covariance Structure	Diagonal
11	1	NN1218-4131	Estimation Method	REML
12	1	NN1218-4131	Residual Variance Method	Profile
13	1	NN1218-4131	Fixed Effects SE Method	Model-Based
14	1	NN1218-4131	Degrees of Freedom Method	Residual

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Class Level Information

Parameter Code=C105585P Parameter=FPG (mmol/L)

		Input data				Output	
		Study	Country	Region	Visit	Value	Label
		O	b	s			
		1	2	3	4	5	6
1	1	NN1218-4131	TRTPN				
2	1	NN1218-4131	REGION1				
3	1	NN1218-4131	BOLAD1				
		3 2 3 4				5	
		4 ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA				49	
		2 BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULI				85	

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Class Level Information

Parameter Code=FPGU Parameter=FPG (mg/dL)

		Input				Output					
		S				L					
		T				V					
		U				a					
		D				l					
		Y				u					
		I				e					
		D				s					
4	1	NN1218-4131	TRTPN			3	2	3	4		5
5	1	NN1218-4131	REGION1			4	ASIA (EXCLUDING JAPAN)	EUROPE	JAPAN	NORTH AMERICA	49
6	1	NN1218-4131	BOLAD1			2	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	CARBOHYDRATE COUNTING (FLEXIBLE)	BOLUS	INSULI	85

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Dimensions

Parameter Code=C105585P Parameter=FPG (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Covariance Parameters	1
2	1	NN1218-4131	Columns in X	10
3	1	NN1218-4131	Columns in Z	0
4	1	NN1218-4131	Subjects	1
5	1	NN1218-4131	Max Obs per Subject	1017

Parameter Code=FPGU Parameter=FPG (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
6	1	NN1218-4131	Covariance Parameters	1
7	1	NN1218-4131	Columns in X	10
8	1	NN1218-4131	Columns in Z	0
9	1	NN1218-4131	Subjects	1
10	1	NN1218-4131	Max Obs per Subject	1017

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Number of Observations

Parameter Code=C105585P Parameter=FPG (mmol/L)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
1	1	NN1218-4131	Number of Observations Read	1017	1017	1017	1017	1017
2	1	NN1218-4131	Number of Observations Used	1017	1017	1017	1017	1017
3	1	NN1218-4131	Number of Observations Not Used	0	1017	1017	1017	1017

Parameter Code=FPGU Parameter=FPG (mg/dL)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
4	1	NN1218-4131	Number of Observations Read	1017	1017	1017	1017	1017
5	1	NN1218-4131	Number of Observations Used	1017	1017	1017	1017	1017
6	1	NN1218-4131	Number of Observations Not Used	0	1017	1017	1017	1017

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Covariance Parameter Estimates

Parameter Code=C105585P Parameter=FPG (mmol/L)

Obs	_Imputation_	STUDYID	CovParm	Estimate
1	1	NN1218-4131	Residual	6.5315

Parameter Code=FPGU Parameter=FPG (mg/dL)

Obs	_Imputation_	STUDYID	CovParm	Estimate
20001	1	NN1218-4131	Residual	2120.90

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Fit Statistics

Parameter Code=C105585P Parameter=FPG (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	-2 Res Log Likelihood	4803.3
2	1	NN1218-4131	AIC (Smaller is Better)	4805.3
3	1	NN1218-4131	AICC (Smaller is Better)	4805.3
4	1	NN1218-4131	BIC (Smaller is Better)	4810.3

Parameter Code=FPGU Parameter=FPG (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
5	1	NN1218-4131	-2 Res Log Likelihood	10644.1
6	1	NN1218-4131	AIC (Smaller is Better)	10646.1
7	1	NN1218-4131	AICC (Smaller is Better)	10646.1
8	1	NN1218-4131	BIC (Smaller is Better)	10651.1

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Solution for Fixed Effects

Parameter Code=C105585P Parameter=FPG (mmol/L)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1		BOLAD1
1	1	NN1218-4131	TRTPN	2			
2	1	NN1218-4131	TRTPN	3			
3	1	NN1218-4131	TRTPN	4			
4	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)		
5	1	NN1218-4131	REGION1	—	EUROPE		
6	1	NN1218-4131	REGION1	—	JAPAN		
7	1	NN1218-4131	REGION1	—	NORTH AMERICA		
8	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	
9	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE)	BOLUS INSULIN THERAPY
10	1	NN1218-4131	BASE	—			

Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	5.4144	0.2985	1009	18.14	<.0001	0.05	4.8287	6.0001
2	5.7277	0.3020	1009	18.96	<.0001	0.05	5.1350	6.3204
3	5.8065	0.2998	1009	19.37	<.0001	0.05	5.2182	6.3948
4	-0.2773	0.2944	1009	-0.94	0.3465	0.05	-0.8551	0.3004
5	0.1797	0.2061	1009	0.87	0.3836	0.05	-0.2248	0.5842
6	0.8446	0.2303	1009	3.67	0.0003	0.05	0.3926	1.2966
7	0
8	-0.2292	0.1796	1009	-1.28	0.2023	0.05	-0.5816	0.1233
9	0
10	-0.7834	0.03395	1009	-23.07	<.0001	0.05	-0.8500	-0.7168

Fast-acting insulin aspart
NN1218-4131

Clinical Trial Report
Statistical document

Date:
Version:

14 February 2018
1.0

Status:
Page:

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Novo Nordisk

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Solution for Fixed Effects

Parameter Code=FPGU Parameter=FPG (mg/dL)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
11	1	NN1218-4131	TRTPN	2				
12	1	NN1218-4131	TRTPN	3				
13	1	NN1218-4131	TRTPN	4				
14	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
15	1	NN1218-4131	REGION1	—	EUROPE			
16	1	NN1218-4131	REGION1	—	JAPAN			
17	1	NN1218-4131	REGION1	—	NORTH AMERICA			
18	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
19	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
20	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
11	97.5678	5.3784	1009	18.14	<.0001	0.05	87.0137	108.12
12	103.21	5.4428	1009	18.96	<.0001	0.05	92.5334	113.89
13	104.63	5.4023	1009	19.37	<.0001	0.05	94.0324	115.23
14	-4.9974	5.3057	1009	-0.94	0.3465	0.05	-15.4089	5.4140
15	3.2378	3.7145	1009	0.87	0.3836	0.05	-4.0512	10.5269
16	15.2189	4.1507	1009	3.67	0.0003	0.05	7.0738	23.3639
17	0
18	-4.1294	3.2365	1009	-1.28	0.2023	0.05	-10.4804	2.2217
19	0
20	-0.7834	0.03395	1009	-23.07	<.0001	0.05	-0.8500	-0.7168

nn1218/nn1218-4131/ctr_20180214_er
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Fasting plasma glucose 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Least Squares Means

O b s	I m p u t a t i o n	P A R M S	P A R M	U N I T	S T U D Y	E F F T	T R T P N	M A R G I N S	E S T I M A T E	S T D E R	D F	t V a l u e	P r o b a b i l i t y	A d j u s t e d	L o w e r	U p p e r
1	1	C105585P	FPG	(mmol/L)	NN1218-4131	TRTPN	2	WORK.IMPUTE	0.1560	0.1386	1009	1.13	0.2605	0.05	-0.1159	0.4280
2	1	C105585P	FPG	(mmol/L)	NN1218-4131	TRTPN	3	WORK.IMPUTE	0.4694	0.1392	1009	3.37	0.0008	0.05	0.1962	0.7425
3	1	C105585P	FPG	(mmol/L)	NN1218-4131	TRTPN	4	WORK.IMPUTE	0.5481	0.1392	1009	3.94	<.0001	0.05	0.2751	0.8212
4	1	FPGU	FPG	(mg/dL)	NN1218-4131	TRTPN	2	WORK.IMPUTE	2.8118	2.4974	1009	1.13	0.2605	0.05	-2.0888	7.7124
5	1	FPGU	FPG	(mg/dL)	NN1218-4131	TRTPN	3	WORK.IMPUTE	8.4579	2.5080	1009	3.37	0.0008	0.05	3.5364	13.3794
6	1	FPGU	FPG	(mg/dL)	NN1218-4131	TRTPN	4	WORK.IMPUTE	9.8774	2.5076	1009	3.94	<.0001	0.05	4.9567	14.7981

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Least Squares Means Estimate

Parameter Code=C105585P Parameter=FPG (mmol/L)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
1	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
2	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	WORK.IMPUTE	-0.3921	0.1965	1009	-2.00	0.0463	0.05	-0.7777	-0.00647
2	WORK.IMPUTE	-0.07877	0.1969	1009	-0.40	0.6892	0.05	-0.4652	0.3076

Parameter Code=FPGU Parameter=FPG (mg/dL)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
3	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
4	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
3	WORK.IMPUTE	-7.0656	3.5412	1009	-2.00	0.0463	0.05	-14.0145	-0.1167
4	WORK.IMPUTE	-1.4195	3.5481	1009	-0.40	0.6892	0.05	-8.3821	5.5431

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=C105585P Parameter=FPG (mmol/L) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000247	0.019113	0.019359	1.23E8	0.012919	0.012755	0.999999

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.167674	0.139138	-0.10503	0.440380	1.23E8	0.101472	0.228715

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	1.21	0.2282

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=FPGU Parameter=FPG (mg/dL) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.080176	6.206220	6.286400	1.23E8	0.012919	0.012755	0.999999

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	3.021483	2.507269	-1.89267	7.935641	1.23E8	1.828517	4.121446

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	1.21	0.2282

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=C105585P Parameter=FPG (mmol/L) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000525	0.019276	0.019802	2.84E7	0.027263	0.026539	0.999999

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.459263	0.140718	0.183460	0.735066	2.84E7	0.362986	0.548597

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	3.26	0.0011

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=FPGU Parameter=FPG (mg/dL) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.170638	6.259348	6.429994	2.84E7	0.027263	0.026539	0.999999

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits	DF	Minimum	Maximum
Estimate	8.275918	2.535743	3.305952 13.24588	2.84E7	6.541012	9.885719

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	3.26	0.0011

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=C105585P Parameter=FPG (mmol/L) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000677	0.019270	0.019946	1.74E7	0.035121	0.033930	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.557184	0.141232	0.280375	0.833993	1.74E7	0.442166	0.662431

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	3.95	<.0001

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=FPGU Parameter=FPG (mg/dL) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.219750	6.257240	6.477001	1.74E7	0.035121	0.033930	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits	DF	Minimum	Maximum
Estimate	10.040458	2.544995	5.052358 15.02856	1.74E7	7.967835	11.937010

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	3.95	<.0001

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=C105585P Label=Faster aspart (meal) - NovoRapid (meal) Parameter=FPG (mmol/L) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000911	0.038429	0.039340	3.73E7	0.023702	0.023153	0.999999

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.389510	0.198342	-0.77825	-0.00077	3.73E7	-0.508304	-0.264264

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-1.96	0.0495

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=C105585P Label=Faster aspart (post) - NovoRapid (meal) Parameter=FPG (mmol/L) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.001202	0.038580	0.039781	2.19E7	0.031151	0.030210	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.097921	0.199453	-0.48884	0.293000	2.19E7	-0.229001	0.046634

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-0.49	0.6235

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 1159 of 4425	Novo Nordisk
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Fasting plasma glucose 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=FPGU Label=Faster aspart (meal) - NovoRapid (meal) Parameter=FPG (mg/dL) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.295752	12.478577	12.774344	3.73E7	0.023702	0.023153	0.999999

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-7.018975	3.574121	-14.0241	-0.01383	3.73E7	-9.159645	-4.762030

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-1.96	0.0495

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Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 1160 of 4425	Novo Nordisk
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Fasting plasma glucose 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=FPGU Label=Faster aspart (post) - NovoRapid (meal) Parameter=FPG (mg/dL) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.390224	12.527620	12.917864	2.19E7	0.031151	0.030210	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-1.764540	3.594143	-8.80893	5.279851	2.19E7	-4.126592	0.840346

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-0.49	0.6235

nn1218/nn1218-4131/ctr_20180214_er
09FEB2018:20:27:20 - a_lab_stat_diff.sas/a_fpg_stat_in_fas_app.txt

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure Model Information

Parameter Code=C105585P Parameter=FPG (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Data Set	WORK.IMPUTE_ABS
2	1	NN1218-4131	Dependent Variable	eotVisitAbs
3	1	NN1218-4131	Covariance Structure	Diagonal
4	1	NN1218-4131	Estimation Method	REML
5	1	NN1218-4131	Residual Variance Method	Profile
6	1	NN1218-4131	Fixed Effects SE Method	Model-Based
7	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=FPGU Parameter=FPG (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
8	1	NN1218-4131	Data Set	WORK.IMPUTE_ABS
9	1	NN1218-4131	Dependent Variable	eotVisitAbs
10	1	NN1218-4131	Covariance Structure	Diagonal
11	1	NN1218-4131	Estimation Method	REML
12	1	NN1218-4131	Residual Variance Method	Profile
13	1	NN1218-4131	Fixed Effects SE Method	Model-Based
14	1	NN1218-4131	Degrees of Freedom Method	Residual

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Class Level Information

Parameter Code=C105585P Parameter=FPG (mmol/L)

		Input		Output		Level		Variable		Length	
O	b	s	—	S	T	C	L	V	a	l	g
				D	U	D	e	a			t
				Y	I	s	v	l			h
				D	s	s		s			
1	1	NN1218-4131	TRTPN				3	2	3	4	5
2	1	NN1218-4131	REGION1				4	ASIA (EXCLUDING JAPAN)	EUROPE	JAPAN	49
3	1	NN1218-4131	BOLAD1				2	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	CARBOHYDRATE COUNTING (FLEXIBLE)	BOLUS INSULI	85

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Class Level Information

Parameter Code=FPGU Parameter=FPG (mg/dL)

		Input		Status		Level		Variable		Minimum	
Obs		on		Y		I		D		e	
s		—		D		s		s		h	
4	1	NN1218-4131	TRTPN	3	2	3	4				5
5	1	NN1218-4131	REGION1	4	ASIA (EXCLUDING JAPAN)	EUROPE	JAPAN	NORTH AMERICA			49
6	1	NN1218-4131	BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	CARBOHYDRATE COUNTING (FLEXIBLE)	BOLUS INSULI				85

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Dimensions

Parameter Code=C105585P Parameter=FPG (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Covariance Parameters	1
2	1	NN1218-4131	Columns in X	10
3	1	NN1218-4131	Columns in Z	0
4	1	NN1218-4131	Subjects	1
5	1	NN1218-4131	Max Obs per Subject	1017

Parameter Code=FPGU Parameter=FPG (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
6	1	NN1218-4131	Covariance Parameters	1
7	1	NN1218-4131	Columns in X	10
8	1	NN1218-4131	Columns in Z	0
9	1	NN1218-4131	Subjects	1
10	1	NN1218-4131	Max Obs per Subject	1017

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Number of Observations

Parameter Code=C105585P Parameter=FPG (mmol/L)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
1	1	NN1218-4131	Number of Observations Read	1017	1017	1017	1017	1017
2	1	NN1218-4131	Number of Observations Used	1017	1017	1017	1017	1017
3	1	NN1218-4131	Number of Observations Not Used	0	1017	1017	1017	1017

Parameter Code=FPGU Parameter=FPG (mg/dL)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
4	1	NN1218-4131	Number of Observations Read	1017	1017	1017	1017	1017
5	1	NN1218-4131	Number of Observations Used	1017	1017	1017	1017	1017
6	1	NN1218-4131	Number of Observations Not Used	0	1017	1017	1017	1017

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Covariance Parameter Estimates

Parameter Code=C105585P Parameter=FPG (mmol/L)

Obs	_Imputation_	STUDYID	CovParm	Estimate
1	1	NN1218-4131	Residual	6.5315

Parameter Code=FPGU Parameter=FPG (mg/dL)

Obs	_Imputation_	STUDYID	CovParm	Estimate
20001	1	NN1218-4131	Residual	2120.90

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Fit Statistics

Parameter Code=C105585P Parameter=FPG (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	-2 Res Log Likelihood	4803.3
2	1	NN1218-4131	AIC (Smaller is Better)	4805.3
3	1	NN1218-4131	AICC (Smaller is Better)	4805.3
4	1	NN1218-4131	BIC (Smaller is Better)	4810.3

Parameter Code=FPGU Parameter=FPG (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
5	1	NN1218-4131	-2 Res Log Likelihood	10644.1
6	1	NN1218-4131	AIC (Smaller is Better)	10646.1
7	1	NN1218-4131	AICC (Smaller is Better)	10646.1
8	1	NN1218-4131	BIC (Smaller is Better)	10651.1

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Solution for Fixed Effects

Parameter Code=C105585P Parameter=FPG (mmol/L)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
1	1	NN1218-4131	TRTPN	2				
2	1	NN1218-4131	TRTPN	3				
3	1	NN1218-4131	TRTPN	4				
4	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
5	1	NN1218-4131	REGION1	—	EUROPE			
6	1	NN1218-4131	REGION1	—	JAPAN			
7	1	NN1218-4131	REGION1	—	NORTH AMERICA			
8	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
9	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
10	1	NN1218-4131	BASE	—				

Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	5.4144	0.2985	1009	18.14	<.0001	0.05	4.8287	6.0001
2	5.7277	0.3020	1009	18.96	<.0001	0.05	5.1350	6.3204
3	5.8065	0.2998	1009	19.37	<.0001	0.05	5.2182	6.3948
4	-0.2773	0.2944	1009	-0.94	0.3465	0.05	-0.8551	0.3004
5	0.1797	0.2061	1009	0.87	0.3836	0.05	-0.2248	0.5842
6	0.8446	0.2303	1009	3.67	0.0003	0.05	0.3926	1.2966
7	0
8	-0.2292	0.1796	1009	-1.28	0.2023	0.05	-0.5816	0.1233
9	0
10	0.2166	0.03395	1009	6.38	<.0001	0.05	0.1500	0.2832

Fast-acting insulin aspart
NN1218-4131

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1.0

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Fasting plasma glucose 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Solution for Fixed Effects

Parameter Code=FPGU Parameter=FPG (mg/dL)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1		BOLAD1	
11	1	NN1218-4131	TRTPN	2				
12	1	NN1218-4131	TRTPN	3				
13	1	NN1218-4131	TRTPN	4				
14	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
15	1	NN1218-4131	REGION1	—	EUROPE			
16	1	NN1218-4131	REGION1	—	JAPAN			
17	1	NN1218-4131	REGION1	—	NORTH AMERICA			
18	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
19	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE)	BOLUS INSULIN THERAPY	
20	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
11	97.5678	5.3784	1009	18.14	<.0001	0.05	87.0137	108.12
12	103.21	5.4428	1009	18.96	<.0001	0.05	92.5334	113.89
13	104.63	5.4023	1009	19.37	<.0001	0.05	94.0324	115.23
14	-4.9974	5.3057	1009	-0.94	0.3465	0.05	-15.4089	5.4140
15	3.2378	3.7145	1009	0.87	0.3836	0.05	-4.0512	10.5269
16	15.2189	4.1507	1009	3.67	0.0003	0.05	7.0738	23.3639
17	0
18	-4.1294	3.2365	1009	-1.28	0.2023	0.05	-10.4804	2.2217
19	0
20	0.2166	0.03395	1009	6.38	<.0001	0.05	0.1500	0.2832

nn1218/nn1218-4131/ctr_20180214_er
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Fasting plasma glucose 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Least Squares Means

		Impute		PARC		STUDY		Efficient		Marginal		Estimate		Standard Error		t Value		Pr > t		Alpha		Lower		Upper	
Obs																									
1	1	C105585P	FPG	(mmol/L)	NN1218-4131	TRTPN	2	WORK.IMPUTE	0.1560	0.1386	1009	1.13	0.2605	0.05	-0.1159	0.4280									
20001	1	FPGU	FPG	(mg/dL)	NN1218-4131	TRTPN	2	WORK.IMPUTE	2.8118	2.4974	1009	1.13	0.2605	0.05	-2.0888	7.7124									
40001	1	C105585P	FPG	(mmol/L)	NN1218-4131	TRTPN	3	WORK.IMPUTE	0.4694	0.1392	1009	3.37	0.0008	0.05	0.1962	0.7425									
60001	1	FPGU	FPG	(mg/dL)	NN1218-4131	TRTPN	3	WORK.IMPUTE	8.4579	2.5080	1009	3.37	0.0008	0.05	3.5364	13.3794									
80001	1	C105585P	FPG	(mmol/L)	NN1218-4131	TRTPN	4	WORK.IMPUTE	0.5481	0.1392	1009	3.94	<.0001	0.05	0.2751	0.8212									
100001	1	FPGU	FPG	(mg/dL)	NN1218-4131	TRTPN	4	WORK.IMPUTE	9.8774	2.5076	1009	3.94	<.0001	0.05	4.9567	14.7981									

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Least Squares Means Estimate

Parameter Code=C105585P Parameter=FPG (mmol/L)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
1	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
20001	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	WORK.IMPUTE	-0.3921	0.1965	1009	-2.00	0.0463	0.05	-0.7777	-0.00647
20001	WORK.IMPUTE	-0.07877	0.1969	1009	-0.40	0.6892	0.05	-0.4652	0.3076

Parameter Code=FPGU Parameter=FPG (mg/dL)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
40001	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
60001	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
40001	WORK.IMPUTE	-7.0656	3.5412	1009	-2.00	0.0463	0.05	-14.0145	-0.1167
60001	WORK.IMPUTE	-1.4195	3.5481	1009	-0.40	0.6892	0.05	-8.3821	5.5431

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=C105585P Parameter=FPG (mmol/L) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000247	0.019113	0.019359	1.23E8	0.012919	0.012755	0.999999

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits	DF	Minimum	Maximum
Estimate	7.001696	0.139138	6.728990 7.274401	1.23E8	6.935493	7.062737

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	50.32	<.0001

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=FPGU Parameter=FPG (mg/dL) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.080176	6.206220	6.286400	1.23E8	0.012919	0.012755	0.999999

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	126.170553	2.507269	121.2564	131.0847	1.23E8	124.977587	127.270515

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	50.32	<.0001

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=C105585P Parameter=FPG (mmol/L) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000525	0.019276	0.019802	2.84E7	0.027263	0.026539	0.999999

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	7.293285	0.140718	7.017482	7.569087	2.84E7	7.197008	7.382619

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	51.83	<.0001

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=FPGU Parameter=FPG (mg/dL) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.170638	6.259348	6.429994	2.84E7	0.027263	0.026539	0.999999

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	131.424988	2.535743	126.4550	136.3950	2.84E7	129.690082	133.034789

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	51.83	<.0001

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=C105585P Parameter=FPG (mmol/L) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000677	0.019270	0.019946	1.74E7	0.035121	0.033930	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	7.391206	0.141232	7.114397	7.668015	1.74E7	7.276188	7.496453

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	52.33	<.0001

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=FPGU Parameter=FPG (mg/dL) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.219750	6.257240	6.477001	1.74E7	0.035121	0.033930	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	133.189528	2.544995	128.2014	138.1776	1.74E7	131.116904	135.086080

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	52.33	<.0001

15: Fasting plasma glucose 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=FPGU Planned Treatment for Period 30 (N)=2

Obs	PARAM	Description	Value
1	FPG (mg/dL)	Data Set	WORK.ENDPOINT_PARAM
2	FPG (mg/dL)	Method	Monotone-data_MCMC
3	FPG (mg/dL)	Multiple Imputation Chain	Multiple Chains
4	FPG (mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
5	FPG (mg/dL)	Start	Starting Value
6	FPG (mg/dL)	Prior	Jeffreys
7	FPG (mg/dL)	Number of Imputations	20000
8	FPG (mg/dL)	Number of Burn-in Iterations	200
9	FPG (mg/dL)	Seed for random number generator	1234

Parameter Code=FPGU Planned Treatment for Period 30 (N)=3

Obs	PARAM	Description	Value
10	FPG (mg/dL)	Data Set	WORK.ENDPOINT_PARAM
11	FPG (mg/dL)	Method	Monotone-data_MCMC
12	FPG (mg/dL)	Multiple Imputation Chain	Multiple Chains
13	FPG (mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
14	FPG (mg/dL)	Start	Starting Value
15	FPG (mg/dL)	Prior	Jeffreys
16	FPG (mg/dL)	Number of Imputations	20000
17	FPG (mg/dL)	Number of Burn-in Iterations	200
18	FPG (mg/dL)	Seed for random number generator	1908816431

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=FPGU Planned Treatment for Period 30 (N)=4

Obs	PARAM	Description	Value
19	FPG (mg/dL)	Data Set	WORK.ENDPOINT_PARAM
20	FPG (mg/dL)	Method	Monotone-data_MCMC
21	FPG (mg/dL)	Multiple Imputation Chain	Multiple Chains
22	FPG (mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
23	FPG (mg/dL)	Start	Starting Value
24	FPG (mg/dL)	Prior	Jeffreys
25	FPG (mg/dL)	Number of Imputations	20000
26	FPG (mg/dL)	Number of Burn-in Iterations	200
27	FPG (mg/dL)	Seed for random number generator	1429674529

Fast-acting insulin aspart
NN1218-4131

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Fasting plasma glucose 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC
Missing data pattern

Parameter Code=FPGU Planned Treatment for Period 30 (N)=2

Obs	PARAM	Group	BASE_ Miss_	visit2200_ Miss_	visit3600_ Miss_	Freq	Percent	BASE	visit2200	visit3600
1	FPG (mg/dL)	1	X	X	X	325	95.31	123.284523	26.320289	2.118043
2	FPG (mg/dL)	2	X	X	O	4	1.17	116.679500	68.926500	.
3	FPG (mg/dL)	3	X	.	X	10	2.93	110.642800	.	16.218000
4	FPG (mg/dL)	4	X	O	O	2	0.59	129.744000	.	.

Parameter Code=FPGU Planned Treatment for Period 30 (N)=3

Obs	PARAM	Group	BASE_ Miss_	visit2200_ Miss_	visit3600_ Miss_	Freq	Percent	BASE	visit2200	visit3600
5	FPG (mg/dL)	1	X	X	X	324	95.86	123.737333	27.814204	8.097877
6	FPG (mg/dL)	2	X	X	O	9	2.66	139.955333	-0.400444	.
7	FPG (mg/dL)	3	X	.	X	4	1.18	134.699500	.	3.604000
8	FPG (mg/dL)	4	X	O	O	1	0.30	149.566000	.	.

Parameter Code=FPGU Planned Treatment for Period 30 (N)=4

Obs	PARAM	Group	BASE_ Miss_	visit2200_ Miss_	visit3600_ Miss_	Freq	Percent	BASE	visit2200	visit3600
9	FPG (mg/dL)	1	X	X	X	319	94.38	122.507755	27.459317	10.484364
10	FPG (mg/dL)	2	X	X	O	11	3.25	130.399273	42.592727	.
11	FPG (mg/dL)	3	X	.	X	5	1.48	107.399200	.	1.802000
12	FPG (mg/dL)	4	X	O	O	3	0.89	84.093333	.	.

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Fasting plasma glucose 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=FPGU Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM	Description	Value
1	1	FPG (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	FPG (mg/dL)	Method	Monotone
3	1	FPG (mg/dL)	Number of Imputations	1
4	1	FPG (mg/dL)	Seed for random number generator	4321

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=FPGU Planned Treatment for Period 30 (N)=2

O b s	I m p u t a t i o n _	P A R A M E T E R S	G r o u p	R E G I O N 1	B O L U S I N G 1	B O L U S I N G 2	B O L U S I N G 3	B O L U S I N G 4	B O L U S I N G 5	F r e q	P e r c e n t	B A S E	v i s i t s 2 0 0	v i s i t s 3 6 0 0
1	1	FPG (mg/dL)	1	X	X	X	X	X		335	98.24	122.907158	26.015533	2.538937
2	1	FPG (mg/dL)	2	X	X	X	X	.		4	1.17	116.679500	68.926500	.
3	1	FPG (mg/dL)	3	X	X	X	.	.		2	0.59	129.744000	.	.

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=FPGU Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
1	1	FPG (mg/dL)	Intercept			-0.01201	0.023512
2	1	FPG (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)		-0.16284	-0.127076
3	1	FPG (mg/dL)	REGION1	EUROPE		-0.09006	-0.226333
4	1	FPG (mg/dL)	REGION1	JAPAN		0.16524	0.145826
5	1	FPG (mg/dL)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.01272	-0.060362
6	1	FPG (mg/dL)	BASE			-0.44114	-0.457013

Parameter Code=FPGU Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	FPG (mg/dL)	Intercept			0.01197	-0.013173
8	1	FPG (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)		-0.07789	-0.010358
9	1	FPG (mg/dL)	REGION1	EUROPE		-0.01794	-0.019153
10	1	FPG (mg/dL)	REGION1	JAPAN		0.09703	0.095465
11	1	FPG (mg/dL)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.09046	-0.039935
12	1	FPG (mg/dL)	BASE			-0.47035	-0.390890
13	1	FPG (mg/dL)	visit2200			0.21242	0.246157

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=FPGU Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM	Description	Value
1	1	FPG (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	FPG (mg/dL)	Method	Monotone
3	1	FPG (mg/dL)	Number of Imputations	1
4	1	FPG (mg/dL)	Seed for random number generator	4322

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=FPGU Planned Treatment for Period 30 (N)=3

O b s	I m p u t a t i o n _	P A R A M	G r o u p	R E G I O N 1					B O L U S I N G 1					B O L U S I N G 2					B O L U S I N G 3					P e r c e n t					B A S E					v i s i t 2 0 0					v i s i t 3 0 0																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																									
				M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=FPGU Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
1	1	FPG (mg/dL)	Intercept			-0.05430	0.045291
2	1	FPG (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)		-0.26837	-0.127887
3	1	FPG (mg/dL)	REGION1	EUROPE		0.05311	0.052122
4	1	FPG (mg/dL)	REGION1	JAPAN		0.09549	0.003769
5	1	FPG (mg/dL)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.06691	0.093381
6	1	FPG (mg/dL)	BASE			-0.46639	-0.520825

Parameter Code=FPGU Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	FPG (mg/dL)	Intercept			-0.03765	0.013818
8	1	FPG (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)		-0.17812	-0.020170
9	1	FPG (mg/dL)	REGION1	EUROPE		-0.05112	-0.216244
10	1	FPG (mg/dL)	REGION1	JAPAN		0.21911	0.323221
11	1	FPG (mg/dL)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.06642	-0.031990
12	1	FPG (mg/dL)	BASE			-0.52112	-0.551603
13	1	FPG (mg/dL)	visit2200			0.16822	0.158540

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=FPGU Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM	Description	Value
1	1	FPG (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	FPG (mg/dL)	Method	Monotone
3	1	FPG (mg/dL)	Number of Imputations	1
4	1	FPG (mg/dL)	Seed for random number generator	4323

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=FPGU Planned Treatment for Period 30 (N)=4

O b s	I m p u t a t i o n _	P A R A M E T E R C O D E	G R O U P	R E G I O N _	B O D Y _	L E G E N D _	S T A T I S T I C I A N _	S T A T I S T I C I A N _	F R E Q U E N C Y	P E R C E N T _	B E T W E E N _	V A R I A N C E _	V A R I A N C E _
1	1	FPG (mg/dL)	1	X	X	X	X	X	324	95.86	122.274599	27.526136	10.350377
2	1	FPG (mg/dL)	2	X	X	X	X	.	11	3.25	130.399273	42.592727	.
3	1	FPG (mg/dL)	3	X	X	X	.	.	3	0.89	84.093333	.	.

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=FPGU Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
1	1	FPG (mg/dL)	Intercept			0.01861	-0.028330
2	1	FPG (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)		0.02964	0.079454
3	1	FPG (mg/dL)	REGION1	EUROPE		0.06718	-0.046655
4	1	FPG (mg/dL)	REGION1	JAPAN		0.08949	0.127993
5	1	FPG (mg/dL)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.05258	-0.051134
6	1	FPG (mg/dL)	BASE			-0.52878	-0.605249

Parameter Code=FPGU Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	FPG (mg/dL)	Intercept			0.00714	-0.014144
8	1	FPG (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)		-0.10630	-0.080507
9	1	FPG (mg/dL)	REGION1	EUROPE		0.06798	0.163816
10	1	FPG (mg/dL)	REGION1	JAPAN		0.17635	0.149225
11	1	FPG (mg/dL)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.08093	-0.058451
12	1	FPG (mg/dL)	BASE			-0.49400	-0.540078
13	1	FPG (mg/dL)	visit2200			0.17027	0.214239

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=C105585P Planned Treatment for Period 30 (N)=2

Obs	PARAM	Description	Value
1	FPG (mmol/L)	Data Set	WORK.ENDPOINT_PARAM
2	FPG (mmol/L)	Method	Monotone-data_MCMC
3	FPG (mmol/L)	Multiple Imputation Chain	Multiple Chains
4	FPG (mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
5	FPG (mmol/L)	Start	Starting Value
6	FPG (mmol/L)	Prior	Jeffreys
7	FPG (mmol/L)	Number of Imputations	20000
8	FPG (mmol/L)	Number of Burn-in Iterations	200
9	FPG (mmol/L)	Seed for random number generator	1234

Parameter Code=C105585P Planned Treatment for Period 30 (N)=3

Obs	PARAM	Description	Value
10	FPG (mmol/L)	Data Set	WORK.ENDPOINT_PARAM
11	FPG (mmol/L)	Method	Monotone-data_MCMC
12	FPG (mmol/L)	Multiple Imputation Chain	Multiple Chains
13	FPG (mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
14	FPG (mmol/L)	Start	Starting Value
15	FPG (mmol/L)	Prior	Jeffreys
16	FPG (mmol/L)	Number of Imputations	20000
17	FPG (mmol/L)	Number of Burn-in Iterations	200
18	FPG (mmol/L)	Seed for random number generator	1908816431

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=C105585P Planned Treatment for Period 30 (N)=4

Obs	PARAM	Description	Value
19	FPG (mmol/L)	Data Set	WORK.ENDPOINT_PARAM
20	FPG (mmol/L)	Method	Monotone-data_MCMC
21	FPG (mmol/L)	Multiple Imputation Chain	Multiple Chains
22	FPG (mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
23	FPG (mmol/L)	Start	Starting Value
24	FPG (mmol/L)	Prior	Jeffreys
25	FPG (mmol/L)	Number of Imputations	20000
26	FPG (mmol/L)	Number of Burn-in Iterations	200
27	FPG (mmol/L)	Seed for random number generator	1429674529

Fast-acting insulin aspart
NN1218-4131

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Fasting plasma glucose 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC
Missing data pattern

Parameter Code=C105585P Planned Treatment for Period 30 (N)=2

Obs	PARAM	Group	BASE_ Miss_	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
1	FPG (mmol/L)	1	X	X	X	325	95.31	6.841538	1.460615	0.117538
2	FPG (mmol/L)	2	X	X	O	4	1.17	6.475000	3.825000	.
3	FPG (mmol/L)	3	X	.	X	10	2.93	6.140000	.	0.900000
4	FPG (mmol/L)	4	X	O	O	2	0.59	7.200000	.	.

Parameter Code=C105585P Planned Treatment for Period 30 (N)=3

Obs	PARAM	Group	BASE_ Miss_	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
5	FPG (mmol/L)	1	X	X	X	324	95.86	6.866667	1.543519	0.449383
6	FPG (mmol/L)	2	X	X	O	9	2.66	7.766667	-0.022222	.
7	FPG (mmol/L)	3	X	.	X	4	1.18	7.475000	.	0.200000
8	FPG (mmol/L)	4	X	O	O	1	0.30	8.300000	.	.

Parameter Code=C105585P Planned Treatment for Period 30 (N)=4

Obs	PARAM	Group	BASE_ Miss_	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
9	FPG (mmol/L)	1	X	X	X	319	94.38	6.798433	1.523824	0.581818
10	FPG (mmol/L)	2	X	X	O	11	3.25	7.236364	2.363636	.
11	FPG (mmol/L)	3	X	.	X	5	1.48	5.960000	.	0.100000
12	FPG (mmol/L)	4	X	O	O	3	0.89	4.666667	.	.

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Fasting plasma glucose 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=C105585P Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM	Description	Value
1	1	FPG (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	FPG (mmol/L)	Method	Monotone
3	1	FPG (mmol/L)	Number of Imputations	1
4	1	FPG (mmol/L)	Seed for random number generator	4321

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=C105585P Planned Treatment for Period 30 (N)=2

O b s	I m p u t a t i o n _	P A R A M E T E R S	G r o u p	R E G I O N 1	B O L D 1	B O L D 2	B O L D 3	B O L D 4	B O L D 5	F r e q	P e r c e n t	B A S E	v i s i t 2 0 0	v i s i t 3 6 0 0
1	1	FPG (mmol/L)	1	X	X	X	X	X		335	98.24	6.820597	1.443703	0.140896
2	1	FPG (mmol/L)	2	X	X	X	X	.		4	1.17	6.475000	3.825000	.
3	1	FPG (mmol/L)	3	X	X	X	.	.		2	0.59	7.200000	.	.

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=C105585P Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2200

Obs	N	M	P	F	E	R	B	O	I
1	1	FPG (mmol/L)	Intercept					-0.01201	0.023512
2	1	FPG (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)				-0.16284	-0.127076
3	1	FPG (mmol/L)	REGION1	EUROPE				-0.09006	-0.226333
4	1	FPG (mmol/L)	REGION1	JAPAN				0.16524	0.145826
5	1	FPG (mmol/L)	BOLAD1			BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.01272	-0.060362
6	1	FPG (mmol/L)	BASE					-0.44114	-0.457013

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=C105585P Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

Obs	N	Imputed	Variable	Type	Value	R	E	B	O	I
7	1	FPG (mmol/L)	Intercept						0.01197	-0.013173
8	1	FPG (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)					-0.07789	-0.010358
9	1	FPG (mmol/L)	REGION1	EUROPE					-0.01794	-0.019153
10	1	FPG (mmol/L)	REGION1	JAPAN					0.09703	0.095465
11	1	FPG (mmol/L)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)				-0.09046	-0.039935
12	1	FPG (mmol/L)	BASE						-0.47035	-0.390890
13	1	FPG (mmol/L)	visit2200						0.21242	0.246157

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=C105585P Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM	Description	Value
1	1	FPG (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	FPG (mmol/L)	Method	Monotone
3	1	FPG (mmol/L)	Number of Imputations	1
4	1	FPG (mmol/L)	Seed for random number generator	4322

Fast-acting insulin aspart
NN1218-4131

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Fasting plasma glucose 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=C105585P Planned Treatment for Period 30 (N)=3

O b s	I m p u t a t i o n _	P A R A M _	G r o u p	R E G I O N 1	B O L D 1	B L A N D S E	v i s i t 2	v i s i t 3	F r e q	P e r c e n t	B A S E	v i s i t 2	v i s i t 3
1	1	FPG (mmol/L)	1	X	X	X	X	X	328	97.04	6.874085	1.511102	0.446341
2	1	FPG (mmol/L)	2	X	X	X	X	.	9	2.66	7.766667	-0.022222	.
3	1	FPG (mmol/L)	3	X	X	X	.	.	1	0.30	8.300000	.	.

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=C105585P Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2200

Imputed a t i o n s		P A R A M E T E R	E F F E C T	R E G I O N	B O L U S	O b s e r v e d	
1	1	FPG (mmol/L)	Intercept			-0.05430	0.045291
2	1	FPG (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)		-0.26837	-0.127887
3	1	FPG (mmol/L)	REGION1	EUROPE		0.05311	0.052122
4	1	FPG (mmol/L)	REGION1	JAPAN		0.09549	0.003769
5	1	FPG (mmol/L)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.06691	0.093381
6	1	FPG (mmol/L)	BASE			-0.46639	-0.520825

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=C105585P Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

Obs	N	Imputed	Variable	Type	Value	R	E	B	O	I
7	1	FPG (mmol/L)	Intercept						-0.03765	0.013818
8	1	FPG (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)					-0.17812	-0.020170
9	1	FPG (mmol/L)	REGION1	EUROPE					-0.05112	-0.216244
10	1	FPG (mmol/L)	REGION1	JAPAN					0.21911	0.323221
11	1	FPG (mmol/L)	BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)					0.06642	-0.031990
12	1	FPG (mmol/L)	BASE						-0.52112	-0.551603
13	1	FPG (mmol/L)	visit2200						0.16822	0.158540

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=C105585P Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM	Description	Value
1	1	FPG (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	FPG (mmol/L)	Method	Monotone
3	1	FPG (mmol/L)	Number of Imputations	1
4	1	FPG (mmol/L)	Seed for random number generator	4323

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=C105585P Planned Treatment for Period 30 (N)=4

O b s	I m p u t a t i o n _	P A R A M E T E R S	G r o u p	R E G I O N 1	B O L U S 1	B L A N K 1	B L A N K 2	B L A N K 3	F r e q	P e r c e n t	B A S E	v i s i t 2 0 0	v i s i t 3 6 0 0
1	1	FPG (mmol/L)	1	X	X	X	X	X	324	95.86	6.785494	1.527533	0.574383
2	1	FPG (mmol/L)	2	X	X	X	X	.	11	3.25	7.236364	2.363636	.
3	1	FPG (mmol/L)	3	X	X	X	.	.	3	0.89	4.666667	.	.

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=C105585P Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2200

Imputed a t i v e s		P A R A M E T E R S	E f f e c t	R E G I O N 1	B O L A D 1	O b s e r v e d	\bar{I}
1	1	FPG (mmol/L)	Intercept			0.01861	-0.028330
2	1	FPG (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)		0.02964	0.079454
3	1	FPG (mmol/L)	REGION1	EUROPE		0.06718	-0.046655
4	1	FPG (mmol/L)	REGION1	JAPAN		0.08949	0.127993
5	1	FPG (mmol/L)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.05258	-0.051134
6	1	FPG (mmol/L)	BASE			-0.52878	-0.605249

Fast-acting insulin aspart
NN1218-4131

Clinical Trial Report
Statistical document

Date: 14 February 2018
Version: 1.0

Status: Final
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Novo Nordisk

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=C105585P Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

Obs	N	Imputed	P	E	R	B	O		\bar{I}
7	1	FPG (mmol/L)	Intercept					0.00714	-0.014144
8	1	FPG (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)				-0.10630	-0.080507
9	1	FPG (mmol/L)	REGION1	EUROPE				0.06798	0.163816
10	1	FPG (mmol/L)	REGION1	JAPAN				0.17635	0.149225
11	1	FPG (mmol/L)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)			-0.08093	-0.058451
12	1	FPG (mmol/L)	BASE					-0.49400	-0.540078
13	1	FPG (mmol/L)	visit2200					0.17027	0.214239

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Model Information

Parameter Code=C105585P Parameter=FPG (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Data Set	WORK.IMPUTE
2	1	NN1218-4131	Dependent Variable	eotVisit
3	1	NN1218-4131	Covariance Structure	Diagonal
4	1	NN1218-4131	Estimation Method	REML
5	1	NN1218-4131	Residual Variance Method	Profile
6	1	NN1218-4131	Fixed Effects SE Method	Model-Based
7	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=FPGU Parameter=FPG (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
8	1	NN1218-4131	Data Set	WORK.IMPUTE
9	1	NN1218-4131	Dependent Variable	eotVisit
10	1	NN1218-4131	Covariance Structure	Diagonal
11	1	NN1218-4131	Estimation Method	REML
12	1	NN1218-4131	Residual Variance Method	Profile
13	1	NN1218-4131	Fixed Effects SE Method	Model-Based
14	1	NN1218-4131	Degrees of Freedom Method	Residual

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Dimensions

Parameter Code=C105585P Parameter=FPG (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Covariance Parameters	1
2	1	NN1218-4131	Columns in X	10
3	1	NN1218-4131	Columns in Z	0
4	1	NN1218-4131	Subjects	1
5	1	NN1218-4131	Max Obs per Subject	1017

Parameter Code=FPGU Parameter=FPG (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
6	1	NN1218-4131	Covariance Parameters	1
7	1	NN1218-4131	Columns in X	10
8	1	NN1218-4131	Columns in Z	0
9	1	NN1218-4131	Subjects	1
10	1	NN1218-4131	Max Obs per Subject	1017

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Number of Observations

Parameter Code=C105585P Parameter=FPG (mmol/L)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
1	1	NN1218-4131	Number of Observations Read	1017	1017	1017	1017	1017
2	1	NN1218-4131	Number of Observations Used	1017	1017	1017	1017	1017
3	1	NN1218-4131	Number of Observations Not Used	0	1017	1017	1017	1017

Parameter Code=FPGU Parameter=FPG (mg/dL)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
4	1	NN1218-4131	Number of Observations Read	1017	1017	1017	1017	1017
5	1	NN1218-4131	Number of Observations Used	1017	1017	1017	1017	1017
6	1	NN1218-4131	Number of Observations Not Used	0	1017	1017	1017	1017

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Covariance Parameter Estimates

Parameter Code=C105585P Parameter=FPG (mmol/L)

Obs	_Imputation_	STUDYID	CovParm	Estimate
1	1	NN1218-4131	Residual	6.4797

Parameter Code=FPGU Parameter=FPG (mg/dL)

Obs	_Imputation_	STUDYID	CovParm	Estimate
20001	1	NN1218-4131	Residual	2104.08

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Fit Statistics

Parameter Code=C105585P Parameter=FPG (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	-2 Res Log Likelihood	4795.3
2	1	NN1218-4131	AIC (Smaller is Better)	4797.3
3	1	NN1218-4131	AICC (Smaller is Better)	4797.3
4	1	NN1218-4131	BIC (Smaller is Better)	4802.2

Parameter Code=FPGU Parameter=FPG (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
5	1	NN1218-4131	-2 Res Log Likelihood	10636.1
6	1	NN1218-4131	AIC (Smaller is Better)	10638.1
7	1	NN1218-4131	AICC (Smaller is Better)	10638.1
8	1	NN1218-4131	BIC (Smaller is Better)	10643.0

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Solution for Fixed Effects

Parameter Code=C105585P Parameter=FPG (mmol/L)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
1	1	NN1218-4131	TRTPN	2				
2	1	NN1218-4131	TRTPN	3				
3	1	NN1218-4131	TRTPN	4				
4	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
5	1	NN1218-4131	REGION1	—	EUROPE			
6	1	NN1218-4131	REGION1	—	JAPAN			
7	1	NN1218-4131	REGION1	—	NORTH AMERICA			
8	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
9	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
10	1	NN1218-4131	BASE	—				

Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	5.4125	0.2973	1009	18.21	<.0001	0.05	4.8291	5.9958
2	5.7274	0.3008	1009	19.04	<.0001	0.05	5.1370	6.3177
3	5.7800	0.2986	1009	19.36	<.0001	0.05	5.1940	6.3659
4	-0.3342	0.2933	1009	-1.14	0.2547	0.05	-0.9097	0.2412
5	0.1602	0.2053	1009	0.78	0.4354	0.05	-0.2427	0.5631
6	0.7211	0.2294	1009	3.14	0.0017	0.05	0.2709	1.1713
7	0
8	-0.1725	0.1789	1009	-0.96	0.3351	0.05	-0.5236	0.1785
9	0
10	-0.7850	0.03382	1009	-23.21	<.0001	0.05	-0.8514	-0.7187

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Solution for Fixed Effects

Parameter Code=FPGU Parameter=FPG (mg/dL)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1			BOLAD1
11	1	NN1218-4131	TRTPN	2				
12	1	NN1218-4131	TRTPN	3				
13	1	NN1218-4131	TRTPN	4				
14	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
15	1	NN1218-4131	REGION1	—	EUROPE			
16	1	NN1218-4131	REGION1	—	JAPAN			
17	1	NN1218-4131	REGION1	—	NORTH AMERICA			
18	1	NN1218-4131	BOLAD1	—				BOLUS INSULIN ALGORITHM (SLIDING SCALE)
19	1	NN1218-4131	BOLAD1	—				CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY
20	1	NN1218-4131	BASE	—				

Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
11	97.5326	5.3570	1009	18.21	<.0001	0.05	87.0204	108.04
12	103.21	5.4212	1009	19.04	<.0001	0.05	92.5691	113.85
13	104.16	5.3808	1009	19.36	<.0001	0.05	93.5966	114.71
14	-6.0231	5.2846	1009	-1.14	0.2547	0.05	-16.3931	4.3470
15	2.8870	3.6998	1009	0.78	0.4354	0.05	-4.3730	10.1471
16	12.9945	4.1342	1009	3.14	0.0017	0.05	4.8818	21.1072
17	0
18	-3.1089	3.2236	1009	-0.96	0.3351	0.05	-9.4346	3.2169
19	0
20	-0.7850	0.03382	1009	-23.21	<.0001	0.05	-0.8514	-0.7187

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Least Squares Means

Obs		Input atom	PAR Model	PAR Model	STUDY ID	Eff fect	TRT Type	Margin s	Estimate	Std Err	DF	t Value	P rob t	Al pha	Low er	Up per
1	1	C105585P	FPG	(mmol/L)	NN1218-4131	TRTPN	2	WORK.IMPUTE	0.1323	0.1380	1009	0.96	0.3382	0.05	-0.1386	0.4031
2	1	C105585P	FPG	(mmol/L)	NN1218-4131	TRTPN	3	WORK.IMPUTE	0.4472	0.1386	1009	3.23	0.0013	0.05	0.1751	0.7192
3	1	C105585P	FPG	(mmol/L)	NN1218-4131	TRTPN	4	WORK.IMPUTE	0.4998	0.1386	1009	3.61	0.0003	0.05	0.2278	0.7718
4	1	FPGU	FPG	(mg/dL)	NN1218-4131	TRTPN	2	WORK.IMPUTE	2.3835	2.4874	1009	0.96	0.3382	0.05	-2.4976	7.2647
5	1	FPGU	FPG	(mg/dL)	NN1218-4131	TRTPN	3	WORK.IMPUTE	8.0582	2.4981	1009	3.23	0.0013	0.05	3.1562	12.9601
6	1	FPGU	FPG	(mg/dL)	NN1218-4131	TRTPN	4	WORK.IMPUTE	9.0064	2.4976	1009	3.61	0.0003	0.05	4.1053	13.9076

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Least Squares Means Estimate

Parameter Code=C105585P Parameter=FPG (mmol/L)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
1	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
2	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	WORK.IMPUTE	-0.3675	0.1957	1009	-1.88	0.0607	0.05	-0.7516	0.01656
2	WORK.IMPUTE	-0.05262	0.1961	1009	-0.27	0.7885	0.05	-0.4375	0.3322

Parameter Code=FPGU Parameter=FPG (mg/dL)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
3	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
4	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
3	WORK.IMPUTE	-6.6229	3.5271	1009	-1.88	0.0607	0.05	-13.5442	0.2984
4	WORK.IMPUTE	-0.9483	3.5340	1009	-0.27	0.7885	0.05	-7.8832	5.9866

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=C105585P Parameter=FPG (mmol/L) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000298	0.018911	0.019209	8.3E7	0.015771	0.015526	0.999999

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.149354	0.138598	-0.12229	0.421000	8.3E7	0.071723	0.216850

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	1.08	0.2812

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=FPGU Parameter=FPG (mg/dL) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.096841	6.140798	6.237644	8.3E7	0.015771	0.015526	0.999999

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	2.691352	2.497528	-2.20371	7.586416	8.3E7	1.292441	3.907641

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	1.08	0.2812

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=C105585P Parameter=FPG (mmol/L) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000574	0.019073	0.019646	2.35E7	0.030072	0.029194	0.999999

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.450724	0.140166	0.176004	0.725444	2.35E7	0.351898	0.545292

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	3.22	0.0013

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=FPGU Parameter=FPG (mg/dL) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.186235	6.193366	6.379610	2.35E7	0.030072	0.029194	0.999999

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits	DF	Minimum	Maximum
Estimate	8.122045	2.525789	3.171589 13.07250	2.35E7	6.341196	9.826162

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	3.22	0.0013

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=C105585P Parameter=FPG (mmol/L) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000841	0.019066	0.019907	1.12E7	0.044086	0.042224	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.549219	0.141092	0.272683	0.825755	1.12E7	0.436167	0.669068

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	3.89	<.0001

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=FPGU Parameter=FPG (mg/dL) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.272932	6.191281	6.464227	1.12E7	0.044086	0.042224	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits	DF	Minimum	Maximum
Estimate	9.896929	2.542484	4.913750 14.88011	1.12E7	7.859733	12.056607

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	3.89	<.0001

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=C105585P Label=Faster aspart (meal) - NovoRapid (meal) Parameter=FPG (mmol/L) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.001140	0.038024	0.039164	2.36E7	0.029980	0.029107	0.999999

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.399866	0.197898	-0.78774	-0.01199	2.36E7	-0.537956	-0.272840

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-2.02	0.0433

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=C105585P Label=Faster aspart (post) - NovoRapid (meal) Parameter=FPG (mmol/L) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.001405	0.038173	0.039578	1.59E7	0.036808	0.035502	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.098495	0.198943	-0.48842	0.291425	1.59E7	-0.228449	0.044358

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-0.50	0.6205

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=FPGU Label=Faster aspart (meal) - NovoRapid (meal) Parameter=FPG (mg/dL) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.370141	12.347037	12.717197	2.36E7	0.029980	0.029107	0.999999

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-7.205577	3.566118	-14.1950	-0.21611	2.36E7	-9.693963	-4.916584

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-2.02	0.0433

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=FPGU Label=Faster aspart (post) - NovoRapid (meal) Parameter=FPG (mg/dL) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.456239	12.395563	12.851824	1.59E7	0.036808	0.035502	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-1.774884	3.584944	-8.80125	5.251478	1.59E7	-4.116659	0.799340

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-0.50	0.6205

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure Model Information

Parameter Code=C105585P Parameter=FPG (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Data Set	WORK.IMPUTE_ABS
2	1	NN1218-4131	Dependent Variable	eotVisitAbs
3	1	NN1218-4131	Covariance Structure	Diagonal
4	1	NN1218-4131	Estimation Method	REML
5	1	NN1218-4131	Residual Variance Method	Profile
6	1	NN1218-4131	Fixed Effects SE Method	Model-Based
7	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=FPGU Parameter=FPG (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
8	1	NN1218-4131	Data Set	WORK.IMPUTE_ABS
9	1	NN1218-4131	Dependent Variable	eotVisitAbs
10	1	NN1218-4131	Covariance Structure	Diagonal
11	1	NN1218-4131	Estimation Method	REML
12	1	NN1218-4131	Residual Variance Method	Profile
13	1	NN1218-4131	Fixed Effects SE Method	Model-Based
14	1	NN1218-4131	Degrees of Freedom Method	Residual

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Class Level Information

Parameter Code=C105585P Parameter=FPG (mmol/L)

		Input data				Output	
		Study	Country	Region	Visit	Value	Label
		O	b	s			
		1	2	3	4	5	6
1	1	NN1218-4131	TRTPN				
2	1	NN1218-4131	REGION1				
3	1	NN1218-4131	BOLAD1				

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Class Level Information

Parameter Code=FPGU Parameter=FPG (mg/dL)

O b s	I m p u t a t i o n s	S T U D Y I D	C l a s s	L e v e l s	V a r i a n c e s	m i n
4	1	NN1218-4131	TRTPN	3 2 3 4		5
5	1	NN1218-4131	REGION1	4 ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA		49
6	1	NN1218-4131	BOLAD1	2 BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULI		85

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Dimensions

Parameter Code=C105585P Parameter=FPG (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Covariance Parameters	1
2	1	NN1218-4131	Columns in X	10
3	1	NN1218-4131	Columns in Z	0
4	1	NN1218-4131	Subjects	1
5	1	NN1218-4131	Max Obs per Subject	1017

Parameter Code=FPGU Parameter=FPG (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
6	1	NN1218-4131	Covariance Parameters	1
7	1	NN1218-4131	Columns in X	10
8	1	NN1218-4131	Columns in Z	0
9	1	NN1218-4131	Subjects	1
10	1	NN1218-4131	Max Obs per Subject	1017

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Number of Observations

Parameter Code=C105585P Parameter=FPG (mmol/L)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
1	1	NN1218-4131	Number of Observations Read	1017	1017	1017	1017	1017
2	1	NN1218-4131	Number of Observations Used	1017	1017	1017	1017	1017
3	1	NN1218-4131	Number of Observations Not Used	0	1017	1017	1017	1017

Parameter Code=FPGU Parameter=FPG (mg/dL)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
4	1	NN1218-4131	Number of Observations Read	1017	1017	1017	1017	1017
5	1	NN1218-4131	Number of Observations Used	1017	1017	1017	1017	1017
6	1	NN1218-4131	Number of Observations Not Used	0	1017	1017	1017	1017

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Covariance Parameter Estimates

Parameter Code=C105585P Parameter=FPG (mmol/L)

Obs	_Imputation_	STUDYID	CovParm	Estimate
1	1	NN1218-4131	Residual	6.4797

Parameter Code=FPGU Parameter=FPG (mg/dL)

Obs	_Imputation_	STUDYID	CovParm	Estimate
20001	1	NN1218-4131	Residual	2104.08

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Fit Statistics

Parameter Code=C105585P Parameter=FPG (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	-2 Res Log Likelihood	4795.3
2	1	NN1218-4131	AIC (Smaller is Better)	4797.3
3	1	NN1218-4131	AICC (Smaller is Better)	4797.3
4	1	NN1218-4131	BIC (Smaller is Better)	4802.2

Parameter Code=FPGU Parameter=FPG (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
5	1	NN1218-4131	-2 Res Log Likelihood	10636.1
6	1	NN1218-4131	AIC (Smaller is Better)	10638.1
7	1	NN1218-4131	AICC (Smaller is Better)	10638.1
8	1	NN1218-4131	BIC (Smaller is Better)	10643.0

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Solution for Fixed Effects

Parameter Code=C105585P Parameter=FPG (mmol/L)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
1	1	NN1218-4131	TRTPN	2				
2	1	NN1218-4131	TRTPN	3				
3	1	NN1218-4131	TRTPN	4				
4	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
5	1	NN1218-4131	REGION1	—	EUROPE			
6	1	NN1218-4131	REGION1	—	JAPAN			
7	1	NN1218-4131	REGION1	—	NORTH AMERICA			
8	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
9	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
10	1	NN1218-4131	BASE	—				

Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	5.4125	0.2973	1009	18.21	<.0001	0.05	4.8291	5.9958
2	5.7274	0.3008	1009	19.04	<.0001	0.05	5.1370	6.3177
3	5.7800	0.2986	1009	19.36	<.0001	0.05	5.1940	6.3659
4	-0.3342	0.2933	1009	-1.14	0.2547	0.05	-0.9097	0.2412
5	0.1602	0.2053	1009	0.78	0.4354	0.05	-0.2427	0.5631
6	0.7211	0.2294	1009	3.14	0.0017	0.05	0.2709	1.1713
7	0
8	-0.1725	0.1789	1009	-0.96	0.3351	0.05	-0.5236	0.1785
9	0
10	0.2150	0.03382	1009	6.36	<.0001	0.05	0.1486	0.2813

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Solution for Fixed Effects

Parameter Code=FPGU Parameter=FPG (mg/dL)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1		BOLAD1
11	1	NN1218-4131	TRTPN	2			
12	1	NN1218-4131	TRTPN	3			
13	1	NN1218-4131	TRTPN	4			
14	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)		
15	1	NN1218-4131	REGION1	—	EUROPE		
16	1	NN1218-4131	REGION1	—	JAPAN		
17	1	NN1218-4131	REGION1	—	NORTH AMERICA		
18	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	
19	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE)	BOLUS INSULIN THERAPY
20	1	NN1218-4131	BASE	—			

Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
11	97.5326	5.3570	1009	18.21	<.0001	0.05	87.0204	108.04
12	103.21	5.4212	1009	19.04	<.0001	0.05	92.5691	113.85
13	104.16	5.3808	1009	19.36	<.0001	0.05	93.5966	114.71
14	-6.0231	5.2846	1009	-1.14	0.2547	0.05	-16.3931	4.3470
15	2.8870	3.6998	1009	0.78	0.4354	0.05	-4.3730	10.1471
16	12.9945	4.1342	1009	3.14	0.0017	0.05	4.8818	21.1072
17	0
18	-3.1089	3.2236	1009	-0.96	0.3351	0.05	-9.4346	3.2169
19	0
20	0.2150	0.03382	1009	6.36	<.0001	0.05	0.1486	0.2813

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Least Squares Means

		Impute		PARC		PARC		STUDY		Efficient		Margins		Estimate		Standard Error		t Value		Pr > t		Alpha		Lower		Upper	
Obs	—																										
1	1	C105585P	FPG	(mmol/L)	NN1218-4131	TRTPN	2	WORK.IMPUTE	0.1323	0.1380	1009	0.96	0.3382	0.05	-0.1386	0.4031											
20001	1	FPGU	FPG	(mg/dL)	NN1218-4131	TRTPN	2	WORK.IMPUTE	2.3835	2.4874	1009	0.96	0.3382	0.05	-2.4976	7.2647											
40001	1	C105585P	FPG	(mmol/L)	NN1218-4131	TRTPN	3	WORK.IMPUTE	0.4472	0.1386	1009	3.23	0.0013	0.05	0.1751	0.7192											
60001	1	FPGU	FPG	(mg/dL)	NN1218-4131	TRTPN	3	WORK.IMPUTE	8.0582	2.4981	1009	3.23	0.0013	0.05	3.1562	12.9601											
80001	1	C105585P	FPG	(mmol/L)	NN1218-4131	TRTPN	4	WORK.IMPUTE	0.4998	0.1386	1009	3.61	0.0003	0.05	0.2278	0.7718											
100001	1	FPGU	FPG	(mg/dL)	NN1218-4131	TRTPN	4	WORK.IMPUTE	9.0064	2.4976	1009	3.61	0.0003	0.05	4.1053	13.9076											

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Least Squares Means Estimate

Parameter Code=C105585P Parameter=FPG (mmol/L)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
1	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
20001	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	WORK.IMPUTE	-0.3675	0.1957	1009	-1.88	0.0607	0.05	-0.7516	0.01656
20001	WORK.IMPUTE	-0.05262	0.1961	1009	-0.27	0.7885	0.05	-0.4375	0.3322

Parameter Code=FPGU Parameter=FPG (mg/dL)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
40001	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
60001	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
40001	WORK.IMPUTE	-6.6229	3.5271	1009	-1.88	0.0607	0.05	-13.5442	0.2984
60001	WORK.IMPUTE	-0.9483	3.5340	1009	-0.27	0.7885	0.05	-7.8832	5.9866

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=C105585P Parameter=FPG (mmol/L) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000298	0.018911	0.019209	8.3E7	0.015771	0.015526	0.999999

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits	DF	Minimum	Maximum
Estimate	6.983375	0.138598	6.711729 7.255021	8.3E7	6.905744	7.050872

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	50.39	<.0001

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=FPGU Parameter=FPG (mg/dL) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.096841	6.140798	6.237644	8.3E7	0.015771	0.015526	0.999999

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	125.840422	2.497528	120.9454	130.7355	8.3E7	124.441511	127.056711

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	50.39	<.0001

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=C105585P Parameter=FPG (mmol/L) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000574	0.019073	0.019646	2.35E7	0.030072	0.029194	0.999999

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	7.284746	0.140166	7.010025	7.559466	2.35E7	7.185919	7.379314

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	51.97	<.0001

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=FPGU Parameter=FPG (mg/dL) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.186235	6.193366	6.379610	2.35E7	0.030072	0.029194	0.999999

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	131.271115	2.525789	126.3207	136.2216	2.35E7	129.490266	132.975232

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	51.97	<.0001

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=C105585P Parameter=FPG (mmol/L) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000841	0.019066	0.019907	1.12E7	0.044086	0.042224	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	7.383241	0.141092	7.106705	7.659777	1.12E7	7.270189	7.503090

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	52.33	<.0001

Fasting plasma glucose 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=FPGU Parameter=FPG (mg/dL) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.272932	6.191281	6.464227	1.12E7	0.044086	0.042224	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	133.045998	2.542484	128.0628	138.0292	1.12E7	131.008803	135.205677

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	52.33	<.0001

16: 1,5-anhydroglucitol 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=AG_1_5_S Planned Treatment for Period 30 (N)=2

Obs	PARAM	Description	Value
1	1,5-anhydroglucitol (ug/mL)	Data Set	WORK.ENDPOINT_PARAM
2	1,5-anhydroglucitol (ug/mL)	Method	Monotone-data_MCMC
3	1,5-anhydroglucitol (ug/mL)	Multiple Imputation Chain	Multiple Chains
4	1,5-anhydroglucitol (ug/mL)	Initial Estimates for MCMC	EM Posterior Mode
5	1,5-anhydroglucitol (ug/mL)	Start	Starting Value
6	1,5-anhydroglucitol (ug/mL)	Prior	Jeffreys
7	1,5-anhydroglucitol (ug/mL)	Number of Imputations	100
8	1,5-anhydroglucitol (ug/mL)	Number of Burn-in Iterations	200
9	1,5-anhydroglucitol (ug/mL)	Seed for random number generator	6807

Parameter Code=AG_1_5_S Planned Treatment for Period 30 (N)=3

Obs	PARAM	Description	Value
10	1,5-anhydroglucitol (ug/mL)	Data Set	WORK.ENDPOINT_PARAM
11	1,5-anhydroglucitol (ug/mL)	Method	Monotone-data_MCMC
12	1,5-anhydroglucitol (ug/mL)	Multiple Imputation Chain	Multiple Chains
13	1,5-anhydroglucitol (ug/mL)	Initial Estimates for MCMC	EM Posterior Mode
14	1,5-anhydroglucitol (ug/mL)	Start	Starting Value
15	1,5-anhydroglucitol (ug/mL)	Prior	Jeffreys
16	1,5-anhydroglucitol (ug/mL)	Number of Imputations	100
17	1,5-anhydroglucitol (ug/mL)	Number of Burn-in Iterations	200
18	1,5-anhydroglucitol (ug/mL)	Seed for random number generator	628601646

1,5-anhydroglucitol 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=AG_1_5_S Planned Treatment for Period 30 (N)=4

Obs	PARAM	Description	Value
19	1,5-anhydroglucitol (ug/mL)	Data Set	WORK.ENDPOINT_PARAM
20	1,5-anhydroglucitol (ug/mL)	Method	Monotone-data_MCMC
21	1,5-anhydroglucitol (ug/mL)	Multiple Imputation Chain	Multiple Chains
22	1,5-anhydroglucitol (ug/mL)	Initial Estimates for MCMC	EM Posterior Mode
23	1,5-anhydroglucitol (ug/mL)	Start	Starting Value
24	1,5-anhydroglucitol (ug/mL)	Prior	Jeffreys
25	1,5-anhydroglucitol (ug/mL)	Number of Imputations	100
26	1,5-anhydroglucitol (ug/mL)	Number of Burn-in Iterations	200
27	1,5-anhydroglucitol (ug/mL)	Seed for random number generator	1413053051

Fast-acting insulin aspart
NN1218-4131

Clinical Trial Report
Statistical document

Date:
Version:

14 February 2018
1.0

Status:
Page:

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Novo Nordisk

1,5-anhydroglucitol 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with MCMC
Missing data pattern

Parameter Code=AG_1_5_S Planned Treatment for Period 30 (N)=2

Obs	PARAM	Group	BASE_ Miss	visit1400_ Miss	visit1800_ Miss	visit2200_ Miss	visit2600_ Miss	visit3000_ Miss	visit3400_ Miss	visit3600_ Miss
1	1,5-anhydroglucitol (ug/mL)	1	X	X	X	X	X	X	X	X
2	1,5-anhydroglucitol (ug/mL)	2	X	X	X	X	X	X	X	O
3	1,5-anhydroglucitol (ug/mL)	3	X	X	X	X	X	X	.	X
4	1,5-anhydroglucitol (ug/mL)	4	X	X	X	X	X	.	X	X
5	1,5-anhydroglucitol (ug/mL)	5	X	X	X	X	.	X	X	X
6	1,5-anhydroglucitol (ug/mL)	6	X	X	X	.	X	X	X	X
7	1,5-anhydroglucitol (ug/mL)	7	X	X	X	O	O	O	O	O
8	1,5-anhydroglucitol (ug/mL)	8	X	X	.	X	X	X	X	X
9	1,5-anhydroglucitol (ug/mL)	9	X	X	.	X	X	X	.	X
10	1,5-anhydroglucitol (ug/mL)	10	X	X	.	.	X	X	X	X
11	1,5-anhydroglucitol (ug/mL)	11	X	X	O	O	O	O	O	O

Obs	Freq	Percent	BASE	visit1400	visit1800	visit2200	visit2600	visit3000	visit3400	visit3600
1	313	91.79	4.758786	0.220767	0.274760	0.237061	0.239297	0.289137	0.205112	0.176997
2	1	0.29	6.000000	-1.300000	1.300000	0.600000	-0.300000	-1.300000	-0.600000	.
3	5	1.47	3.180000	0.500000	0.400000	0.700000	1.140000	1.280000	.	-0.420000
4	2	0.59	2.550000	1.650000	3.550000	3.100000	3.850000	.	2.650000	2.800000
5	3	0.88	4.733333	0.466667	0.500000	0.500000	.	3.166667	2.133333	1.933333
6	1	0.29	7.700000	0.600000	-3.400000	.	-4.200000	-4.800000	-1.500000	2.000000
7	1	0.29	5.500000	2.400000	1.900000
8	3	0.88	3.300000	-0.433333	.	-0.033333	-0.466667	0.033333	0.033333	0.566667
9	1	0.29	5.800000	0.400000	.	0.700000	1.100000	-0.100000	.	-0.500000
10	1	0.29	2.400000	-0.500000	.	.	-0.700000	-0.200000	0.200000	0.300000
11	2	0.59	5.900000	-0.650000

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1,5-anhydroglucitol 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with MCMC
Missing data pattern

Parameter Code=AG_1_5_S Planned Treatment for Period 30 (N)=2

(continued)

Obs	PARAM	Group	BASE_ Miss	visit1400_ Miss	visit1800_ Miss	visit2200_ Miss	visit2600_ Miss	visit3000_ Miss	visit3400_ Miss	visit3600_ Miss
12	1,5-anhydroglucitol (ug/mL)	12	X	.	X	X	X	X	X	X
13	1,5-anhydroglucitol (ug/mL)	13	X	.	X	X	X	.	.	X

Obs	Freq	Percent	BASE	visit1400	visit1800	visit2200	visit2600	visit3000	visit3400	visit3600
12	7	2.05	3.228571	.	1.300000	-0.257143	0.314286	-0.057143	0.585714	1.114286
13	1	0.29	12.900000	.	-4.200000	-1.600000	-0.500000	.	.	-2.200000

Parameter Code=AG_1_5_S Planned Treatment for Period 30 (N)=3

Obs	PARAM	Group	BASE_ Miss	visit1400_ Miss	visit1800_ Miss	visit2200_ Miss	visit2600_ Miss	visit3000_ Miss	visit3400_ Miss	visit3600_ Miss
14	1,5-anhydroglucitol (ug/mL)	1	X	X	X	X	X	X	X	X
15	1,5-anhydroglucitol (ug/mL)	2	X	X	X	X	X	X	.	X
16	1,5-anhydroglucitol (ug/mL)	3	X	X	X	X	X	X	0	0

Obs	Freq	Percent	BASE	visit1400	visit1800	visit2200	visit2600	visit3000	visit3400	visit3600
14	312	92.86	4.598077	-0.025641	-0.119231	-0.127244	-0.048718	-0.085256	0.000321	-0.100000
15	3	0.89	6.900000	0.533333	0.533333	0.300000	-1.533333	-2.400000	.	-1.266667
16	1	0.30	6.400000	-2.300000	-2.600000	-0.500000	3.300000	-2.200000	.	.

1,5-anhydroglucitol 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with MCMC
Missing data pattern

Parameter Code=AG_1_5_S Planned Treatment for Period 30 (N)=3

(continued)

Obs	PARAM	Group	BASE_ Miss	visit1400_ Miss	visit1800_ Miss	visit2200_ Miss	visit2600_ Miss	visit3000_ Miss	visit3400_ Miss	visit3600_ Miss
17	1,5-anhydroglucitol (ug/mL)	4	X	X	X	X	X	.	X	X
18	1,5-anhydroglucitol (ug/mL)	5	X	X	X	X	X	.	.	X
19	1,5-anhydroglucitol (ug/mL)	6	X	X	X	X	X	O	O	O
20	1,5-anhydroglucitol (ug/mL)	7	X	X	X	X	.	X	X	X
21	1,5-anhydroglucitol (ug/mL)	8	X	X	X	X	.	.	X	X
22	1,5-anhydroglucitol (ug/mL)	9	X	X	X	X	.	.	.	X
23	1,5-anhydroglucitol (ug/mL)	10	X	X	X	X	O	O	O	O
24	1,5-anhydroglucitol (ug/mL)	11	X	X	X	.	X	X	X	X
25	1,5-anhydroglucitol (ug/mL)	12	X	X	X	O	O	O	O	O
26	1,5-anhydroglucitol (ug/mL)	13	X	X	.	X	X	X	X	X
27	1,5-anhydroglucitol (ug/mL)	14	X	X	O	O	O	O	O	O

Obs	Freq	Percent	BASE	visit1400	visit1800	visit2200	visit2600	visit3000	visit3400	visit3600
17	1	0.30	2.500000	-0.800000	0.400000	-0.800000	-1.500000	.	-1.400000	-1.300000
18	1	0.30	4.900000	0.900000	3.100000	-0.200000	-2.100000	.	.	0.300000
19	1	0.30	3.800000	-0.600000	0.100000	1.500000	-0.100000	.	.	.
20	2	0.60	4.750000	0.850000	-0.800000	-0.350000	.	0.200000	-0.150000	-0.850000
21	1	0.30	8.100000	-1.000000	0.600000	0.200000	.	.	1.600000	-0.500000
22	1	0.30	2.000000	-0.100000	-0.700000	-0.700000	.	.	.	-0.600000
23	3	0.89	3.566667	-1.133333	-1.200000	-1.433333
24	1	0.30	3.800000	-1.000000	0.100000	.	-1.300000	-0.200000	-0.200000	0.800000
25	1	0.30	2.800000	-1.100000	-1.800000
26	1	0.30	5.600000	0.100000	.	-1.700000	-1.900000	-1.700000	-2.000000	-3.400000
27	1	0.30	4.600000	2.800000

1,5-anhydroglucitol 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with MCMC
Missing data pattern

Parameter Code=AG_1_5_S Planned Treatment for Period 30 (N)=3

(continued)

Obs	PARAM	Group	BASE_ Miss	visit1400_ Miss	visit1800_ Miss	visit2200_ Miss	visit2600_ Miss	visit3000_ Miss	visit3400_ Miss	visit3600_ Miss
28	1,5-anhydroglucitol (ug/mL)	15	X	.	X	X	X	X	X	X
29	1,5-anhydroglucitol (ug/mL)	16	X	.	X	X	X	X	.	X

Obs	Freq	Percent	BASE	visit1400	visit1800	visit2200	visit2600	visit3000	visit3400	visit3600
28	4	1.19	3.100000	.	0.875000	-1.050000	-0.500000	-0.475000	-0.425000	-0.225000
29	2	0.60	4.500000	.	0.650000	0.700000	0.350000	-0.150000	.	-1.050000

Parameter Code=AG_1_5_S Planned Treatment for Period 30 (N)=4

Obs	PARAM	Group	BASE_ Miss	visit1400_ Miss	visit1800_ Miss	visit2200_ Miss	visit2600_ Miss	visit3000_ Miss	visit3400_ Miss	visit3600_ Miss
30	1,5-anhydroglucitol (ug/mL)	1	X	X	X	X	X	X	X	X
31	1,5-anhydroglucitol (ug/mL)	2	X	X	X	X	X	X	X	O
32	1,5-anhydroglucitol (ug/mL)	3	X	X	X	X	X	X	.	X

Obs	Freq	Percent	BASE	visit1400	visit1800	visit2200	visit2600	visit3000	visit3400	visit3600
30	313	92.33	4.675399	0.149201	0.179553	0.055911	0.294249	0.287859	0.252716	0.247923
31	5	1.47	4.240000	-0.280000	-0.180000	-0.400000	0	0.240000	0.140000	.
32	1	0.29	3.800000	0.800000	-1.700000	0.700000	-0.800000	0.300000	.	2.400000

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The MI Procedure with MCMC
Missing data pattern

Parameter Code=AG_1_5_S Planned Treatment for Period 30 (N)=4

(continued)

Obs	PARAM	Group	BASE_ Miss	visit1400_ Miss	visit1800_ Miss	visit2200_ Miss	visit2600_ Miss	visit3000_ Miss	visit3400_ Miss	visit3600_ Miss
33	1,5-anhydroglucitol (ug/mL)	4	X	X	X	X	X	.	X	X
34	1,5-anhydroglucitol (ug/mL)	5	X	X	X	X	X	.	.	X
35	1,5-anhydroglucitol (ug/mL)	6	X	X	X	X	X	O	O	O
36	1,5-anhydroglucitol (ug/mL)	7	X	X	X	X	.	X	X	X
37	1,5-anhydroglucitol (ug/mL)	8	X	X	X	X	.	.	X	X
38	1,5-anhydroglucitol (ug/mL)	9	X	X	X	X	.	.	.	X
39	1,5-anhydroglucitol (ug/mL)	10	X	X	X	X	O	O	O	O
40	1,5-anhydroglucitol (ug/mL)	11	X	X	X	.	X	X	X	X
41	1,5-anhydroglucitol (ug/mL)	12	X	X	.	X	X	X	X	X
42	1,5-anhydroglucitol (ug/mL)	13	X	X	.	X	X	X	O	O
43	1,5-anhydroglucitol (ug/mL)	14	X	X	O	O	O	O	O	O

Obs	Freq	Percent	BASE	visit1400	visit1800	visit2200	visit2600	visit3000	visit3400	visit3600
33	1	0.29	8.400000	-0.300000	0.800000	-2.500000	-1.900000	.	-2.400000	-0.200000
34	1	0.29	1.600000	-0.200000	-0.300000	0.500000	1.400000	.	.	0
35	1	0.29	1.600000	-0.400000	-0.300000	-0.400000	-0.200000	.	.	.
36	1	0.29	5.900000	-0.600000	1.200000	-1.600000	.	-1.100000	-1.300000	0.300000
37	1	0.29	5.500000	2.600000	-3.200000	-2.200000	.	.	-1.900000	-1.200000
38	1	0.29	2.800000	-0.100000	-0.700000	3.400000	.	.	.	1.500000
39	2	0.59	2.850000	-0.500000	-1.200000	-0.700000
40	3	0.88	9.500000	-0.100000	-1.566667	.	-1.200000	-2.233333	-4.000000	-2.833333
41	3	0.88	3.366667	0.833333	.	0.433333	0.466667	0.666667	0.933333	1.466667
42	1	0.29	1.400000	0	.	-0.400000	-0.100000	-0.400000	.	.
43	1	0.29	1.400000	1.900000

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1,5-anhydroglucitol 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with MCMC
Missing data pattern

Parameter Code=AG_1_5_S Planned Treatment for Period 30 (N)=4

(continued)

Obs	PARAM	Group	BASE_ Miss	visit1400_ Miss	visit1800_ Miss	visit2200_ Miss	visit2600_ Miss	visit3000_ Miss	visit3400_ Miss	visit3600_ Miss
44	1,5-anhydroglucitol (ug/mL)	15	X	.	X	X	X	X	X	X
45	1,5-anhydroglucitol (ug/mL)	16	X	.	X	X	X	X	X	O
46	1,5-anhydroglucitol (ug/mL)	17	X	O	O	O	O	O	O	O

Obs	Freq	Percent	BASE	visit1400	visit1800	visit2200	visit2600	visit3000	visit3400	visit3600
44	2	0.59	10.800000	.	0.450000	0.200000	-0.100000	-1.100000	-0.700000	-0.700000
45	1	0.29	5.500000	.	-3.000000	-2.600000	-3.200000	-0.400000	-1.200000	.
46	1	0.29	7.400000

1,5-anhydroglucitol 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=AG_1_5_S Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM	Description	Value
1	1	1,5-anhydroglucitol (ug/mL)	Data Set	WORK.MONOTONE
2	1	1,5-anhydroglucitol (ug/mL)	Method	Monotone
3	1	1,5-anhydroglucitol (ug/mL)	Number of Imputations	1
4	1	1,5-anhydroglucitol (ug/mL)	Seed for random number generator	9894

Parameter Code=AG_1_5_S Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM	Description	Value
5	1	1,5-anhydroglucitol (ug/mL)	Data Set	WORK.MONOTONE
6	1	1,5-anhydroglucitol (ug/mL)	Method	Monotone
7	1	1,5-anhydroglucitol (ug/mL)	Number of Imputations	1
8	1	1,5-anhydroglucitol (ug/mL)	Seed for random number generator	851620022

Parameter Code=AG_1_5_S Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM	Description	Value
9	1	1,5-anhydroglucitol (ug/mL)	Data Set	WORK.MONOTONE
10	1	1,5-anhydroglucitol (ug/mL)	Method	Monotone
11	1	1,5-anhydroglucitol (ug/mL)	Number of Imputations	1
12	1	1,5-anhydroglucitol (ug/mL)	Seed for random number generator	629248725

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The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=AG_1_5_S Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM	Group	REGION1_ Miss	BOLAD1_ Miss	BASE_ Miss	visit1400_ Miss	visit1800_ Miss
1	1	1,5-anhydroglucitol (ug/mL)	1	X	X	X	X	X
2	1	1,5-anhydroglucitol (ug/mL)	2	X	X	X	X	X
3	1	1,5-anhydroglucitol (ug/mL)	3	X	X	X	X	X
4	1	1,5-anhydroglucitol (ug/mL)	4	X	X	X	X	.

Obs	visit2200_ Miss	visit2600_ Miss	visit3000_ Miss	visit3400_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit1400
1	X	X	X	X	X	337	98.83	4.706231	0.228332
2	X	X	X	X	.	1	0.29	6.000000	-1.300000
3	1	0.29	5.500000	2.400000
4	2	0.59	5.900000	-0.650000

Obs	visit1800	visit2200	visit2600	visit3000	visit3400	visit3600
1	0.283083	0.239297	0.273365	0.317511	0.229200	0.218991
2	1.300000	0.600000	-0.300000	-1.300000	-0.600000	.
3	1.900000
4

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The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=AG_1_5_S Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM	Group	REGION1_ Miss	BOLAD1_ Miss	BASE_ Miss	visit1400_ Miss	visit1800_ Miss
5	1	1,5-anhydroglucitol (ug/mL)	1	X	X	X	X	X
6	1	1,5-anhydroglucitol (ug/mL)	2	X	X	X	X	X
7	1	1,5-anhydroglucitol (ug/mL)	3	X	X	X	X	X
8	1	1,5-anhydroglucitol (ug/mL)	4	X	X	X	X	X
9	1	1,5-anhydroglucitol (ug/mL)	5	X	X	X	X	X
10	1	1,5-anhydroglucitol (ug/mL)	6	X	X	X	X	.

Obs	visit2200_ Miss	visit2600_ Miss	visit3000_ Miss	visit3400_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit1400
5	X	X	X	X	X	329	97.92	4.599088	-0.011152
6	X	X	X	.	.	1	0.30	6.400000	-2.300000
7	X	X	.	.	.	1	0.30	3.800000	-0.600000
8	X	3	0.89	3.566667	-1.133333
9	1	0.30	2.800000	-1.100000
10	1	0.30	4.600000	2.800000

Obs	visit1800	visit2200	visit2600	visit3000	visit3400	visit3600
5	-0.088578	-0.140407	-0.088719	-0.124476	-0.013355	-0.134954
6	-2.600000	-0.500000	3.300000	-2.200000	.	.
7	0.100000	1.500000	-0.100000	.	.	.
8	-1.200000	-1.433333
9	-1.800000
10

1,5-anhydroglucitol 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=AG_1_5_S Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM	Group	REGION1_ Miss	BOLAD1_ Miss	BASE_ Miss	visit1400_ Miss	visit1800_ Miss
11	1	1,5-anhydroglucitol (ug/mL)	1	X	X	X	X	X
12	1	1,5-anhydroglucitol (ug/mL)	2	X	X	X	X	X
13	1	1,5-anhydroglucitol (ug/mL)	3	X	X	X	X	X
14	1	1,5-anhydroglucitol (ug/mL)	4	X	X	X	X	X
15	1	1,5-anhydroglucitol (ug/mL)	5	X	X	X	X	X
16	1	1,5-anhydroglucitol (ug/mL)	6	X	X	X	X	.

Obs	visit2200_ Miss	visit2600_ Miss	visit3000_ Miss	visit3400_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit1400
11	X	X	X	X	X	327	96.46	4.744954	0.154081
12	X	X	X	X	.	6	1.77	4.450000	-0.729301
13	X	X	X	.	.	1	0.29	1.400000	0
14	X	X	.	.	.	1	0.29	1.600000	-0.400000
15	X	2	0.59	2.850000	-0.500000
16	1	0.29	1.400000	1.900000

Obs	visit1800	visit2200	visit2600	visit3000	visit3400	visit3600
11	0.157244	0.031376	0.259392	0.238407	0.199813	0.229052
12	-0.650000	-0.766667	-0.533333	0.133333	-0.083333	.
13	-0.432633	-0.400000	-0.100000	-0.400000	.	.
14	-0.300000	-0.400000	-0.200000	.	.	.
15	-1.200000	-0.700000
16

1,5-anhydroglucitol 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression Missing Data Pattern

Parameter Code=AG 1 5 S Planned Treatment for Period 30 (N)=4

(continued)

Obs	_Imputation_	PARAM			Group	REGION1_Miss_	BOLAD1_Miss_	BASE_Miss_	visit1400_Miss_	visit1800_Miss_
17	1	1,5-anhydroglucitol (ug/mL)			7	X	X	X	.	.
Obs	visit2200_Miss_	visit2600_Miss_	visit3000_Miss_	visit3400_Miss_	visit3600_Miss_		Freq	Percent	BASE	visit1400
17		1	0.29	7.400000	.
Obs	visit1800	visit2200	visit2600	visit3000	visit3400		visit3600			
17			

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=AG_1_5_S Planned Treatment for Period 30 (N)=2 Imputed Variable=visit1800

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	1,5-anhydroglucitol (ug/mL)	Intercept	
2	1	1,5-anhydroglucitol (ug/mL)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	1,5-anhydroglucitol (ug/mL)	REGION1	EUROPE
4	1	1,5-anhydroglucitol (ug/mL)	REGION1	JAPAN
5	1	1,5-anhydroglucitol (ug/mL)	BOLAD1	
6	1	1,5-anhydroglucitol (ug/mL)	BASE	
7	1	1,5-anhydroglucitol (ug/mL)	visit1400	

Obs		BOLAD1	ObsVal	_1
1			0.00268	-0.027888
2			-0.05229	0.077711
3			-0.06353	-0.206705
4			0.13597	0.092140
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.00411	0.039265
6			-0.00151	-0.029997
7			0.59902	0.554665

Parameter Code=AG_1_5_S Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
8	1	1,5-anhydroglucitol (ug/mL)	Intercept			0.01341	0.038191
9	1	1,5-anhydroglucitol (ug/mL)	REGION1	ASIA (EXCLUDING JAPAN)		0.15055	0.139167

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=AG_1_5_S Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2200

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10	1	1,5-anhydroglucitol	(ug/mL)	REGION1	EUROPE							-0.01250		-0.004132	
11	1	1,5-anhydroglucitol	(ug/mL)	REGION1	JAPAN							-0.08356		-0.013676	
12	1	1,5-anhydroglucitol	(ug/mL)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)						0.06058		0.020252	
13	1	1,5-anhydroglucitol	(ug/mL)	BASE								-0.03968		-0.046974	
14	1	1,5-anhydroglucitol	(ug/mL)	visit1400								0.14554		0.129329	
15	1	1,5-anhydroglucitol	(ug/mL)	visit1800								0.59568		0.605457	

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=AG_1_5_S Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2600

Obs	_Imputation_	PARAM	Effect	REGION1
16	1	1,5-anhydroglucitol (ug/mL)	Intercept	
17	1	1,5-anhydroglucitol (ug/mL)	REGION1	ASIA (EXCLUDING JAPAN)
18	1	1,5-anhydroglucitol (ug/mL)	REGION1	EUROPE
19	1	1,5-anhydroglucitol (ug/mL)	REGION1	JAPAN
20	1	1,5-anhydroglucitol (ug/mL)	BOLAD1	
21	1	1,5-anhydroglucitol (ug/mL)	BASE	
22	1	1,5-anhydroglucitol (ug/mL)	visit1400	
23	1	1,5-anhydroglucitol (ug/mL)	visit1800	
24	1	1,5-anhydroglucitol (ug/mL)	visit2200	

Obs	BOLAD1	ObsVal	_1
16		0.02838	-0.043261
17		0.03751	-0.019302
18		-0.13371	-0.057277
19		0.08162	0.032633
20	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.04766	-0.042187
21		-0.00502	-0.041450
22		0.15394	0.107005
23		0.01197	0.036611
24		0.68177	0.681449

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=AG_1_5_S Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3000

Obs	_Imputation_	PARAM	Effect	REGION1
25	1	1,5-anhydroglucitol (ug/mL)	Intercept	
26	1	1,5-anhydroglucitol (ug/mL)	REGION1	ASIA (EXCLUDING JAPAN)
27	1	1,5-anhydroglucitol (ug/mL)	REGION1	EUROPE
28	1	1,5-anhydroglucitol (ug/mL)	REGION1	JAPAN
29	1	1,5-anhydroglucitol (ug/mL)	BOLAD1	
30	1	1,5-anhydroglucitol (ug/mL)	BASE	
31	1	1,5-anhydroglucitol (ug/mL)	visit1400	
32	1	1,5-anhydroglucitol (ug/mL)	visit1800	
33	1	1,5-anhydroglucitol (ug/mL)	visit2200	
34	1	1,5-anhydroglucitol (ug/mL)	visit2600	

Obs	BOLAD1	ObsVal	_1
25		-0.01674	-0.011064
26		-0.12731	-0.093934
27		0.01700	0.082625
28		0.05040	-0.040588
29	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.02836	-0.067597
30		-0.10473	-0.147114
31		0.09221	0.044617
32		-0.04881	-0.032204
33		0.20840	0.198546
34		0.52528	0.512966

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Regression Information

Parameter Code=AG_1_5_S Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3400

Obs	_Imputation_	PARAM	Effect	REGION1
35	1	1,5-anhydroglucitol (ug/mL)	Intercept	
36	1	1,5-anhydroglucitol (ug/mL)	REGION1	ASIA (EXCLUDING JAPAN)
37	1	1,5-anhydroglucitol (ug/mL)	REGION1	EUROPE
38	1	1,5-anhydroglucitol (ug/mL)	REGION1	JAPAN
39	1	1,5-anhydroglucitol (ug/mL)	BOLAD1	
40	1	1,5-anhydroglucitol (ug/mL)	BASE	
41	1	1,5-anhydroglucitol (ug/mL)	visit1400	
42	1	1,5-anhydroglucitol (ug/mL)	visit1800	
43	1	1,5-anhydroglucitol (ug/mL)	visit2200	
44	1	1,5-anhydroglucitol (ug/mL)	visit2600	
45	1	1,5-anhydroglucitol (ug/mL)	visit3000	

Obs	BOLAD1	ObsVal	_1
35		0.01280	0.072949
36		0.03241	0.197355
37		-0.04226	-0.126953
38		-0.01517	-0.013613
39	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.03839	-0.054295
40		-0.15495	-0.132055
41		0.05876	0.135013
42		0.13553	0.082832
43		0.10868	0.081773
44		0.11125	0.080522
45		0.47173	0.467132

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=AG_1_5_S Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1
46	1	1,5-anhydroglucitol (ug/mL)	Intercept	
47	1	1,5-anhydroglucitol (ug/mL)	REGION1	ASIA (EXCLUDING JAPAN)
48	1	1,5-anhydroglucitol (ug/mL)	REGION1	EUROPE
49	1	1,5-anhydroglucitol (ug/mL)	REGION1	JAPAN
50	1	1,5-anhydroglucitol (ug/mL)	BOLAD1	
51	1	1,5-anhydroglucitol (ug/mL)	BASE	
52	1	1,5-anhydroglucitol (ug/mL)	visit1400	
53	1	1,5-anhydroglucitol (ug/mL)	visit1800	
54	1	1,5-anhydroglucitol (ug/mL)	visit2200	
55	1	1,5-anhydroglucitol (ug/mL)	visit2600	
56	1	1,5-anhydroglucitol (ug/mL)	visit3000	
57	1	1,5-anhydroglucitol (ug/mL)	visit3400	

Obs	BOLAD1	ObsVal	_1
46		0.00945	0.013415
47		0.09247	0.074718
48		-0.06852	-0.066869
49		-0.07668	-0.043020
50	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.01145	0.025841
51		-0.13966	-0.150557
52		0.05715	0.065131
53		-0.05364	-0.048382
54		0.02524	-0.037496
55		0.09335	0.168712
56		0.02611	0.072058
57		0.70435	0.659230

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=AG_1_5_S Planned Treatment for Period 30 (N)=3 Imputed Variable=visit1800

Obs	_Imputation_	PARAM	Effect	REGION1
58	1	1,5-anhydroglucitol (ug/mL)	Intercept	
59	1	1,5-anhydroglucitol (ug/mL)	REGION1	ASIA (EXCLUDING JAPAN)
60	1	1,5-anhydroglucitol (ug/mL)	REGION1	EUROPE
61	1	1,5-anhydroglucitol (ug/mL)	REGION1	JAPAN
62	1	1,5-anhydroglucitol (ug/mL)	BOLAD1	
63	1	1,5-anhydroglucitol (ug/mL)	BASE	
64	1	1,5-anhydroglucitol (ug/mL)	visit1400	

Obs		BOLAD1	ObsVal	_1
58			0.01334	0.074976
59			0.02529	0.167773
60			-0.06745	-0.151769
61			-0.05087	-0.034699
62	BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.02693	0.033267
63			-0.14136	-0.154174
64			0.53742	0.531024

Parameter Code=AG_1_5_S Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
65	1	1,5-anhydroglucitol (ug/mL)	Intercept			0.01072	0.093011
66	1	1,5-anhydroglucitol (ug/mL)	REGION1	ASIA (EXCLUDING JAPAN)		0.13228	0.269302

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Parameter Code=AG 1 5 S Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2200

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	O	b	s	I m p u t a t i o n —	P A R A M	E f f e c t	R E G I O N 1	B O L U S D 1	O b s V a l	\bar{I}
67	1	1,5-anhydroglucitol	(ug/mL)	REGION1	EUROPE				-0.00937	0.005781
68	1	1,5-anhydroglucitol	(ug/mL)	REGION1	JAPAN				-0.10341	-0.199215
69	1	1,5-anhydroglucitol	(ug/mL)	BOLAD1				BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.07141	0.048090
70	1	1,5-anhydroglucitol	(ug/mL)	BASE					-0.00909	0.012778
71	1	1,5-anhydroglucitol	(ug/mL)	visit1400					0.11696	0.123200
72	1	1,5-anhydroglucitol	(ug/mL)	visit1800					0.63102	0.641444

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Parameter Code=AG_1_5_S Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2600

Obs	_Imputation_	PARAM	Effect	REGION1
73	1	1,5-anhydroglucitol (ug/mL)	Intercept	
74	1	1,5-anhydroglucitol (ug/mL)	REGION1	ASIA (EXCLUDING JAPAN)
75	1	1,5-anhydroglucitol (ug/mL)	REGION1	EUROPE
76	1	1,5-anhydroglucitol (ug/mL)	REGION1	JAPAN
77	1	1,5-anhydroglucitol (ug/mL)	BOLAD1	
78	1	1,5-anhydroglucitol (ug/mL)	BASE	
79	1	1,5-anhydroglucitol (ug/mL)	visit1400	
80	1	1,5-anhydroglucitol (ug/mL)	visit1800	
81	1	1,5-anhydroglucitol (ug/mL)	visit2200	

Obs	BOLAD1	ObsVal	_1
73		-0.01235	0.002804
74		-0.02743	-0.060485
75		-0.04866	0.026733
76		0.07186	0.090733
77	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.06357	0.045201
78		-0.11612	-0.136193
79		0.13806	0.104653
80		0.10196	0.046999
81		0.55135	0.593607

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Parameter Code=AG_1_5_S Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3000

Obs	_Imputation_	PARAM	Effect	REGION1
82	1	1,5-anhydroglucitol (ug/mL)	Intercept	
83	1	1,5-anhydroglucitol (ug/mL)	REGION1	ASIA (EXCLUDING JAPAN)
84	1	1,5-anhydroglucitol (ug/mL)	REGION1	EUROPE
85	1	1,5-anhydroglucitol (ug/mL)	REGION1	JAPAN
86	1	1,5-anhydroglucitol (ug/mL)	BOLAD1	
87	1	1,5-anhydroglucitol (ug/mL)	BASE	
88	1	1,5-anhydroglucitol (ug/mL)	visit1400	
89	1	1,5-anhydroglucitol (ug/mL)	visit1800	
90	1	1,5-anhydroglucitol (ug/mL)	visit2200	
91	1	1,5-anhydroglucitol (ug/mL)	visit2600	

Obs	BOLAD1	ObsVal	_1
82		0.00426	-0.004744
83		0.0006214	-0.084575
84		-0.04427	-0.095336
85		0.03746	0.030422
86	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.00965	0.033923
87		-0.13797	-0.137539
88		0.04480	0.053582
89		-0.00847	-0.029335
90		0.21554	0.218705
91		0.48573	0.471676

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The MI Procedure with Monotone Regression
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Parameter Code=AG_1_5_S Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3400

Obs	_Imputation_	PARAM	Effect	REGION1
92	1	1,5-anhydroglucitol (ug/mL)	Intercept	
93	1	1,5-anhydroglucitol (ug/mL)	REGION1	ASIA (EXCLUDING JAPAN)
94	1	1,5-anhydroglucitol (ug/mL)	REGION1	EUROPE
95	1	1,5-anhydroglucitol (ug/mL)	REGION1	JAPAN
96	1	1,5-anhydroglucitol (ug/mL)	BOLAD1	
97	1	1,5-anhydroglucitol (ug/mL)	BASE	
98	1	1,5-anhydroglucitol (ug/mL)	visit1400	
99	1	1,5-anhydroglucitol (ug/mL)	visit1800	
100	1	1,5-anhydroglucitol (ug/mL)	visit2200	
101	1	1,5-anhydroglucitol (ug/mL)	visit2600	
102	1	1,5-anhydroglucitol (ug/mL)	visit3000	

Obs	BOLAD1	ObsVal	_1
92		0.03371	0.036064
93		0.13175	0.165867
94		-0.12705	-0.179451
95		0.07853	0.085094
96	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.05246	-0.053741
97		-0.01532	-0.088877
98		0.04477	-0.060381
99		0.00994	0.023480
100		0.20919	0.205709
101		0.08436	0.072726
102		0.50644	0.492844

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Parameter Code=AG_1_5_S Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1
103	1	1,5-anhydroglucitol (ug/mL)	Intercept	
104	1	1,5-anhydroglucitol (ug/mL)	REGION1	ASIA (EXCLUDING JAPAN)
105	1	1,5-anhydroglucitol (ug/mL)	REGION1	EUROPE
106	1	1,5-anhydroglucitol (ug/mL)	REGION1	JAPAN
107	1	1,5-anhydroglucitol (ug/mL)	BOLAD1	
108	1	1,5-anhydroglucitol (ug/mL)	BASE	
109	1	1,5-anhydroglucitol (ug/mL)	visit1400	
110	1	1,5-anhydroglucitol (ug/mL)	visit1800	
111	1	1,5-anhydroglucitol (ug/mL)	visit2200	
112	1	1,5-anhydroglucitol (ug/mL)	visit2600	
113	1	1,5-anhydroglucitol (ug/mL)	visit3000	
114	1	1,5-anhydroglucitol (ug/mL)	visit3400	

Obs	BOLAD1	ObsVal	_1
103		0.01759	0.059161
104		0.07235	0.072864
105		-0.02079	-0.045177
106		-0.04308	-0.012198
107	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.04813	0.007373
108		-0.03095	-0.068234
109		0.04541	0.029719
110		-0.00535	0.028843
111		0.02877	-0.047612
112		0.11980	0.151502
113		0.07035	0.162398
114		0.67571	0.616779

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Parameter Code=AG_1_5_S Planned Treatment for Period 30 (N)=4 Imputed Variable=visit1400

Obs	_Imputation_	PARAM	Effect	REGION1
115	1	1,5-anhydroglucitol (ug/mL)	Intercept	
116	1	1,5-anhydroglucitol (ug/mL)	REGION1	ASIA (EXCLUDING JAPAN)
117	1	1,5-anhydroglucitol (ug/mL)	REGION1	EUROPE
118	1	1,5-anhydroglucitol (ug/mL)	REGION1	JAPAN
119	1	1,5-anhydroglucitol (ug/mL)	BOLAD1	
120	1	1,5-anhydroglucitol (ug/mL)	BASE	

Obs	BOLAD1	ObsVal	_1
115		-0.01548	0.010293
116		-0.04517	-0.296180
117		-0.03251	-0.017042
118		0.10293	0.200215
119	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.07525	0.103587
120		0.04614	0.020441

Parameter Code=AG_1_5_S Planned Treatment for Period 30 (N)=4 Imputed Variable=visit1800

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
121	1	1,5-anhydroglucitol (ug/mL)	Intercept			-0.05884	-0.057968
122	1	1,5-anhydroglucitol (ug/mL)	REGION1	ASIA (EXCLUDING JAPAN)		-0.30769	-0.355089
123	1	1,5-anhydroglucitol (ug/mL)	REGION1	EUROPE		-0.00703	-0.039255

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Parameter Code=AG_1_5_S Planned Treatment for Period 30 (N)=4 Imputed Variable=visit1800

(continued)

		Imputed parameter		Effect		Region		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		Observations	
O	b	P	A	E	R	B	O	D	A	s	l
s	—	M	A	t	1	1	1	1	1	1	1
124	1	1,5-anhydroglucitol	(ug/mL)	REGION1	JAPAN					0.09059	0.181122
125	1	1,5-anhydroglucitol	(ug/mL)	BOLAD1						0.11946	0.078378
126	1	1,5-anhydroglucitol	(ug/mL)	BASE						0.08228	0.104954
127	1	1,5-anhydroglucitol	(ug/mL)	visit1400						0.63628	0.652921

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Parameter Code=AG_1_5_S Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
128	1	1,5-anhydroglucitol (ug/mL)	Intercept	
129	1	1,5-anhydroglucitol (ug/mL)	REGION1	ASIA (EXCLUDING JAPAN)
130	1	1,5-anhydroglucitol (ug/mL)	REGION1	EUROPE
131	1	1,5-anhydroglucitol (ug/mL)	REGION1	JAPAN
132	1	1,5-anhydroglucitol (ug/mL)	BOLAD1	
133	1	1,5-anhydroglucitol (ug/mL)	BASE	
134	1	1,5-anhydroglucitol (ug/mL)	visit1400	
135	1	1,5-anhydroglucitol (ug/mL)	visit1800	

Obs	BOLAD1	ObsVal	_1
128		0.02038	-0.014452
129		0.19835	0.170009
130		-0.05429	-0.030558
131		-0.07748	0.004408
132	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.03050	-0.060609
133		-0.06845	-0.068757
134		0.13667	0.079872
135		0.64309	0.667444

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Parameter Code=AG_1_5_S Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2600

Obs	_Imputation_	PARAM	Effect	REGION1
136	1	1,5-anhydroglucitol (ug/mL)	Intercept	
137	1	1,5-anhydroglucitol (ug/mL)	REGION1	ASIA (EXCLUDING JAPAN)
138	1	1,5-anhydroglucitol (ug/mL)	REGION1	EUROPE
139	1	1,5-anhydroglucitol (ug/mL)	REGION1	JAPAN
140	1	1,5-anhydroglucitol (ug/mL)	BOLAD1	
141	1	1,5-anhydroglucitol (ug/mL)	BASE	
142	1	1,5-anhydroglucitol (ug/mL)	visit1400	
143	1	1,5-anhydroglucitol (ug/mL)	visit1800	
144	1	1,5-anhydroglucitol (ug/mL)	visit2200	

Obs	BOLAD1	ObsVal	_1
136		0.00822	0.013273
137		0.17773	0.227263
138		-0.09244	-0.135108
139		-0.14980	-0.174785
140	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.05981	0.082663
141		0.01366	-0.030157
142		0.02880	0.012577
143		0.06435	0.008037
144		0.71156	0.795381

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Parameter Code=AG_1_5_S Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3000

Obs	_Imputation_	PARAM	Effect	REGION1
145	1	1,5-anhydroglucitol (ug/mL)	Intercept	
146	1	1,5-anhydroglucitol (ug/mL)	REGION1	ASIA (EXCLUDING JAPAN)
147	1	1,5-anhydroglucitol (ug/mL)	REGION1	EUROPE
148	1	1,5-anhydroglucitol (ug/mL)	REGION1	JAPAN
149	1	1,5-anhydroglucitol (ug/mL)	BOLAD1	
150	1	1,5-anhydroglucitol (ug/mL)	BASE	
151	1	1,5-anhydroglucitol (ug/mL)	visit1400	
152	1	1,5-anhydroglucitol (ug/mL)	visit1800	
153	1	1,5-anhydroglucitol (ug/mL)	visit2200	
154	1	1,5-anhydroglucitol (ug/mL)	visit2600	

Obs	BOLAD1	ObsVal	_1
145		0.00314	0.036702
146		0.01084	-0.068201
147		-0.09182	-0.134989
148		-0.02746	0.091912
149	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.0004966	-0.022173
150		0.03747	0.060355
151		0.11423	0.149915
152		0.08046	-0.014332
153		0.06818	0.102901
154		0.57693	0.593501

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1,5-anhydroglucitol 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=AG_1_5_S Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3400

Obs	_Imputation_	PARAM	Effect	REGION1
155	1	1,5-anhydroglucitol (ug/mL)	Intercept	
156	1	1,5-anhydroglucitol (ug/mL)	REGION1	ASIA (EXCLUDING JAPAN)
157	1	1,5-anhydroglucitol (ug/mL)	REGION1	EUROPE
158	1	1,5-anhydroglucitol (ug/mL)	REGION1	JAPAN
159	1	1,5-anhydroglucitol (ug/mL)	BOLAD1	
160	1	1,5-anhydroglucitol (ug/mL)	BASE	
161	1	1,5-anhydroglucitol (ug/mL)	visit1400	
162	1	1,5-anhydroglucitol (ug/mL)	visit1800	
163	1	1,5-anhydroglucitol (ug/mL)	visit2200	
164	1	1,5-anhydroglucitol (ug/mL)	visit2600	
165	1	1,5-anhydroglucitol (ug/mL)	visit3000	

Obs	BOLAD1	ObsVal	_1
155		0.01471	0.038239
156		0.12689	0.196551
157		0.01734	0.006453
158		-0.12838	-0.137782
159	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.02412	-0.017894
160		-0.05561	-0.070844
161		-0.09360	-0.020745
162		0.09755	0.094801
163		0.08888	0.083201
164		0.13920	0.109870
165		0.64677	0.656981

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Fast-acting insulin aspart
NN1218-4131

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1,5-anhydroglucitol 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=AG_1_5_S Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1
166	1	1,5-anhydroglucitol (ug/mL)	Intercept	
167	1	1,5-anhydroglucitol (ug/mL)	REGION1	ASIA (EXCLUDING JAPAN)
168	1	1,5-anhydroglucitol (ug/mL)	REGION1	EUROPE
169	1	1,5-anhydroglucitol (ug/mL)	REGION1	JAPAN
170	1	1,5-anhydroglucitol (ug/mL)	BOLAD1	
171	1	1,5-anhydroglucitol (ug/mL)	BASE	
172	1	1,5-anhydroglucitol (ug/mL)	visit1400	
173	1	1,5-anhydroglucitol (ug/mL)	visit1800	
174	1	1,5-anhydroglucitol (ug/mL)	visit2200	
175	1	1,5-anhydroglucitol (ug/mL)	visit2600	
176	1	1,5-anhydroglucitol (ug/mL)	visit3000	
177	1	1,5-anhydroglucitol (ug/mL)	visit3400	

Obs	BOLAD1	ObsVal	_1
166		0.00701	-0.006849
167		0.09441	0.058312
168		0.00422	0.069841
169		-0.05816	-0.060719
170	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.00386	0.006080
171		-0.02857	-0.011125
172		-0.06522	-0.110568
173		0.07444	0.063822
174		0.12010	0.135578
175		-0.10187	-0.127514
176		0.19897	0.173330
177		0.70003	0.720388

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1,5-anhydroglucitol 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Model Information

Parameter Code=AG_1_5_S Parameter=1,5-anhydroglucitol (ug/mL)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Data Set	WORK.IMPUTE
2	1	NN1218-4131	Dependent Variable	eotVisit
3	1	NN1218-4131	Covariance Structure	Diagonal
4	1	NN1218-4131	Estimation Method	REML
5	1	NN1218-4131	Residual Variance Method	Profile
6	1	NN1218-4131	Fixed Effects SE Method	Model-Based
7	1	NN1218-4131	Degrees of Freedom Method	Residual

1,5-anhydroglucitol 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Dimensions

Parameter Code=AG_1_5_S Parameter=1,5-anhydroglucitol (ug/mL)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Covariance Parameters	1
2	1	NN1218-4131	Columns in X	10
3	1	NN1218-4131	Columns in Z	0
4	1	NN1218-4131	Subjects	1
5	1	NN1218-4131	Max Obs per Subject	1016

1,5-anhydroglucitol 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Number of Observations

Parameter Code=AG_1_5_S Parameter=1,5-anhydroglucitol (ug/mL)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
1	1	NN1218-4131	Number of Observations Read	1016	1016	1016	1016	1016
2	1	NN1218-4131	Number of Observations Used	1016	1016	1016	1016	1016
3	1	NN1218-4131	Number of Observations Not Used	0	1016	1016	1016	1016

1,5-anhydroglucitol 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Covariance Parameter Estimates

Parameter Code=AG_1_5_S Parameter=1,5-anhydroglucitol (ug/mL)

Obs	_Imputation_	STUDYID	CovParm	Estimate
1	1	NN1218-4131	Residual	4.5709

1,5-anhydroglucitol 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Fit Statistics

Parameter Code=AG_1_5_S Parameter=1,5-anhydroglucitol (ug/mL)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	-2 Res Log Likelihood	4439.3
2	1	NN1218-4131	AIC (Smaller is Better)	4441.3
3	1	NN1218-4131	AICC (Smaller is Better)	4441.3
4	1	NN1218-4131	BIC (Smaller is Better)	4446.2

Fast-acting insulin aspart
NN1218-4131

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1,5-anhydroglucitol 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Solution for Fixed Effects

Parameter Code=AG_1_5_S Parameter=1,5-anhydroglucitol (ug/mL)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
1	1	NN1218-4131	TRTPN	2				
2	1	NN1218-4131	TRTPN	3				
3	1	NN1218-4131	TRTPN	4				
4	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
5	1	NN1218-4131	REGION1	—	EUROPE			
6	1	NN1218-4131	REGION1	—	JAPAN			
7	1	NN1218-4131	REGION1	—	NORTH AMERICA			
8	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
9	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
10	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	1.0595	0.1934	1008	5.48	<.0001	0.05	0.6799	1.4390
2	0.7109	0.1939	1008	3.67	0.0003	0.05	0.3303	1.0914
3	1.0729	0.1955	1008	5.49	<.0001	0.05	0.6891	1.4566
4	0.3872	0.2481	1008	1.56	0.1189	0.05	-0.09958	0.8740
5	-0.5043	0.1726	1008	-2.92	0.0036	0.05	-0.8430	-0.1656
6	-0.2711	0.1926	1008	-1.41	0.1596	0.05	-0.6491	0.1069
7	0
8	0.1209	0.1503	1008	0.80	0.4214	0.05	-0.1740	0.4157
9	0
10	-0.1544	0.02294	1008	-6.73	<.0001	0.05	-0.1994	-0.1094

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1,5-anhydroglucitol 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Least Squares Means

Obs	_Imputation_	PARAMCD	PARAM		STUDYID	Effect	TRTPN		
1	1	AG_1_5_S	1,5-anhydroglucitol	(ug/mL)	NN1218-4131	TRTPN	2		
2	1	AG_1_5_S	1,5-anhydroglucitol	(ug/mL)	NN1218-4131	TRTPN	3		
3	1	AG_1_5_S	1,5-anhydroglucitol	(ug/mL)	NN1218-4131	TRTPN	4		
Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	WORK.IMPUTE	0.2226	0.1160	1008	1.92	0.0551	0.05	-0.00491	0.4502
2	WORK.IMPUTE	-0.1259	0.1168	1008	-1.08	0.2812	0.05	-0.3551	0.1032
3	WORK.IMPUTE	0.2360	0.1162	1008	2.03	0.0425	0.05	0.007978	0.4641

1,5-anhydroglucitol 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Least Squares Means Estimate

Parameter Code=AG_1_5_S Parameter=1,5-anhydroglucitol (ug/mL)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
1	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
2	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	WORK.IMPUTE	-0.01340	0.1643	1008	-0.08	0.9350	0.05	-0.3358	0.3089
2	WORK.IMPUTE	-0.3620	0.1648	1008	-2.20	0.0283	0.05	-0.6854	-0.03857

1,5-anhydroglucitol 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=AG_1_5_S Parameter=1,5-anhydroglucitol (ug/mL) Study Identifier=NN1218-4

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	100

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000083250	0.013545	0.013629	2.6E6	0.006208	0.006170	0.999938

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.226589	0.116743	-0.00222	0.455402	2.6E6	0.202968	0.252743

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	1.94	0.0523

1,5-anhydroglucitol 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=AG_1_5_S Parameter=1,5-anhydroglucitol (ug/mL) Study Identifier=NN1218-4

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	100

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000175	0.013738	0.013914	616476	0.012835	0.012676	0.999873

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.141146	0.117959	-0.37234	0.090049	616476	-0.168827	-0.101667

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-1.20	0.2315

1,5-anhydroglucitol 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=AG_1_5_S Parameter=1,5-anhydroglucitol (ug/mL) Study Identifier=NN1218-4

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	100

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000202	0.013607	0.013811	452336	0.015016	0.014798	0.999852

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.210802	0.117521	-0.01954	0.441140	452336	0.173149	0.243404

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	1.79	0.0729

1,5-anhydroglucitol 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=AG_1_5_S Label=Faster aspart (meal) - NovoRapid (meal) Parameter=1,5-anhydroglucitol (ug/mL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	100

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000314	0.027184	0.027501	745965	0.011654	0.011523	0.999885

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.015787	0.165834	-0.30924	0.340817	745965	-0.021677	0.061946

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	0.10	0.9242

1,5-anhydroglucitol 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=AG_1_5_S Label=Faster aspart (post) - NovoRapid (meal) Parameter=1,5-anhydroglucitol (ug/mL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	100

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000379	0.027360	0.027743	518927	0.014006	0.013816	0.999862

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.351948	0.166562	-0.67840	-0.02549	518927	-0.394707	-0.302979

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-2.11	0.0346

1,5-anhydroglucitol 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Model Information

Parameter Code=AG_1_5_S Parameter=1,5-anhydroglucitol (ug/mL)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Data Set	WORK.IMPUTE_ABS
2	1	NN1218-4131	Dependent Variable	eotVisitAbs_
3	1	NN1218-4131	Covariance Structure	Diagonal
4	1	NN1218-4131	Estimation Method	REML
5	1	NN1218-4131	Residual Variance Method	Profile
6	1	NN1218-4131	Fixed Effects SE Method	Model-Based
7	1	NN1218-4131	Degrees of Freedom Method	Residual

1,5-anhydroglucitol 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Class Level Information

Parameter Code=AG_1_5_S Parameter=1,5-anhydroglucitol (ug/mL)

I m p u t a t i o n s				S T U D Y I D s				L e v e l s				V a l u e s				m i n i l e g t h			
1	1	NN1218-4131	TRTPN	3	2	3	4									5			
2	1	NN1218-4131	REGION1	4	ASIA (EXCLUDING JAPAN)	EUROPE	JAPAN	NORTH AMERICA								49			
3	1	NN1218-4131	BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	CARBOHYDRATE COUNTING (FLEXIBLE)	BOLUS INSULI	85											

1,5-anhydroglucitol 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Dimensions

Parameter Code=AG_1_5_S Parameter=1,5-anhydroglucitol (ug/mL)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Covariance Parameters	1
2	1	NN1218-4131	Columns in X	10
3	1	NN1218-4131	Columns in Z	0
4	1	NN1218-4131	Subjects	1
5	1	NN1218-4131	Max Obs per Subject	1016

1,5-anhydroglucitol 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Number of Observations

Parameter Code=AG_1_5_S Parameter=1,5-anhydroglucitol (ug/mL)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
1	1	NN1218-4131	Number of Observations Read	1016	1016	1016	1016	1016
2	1	NN1218-4131	Number of Observations Used	1016	1016	1016	1016	1016
3	1	NN1218-4131	Number of Observations Not Used	0	1016	1016	1016	1016

1,5-anhydroglucitol 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Covariance Parameter Estimates

Parameter Code=AG_1_5_S Parameter=1,5-anhydroglucitol (ug/mL)

Obs	_Imputation_	STUDYID	CovParm	Estimate
1	1	NN1218-4131	Residual	4.5709

1,5-anhydroglucitol 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Fit Statistics

Parameter Code=AG_1_5_S Parameter=1,5-anhydroglucitol (ug/mL)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	-2 Res Log Likelihood	4439.3
2	1	NN1218-4131	AIC (Smaller is Better)	4441.3
3	1	NN1218-4131	AICC (Smaller is Better)	4441.3
4	1	NN1218-4131	BIC (Smaller is Better)	4446.2

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The Mixed procedure
Solution for Fixed Effects

Parameter Code=AG_1_5_S Parameter=1,5-anhydroglucitol (ug/mL)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
1	1	NN1218-4131	TRTPN	2				
2	1	NN1218-4131	TRTPN	3				
3	1	NN1218-4131	TRTPN	4				
4	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
5	1	NN1218-4131	REGION1	—	EUROPE			
6	1	NN1218-4131	REGION1	—	JAPAN			
7	1	NN1218-4131	REGION1	—	NORTH AMERICA			
8	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
9	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
10	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	1.0595	0.1934	1008	5.48	<.0001	0.05	0.6799	1.4390
2	0.7109	0.1939	1008	3.67	0.0003	0.05	0.3303	1.0914
3	1.0729	0.1955	1008	5.49	<.0001	0.05	0.6891	1.4566
4	0.3872	0.2481	1008	1.56	0.1189	0.05	-0.09958	0.8740
5	-0.5043	0.1726	1008	-2.92	0.0036	0.05	-0.8430	-0.1656
6	-0.2711	0.1926	1008	-1.41	0.1596	0.05	-0.6491	0.1069
7	0
8	0.1209	0.1503	1008	0.80	0.4214	0.05	-0.1740	0.4157
9	0
10	0.8456	0.02294	1008	36.86	<.0001	0.05	0.8006	0.8906

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1,5-anhydroglucitol 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Least Squares Means

Obs	_Imputation_	PARAMCD	PARAM	STUDYID	Effect	TRTPN
1	1	AG_1_5_S	1,5-anhydroglucitol (ug/mL)	NN1218-4131	TRTPN	2
101	1	AG_1_5_S	1,5-anhydroglucitol (ug/mL)	NN1218-4131	TRTPN	3
201	1	AG_1_5_S	1,5-anhydroglucitol (ug/mL)	NN1218-4131	TRTPN	4

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	WORK.IMPUTE	0.2226	0.1160	1008	1.92	0.0551	0.05	-0.00491	0.4502
101	WORK.IMPUTE	-0.1259	0.1168	1008	-1.08	0.2812	0.05	-0.3551	0.1032
201	WORK.IMPUTE	0.2360	0.1162	1008	2.03	0.0425	0.05	0.007978	0.4641

1,5-anhydroglucitol 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Least Squares Means Estimate

Parameter Code=AG_1_5_S Parameter=1,5-anhydroglucitol (ug/mL)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
1	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
101	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	WORK.IMPUTE	-0.01340	0.1643	1008	-0.08	0.9350	0.05	-0.3358	0.3089
101	WORK.IMPUTE	-0.3620	0.1648	1008	-2.20	0.0283	0.05	-0.6854	-0.03857

1,5-anhydroglucitol 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=AG_1_5_S Parameter=1,5-anhydroglucitol (ug/mL) Study Identifier=NN1218-4

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	100

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000083250	0.013545	0.013629	2.6E6	0.006208	0.006170	0.999938

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits	DF	Minimum	Maximum
Estimate	4.898341	0.116743	4.669529 5.127153	2.6E6	4.874720	4.924495

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	41.96	<.0001

1,5-anhydroglucitol 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=AG_1_5_S Parameter=1,5-anhydroglucitol (ug/mL) Study Identifier=NN1218-4

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	100

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000175	0.013738	0.013914	616476	0.012835	0.012676	0.999873

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	4.530605	0.117959	4.299410	4.761801	616476	4.502925	4.570085

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	38.41	<.0001

1,5-anhydroglucitol 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=AG_1_5_S Parameter=1,5-anhydroglucitol (ug/mL) Study Identifier=NN1218-4

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	100

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000202	0.013607	0.013811	452336	0.015016	0.014798	0.999852

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	4.882554	0.117521	4.652216	5.112892	452336	4.844901	4.915156

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	41.55	<.0001

17: 1,5-anhydroglucitol 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=AG_1_5_S Planned Treatment for Period 30 (N)=2

Obs	PARAM	Description	Value
1	1,5-anhydroglucitol (ug/mL)	Data Set	WORK.ENDPOINT_PARAM
2	1,5-anhydroglucitol (ug/mL)	Method	Monotone-data_MCMC
3	1,5-anhydroglucitol (ug/mL)	Multiple Imputation Chain	Multiple Chains
4	1,5-anhydroglucitol (ug/mL)	Initial Estimates for MCMC	EM Posterior Mode
5	1,5-anhydroglucitol (ug/mL)	Start	Starting Value
6	1,5-anhydroglucitol (ug/mL)	Prior	Jeffreys
7	1,5-anhydroglucitol (ug/mL)	Number of Imputations	100
8	1,5-anhydroglucitol (ug/mL)	Number of Burn-in Iterations	200
9	1,5-anhydroglucitol (ug/mL)	Seed for random number generator	13991

Parameter Code=AG_1_5_S Planned Treatment for Period 30 (N)=3

Obs	PARAM	Description	Value
10	1,5-anhydroglucitol (ug/mL)	Data Set	WORK.ENDPOINT_PARAM
11	1,5-anhydroglucitol (ug/mL)	Method	Monotone-data_MCMC
12	1,5-anhydroglucitol (ug/mL)	Multiple Imputation Chain	Multiple Chains
13	1,5-anhydroglucitol (ug/mL)	Initial Estimates for MCMC	EM Posterior Mode
14	1,5-anhydroglucitol (ug/mL)	Start	Starting Value
15	1,5-anhydroglucitol (ug/mL)	Prior	Jeffreys
16	1,5-anhydroglucitol (ug/mL)	Number of Imputations	100
17	1,5-anhydroglucitol (ug/mL)	Number of Burn-in Iterations	200
18	1,5-anhydroglucitol (ug/mL)	Seed for random number generator	1895618142

1,5-anhydroglucitol 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=AG_1_5_S Planned Treatment for Period 30 (N)=4

Obs	PARAM	Description	Value
19	1,5-anhydroglucitol (ug/mL)	Data Set	WORK.ENDPOINT_PARAM
20	1,5-anhydroglucitol (ug/mL)	Method	Monotone-data_MCMC
21	1,5-anhydroglucitol (ug/mL)	Multiple Imputation Chain	Multiple Chains
22	1,5-anhydroglucitol (ug/mL)	Initial Estimates for MCMC	EM Posterior Mode
23	1,5-anhydroglucitol (ug/mL)	Start	Starting Value
24	1,5-anhydroglucitol (ug/mL)	Prior	Jeffreys
25	1,5-anhydroglucitol (ug/mL)	Number of Imputations	100
26	1,5-anhydroglucitol (ug/mL)	Number of Burn-in Iterations	200
27	1,5-anhydroglucitol (ug/mL)	Seed for random number generator	1328900541

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1,5-anhydroglucitol 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC
Missing data pattern

Parameter Code=AG_1_5_S Planned Treatment for Period 30 (N)=2

Obs	PARAM	Group	BASE_ Miss	visit1400_ Miss	visit1800_ Miss	visit2200_ Miss	visit2600_ Miss	visit3000_ Miss	visit3400_ Miss	visit3600_ Miss
1	1,5-anhydroglucitol (ug/mL)	1	X	X	X	X	X	X	X	X
2	1,5-anhydroglucitol (ug/mL)	2	X	X	X	X	X	X	X	O
3	1,5-anhydroglucitol (ug/mL)	3	X	X	X	X	X	X	.	X
4	1,5-anhydroglucitol (ug/mL)	4	X	X	X	X	X	.	X	X
5	1,5-anhydroglucitol (ug/mL)	5	X	X	X	X	X	O	O	O
6	1,5-anhydroglucitol (ug/mL)	6	X	X	X	X	.	X	X	X
7	1,5-anhydroglucitol (ug/mL)	7	X	X	X	.	X	X	X	X
8	1,5-anhydroglucitol (ug/mL)	8	X	X	X	O	O	O	O	O
9	1,5-anhydroglucitol (ug/mL)	9	X	X	.	X	X	X	X	X
10	1,5-anhydroglucitol (ug/mL)	10	X	X	.	X	X	X	.	X
11	1,5-anhydroglucitol (ug/mL)	11	X	X	.	.	X	X	X	X

Obs	Freq	Percent	BASE	visit1400	visit1800	visit2200	visit2600	visit3000	visit3400	visit3600
1	311	91.20	4.752733	0.233441	0.290675	0.244051	0.248553	0.307717	0.224437	0.190354
2	2	0.59	4.050000	-0.550000	0.450000	0.300000	-0.500000	-0.900000	-0.200000	.
3	5	1.47	3.180000	0.500000	0.400000	0.700000	1.140000	1.280000	.	-0.420000
4	1	0.29	1.700000	1.100000	1.600000	1.200000	1.700000	.	0.800000	1.500000
5	1	0.29	3.400000	2.200000	5.500000	5.000000	6.000000	.	.	.
6	3	0.88	4.733333	0.466667	0.500000	0.500000	.	3.166667	2.133333	1.933333
7	1	0.29	7.700000	0.600000	-3.400000	.	-4.200000	-4.800000	-1.500000	2.000000
8	2	0.59	7.400000	-0.650000	-1.050000
9	3	0.88	3.300000	-0.433333	.	-0.033333	-0.466667	0.033333	0.033333	0.566667
10	1	0.29	5.800000	0.400000	.	0.700000	1.100000	-0.100000	.	-0.500000
11	1	0.29	2.400000	-0.500000	.	.	-0.700000	-0.200000	0.200000	0.300000

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1,5-anhydroglucitol 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC
Missing data pattern

Parameter Code=AG_1_5_S Planned Treatment for Period 30 (N)=2

(continued)

Obs	PARAM	Group	BASE_ Miss	visit1400_ Miss	visit1800_ Miss	visit2200_ Miss	visit2600_ Miss	visit3000_ Miss	visit3400_ Miss	visit3600_ Miss
12	1,5-anhydroglucitol (ug/mL)	12	X	X	O	O	O	O	O	O
13	1,5-anhydroglucitol (ug/mL)	13	X	.	X	X	X	X	X	X
14	1,5-anhydroglucitol (ug/mL)	14	X	.	X	X	X	.	.	X

Obs	Freq	Percent	BASE	visit1400	visit1800	visit2200	visit2600	visit3000	visit3400	visit3600
12	2	0.59	5.900000	-0.650000
13	7	2.05	3.228571	.	1.300000	-0.257143	0.314286	-0.057143	0.585714	1.114286
14	1	0.29	12.900000	.	-4.200000	-1.600000	-0.500000	.	.	-2.200000

Parameter Code=AG_1_5_S Planned Treatment for Period 30 (N)=3

Obs	PARAM	Group	BASE_ Miss	visit1400_ Miss	visit1800_ Miss	visit2200_ Miss	visit2600_ Miss	visit3000_ Miss	visit3400_ Miss	visit3600_ Miss
15	1,5-anhydroglucitol (ug/mL)	1	X	X	X	X	X	X	X	X
16	1,5-anhydroglucitol (ug/mL)	2	X	X	X	X	X	X	X	O

Obs	Freq	Percent	BASE	visit1400	visit1800	visit2200	visit2600	visit3000	visit3400	visit3600
15	309	91.96	4.580906	-0.001294	-0.089320	-0.095146	-0.012298	-0.053398	0.026861	-0.074757
16	1	0.30	7.400000	-2.100000	-3.400000	-4.100000	-4.100000	-3.500000	-4.200000	.

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The MI Procedure with MCMC
Missing data pattern

Parameter Code=AG_1_5_S Planned Treatment for Period 30 (N)=3

(continued)

Obs	PARAM	Group	BASE_ Miss	visit1400_ Miss	visit1800_ Miss	visit2200_ Miss	visit2600_ Miss	visit3000_ Miss	visit3400_ Miss	visit3600_ Miss
17	1,5-anhydroglucitol (ug/mL)	3	X	X	X	X	X	X	.	X
18	1,5-anhydroglucitol (ug/mL)	4	X	X	X	X	X	X	O	O
19	1,5-anhydroglucitol (ug/mL)	5	X	X	X	X	X	.	X	X
20	1,5-anhydroglucitol (ug/mL)	6	X	X	X	X	X	.	.	X
21	1,5-anhydroglucitol (ug/mL)	7	X	X	X	X	X	O	O	O
22	1,5-anhydroglucitol (ug/mL)	8	X	X	X	X	.	X	X	X
23	1,5-anhydroglucitol (ug/mL)	9	X	X	X	X	.	.	X	X
24	1,5-anhydroglucitol (ug/mL)	10	X	X	X	X	.	.	.	X
25	1,5-anhydroglucitol (ug/mL)	11	X	X	X	X	O	O	O	O
26	1,5-anhydroglucitol (ug/mL)	12	X	X	X	.	X	X	X	X
27	1,5-anhydroglucitol (ug/mL)	13	X	X	X	O	O	O	O	O

Obs	Freq	Percent	BASE	visit1400	visit1800	visit2200	visit2600	visit3000	visit3400	visit3600
17	3	0.89	6.900000	0.533333	0.533333	0.300000	-1.533333	-2.400000	.	-1.266667
18	2	0.60	5.850000	-3.100000	-3.050000	-1.800000	-0.300000	-3.050000	.	.
19	1	0.30	2.500000	-0.800000	0.400000	-0.800000	-1.500000	.	-1.400000	-1.300000
20	1	0.30	4.900000	0.900000	3.100000	-0.200000	-2.100000	.	.	0.300000
21	1	0.30	3.800000	-0.600000	0.100000	1.500000	-0.100000	.	.	.
22	2	0.60	4.750000	0.850000	-0.800000	-0.350000	.	0.200000	-0.150000	-0.850000
23	1	0.30	8.100000	-1.000000	0.600000	0.200000	.	.	1.600000	-0.500000
24	1	0.30	2.000000	-0.100000	-0.700000	-0.700000	.	.	.	-0.600000
25	3	0.89	3.566667	-1.133333	-1.200000	-1.433333
26	1	0.30	3.800000	-1.000000	0.100000	.	-1.300000	-0.200000	-0.200000	0.800000
27	1	0.30	2.800000	-1.100000	-1.800000

1,5-anhydroglucitol 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC
Missing data pattern

Parameter Code=AG_1_5_S Planned Treatment for Period 30 (N)=3

(continued)

Obs	PARAM	Group	BASE_ Miss	visit1400_ Miss	visit1800_ Miss	visit2200_ Miss	visit2600_ Miss	visit3000_ Miss	visit3400_ Miss	visit3600_ Miss
28	1,5-anhydroglucitol (ug/mL)	14	X	X	.	X	X	X	X	X
29	1,5-anhydroglucitol (ug/mL)	15	X	X	O	O	O	O	O	O
30	1,5-anhydroglucitol (ug/mL)	16	X	.	X	X	X	X	X	X
31	1,5-anhydroglucitol (ug/mL)	17	X	.	X	X	X	X	.	X
32	1,5-anhydroglucitol (ug/mL)	18	X	O	O	O	O	O	O	O

Obs	Freq	Percent	BASE	visit1400	visit1800	visit2200	visit2600	visit3000	visit3400	visit3600
28	1	0.30	5.600000	0.100000	.	-1.700000	-1.900000	-1.700000	-2.000000	-3.400000
29	1	0.30	4.600000	2.800000
30	4	1.19	3.100000	.	0.875000	-1.050000	-0.500000	-0.475000	-0.425000	-0.225000
31	2	0.60	4.500000	.	0.650000	0.700000	0.350000	-0.150000	.	-1.050000
32	1	0.30	6.400000

1,5-anhydroglucitol 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC
Missing data pattern

Parameter Code=AG_1_5_S Planned Treatment for Period 30 (N)=4

Obs	PARAM	Group	BASE_ Miss	visit1400_ Miss	visit1800_ Miss	visit2200_ Miss	visit2600_ Miss	visit3000_ Miss	visit3400_ Miss	visit3600_ Miss
33	1,5-anhydroglucitol (ug/mL)	1	X	X	X	X	X	X	X	X

Obs	Freq	Percent	BASE	visit1400	visit1800	visit2200	visit2600	visit3000	visit3400	visit3600
33	311	91.74	4.678778	0.145338	0.170096	0.052090	0.300643	0.289068	0.250804	0.256913

Obs	PARAM	Group	BASE_ Miss	visit1400_ Miss	visit1800_ Miss	visit2200_ Miss	visit2600_ Miss	visit3000_ Miss	visit3400_ Miss	visit3600_ Miss
34	1,5-anhydroglucitol (ug/mL)	2	X	X	X	X	X	X	X	O
35	1,5-anhydroglucitol (ug/mL)	3	X	X	X	X	X	X	.	X
36	1,5-anhydroglucitol (ug/mL)	4	X	X	X	X	X	.	X	X
37	1,5-anhydroglucitol (ug/mL)	5	X	X	X	X	X	O	O	O
38	1,5-anhydroglucitol (ug/mL)	6	X	X	X	X	.	X	X	X
39	1,5-anhydroglucitol (ug/mL)	7	X	X	X	X	.	.	X	X

Obs	Freq	Percent	BASE	visit1400	visit1800	visit2200	visit2600	visit3000	visit3400	visit3600
34	5	1.47	4.240000	-0.280000	-0.180000	-0.400000	0	0.240000	0.140000	.
35	1	0.29	3.800000	0.800000	-1.700000	0.700000	-0.800000	0.300000	.	2.400000
36	1	0.29	8.400000	-0.300000	0.800000	-2.500000	-1.900000	.	-2.400000	-0.200000
37	1	0.29	1.600000	-0.200000	-0.300000	0.500000	1.400000	.	.	.
38	1	0.29	5.900000	-0.600000	1.200000	-1.600000	.	-1.100000	-1.300000	0.300000
39	1	0.29	5.500000	2.600000	-3.200000	-2.200000	.	.	-1.900000	-1.200000

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1,5-anhydroglucitol 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC
Missing data pattern

Parameter Code=AG_1_5_S Planned Treatment for Period 30 (N)=4

(continued)

Obs	PARAM	Group	BASE_ Miss	visit1400_ Miss	visit1800_ Miss	visit2200_ Miss	visit2600_ Miss	visit3000_ Miss	visit3400_ Miss	visit3600_ Miss
40	1,5-anhydroglucitol (ug/mL)	8	X	X	X	X	.	.	.	X
41	1,5-anhydroglucitol (ug/mL)	9	X	X	X	X	O	O	O	O
42	1,5-anhydroglucitol (ug/mL)	10	X	X	X	.	X	X	X	X
43	1,5-anhydroglucitol (ug/mL)	11	X	X	.	X	X	X	X	X
44	1,5-anhydroglucitol (ug/mL)	12	X	X	.	X	X	X	O	O
45	1,5-anhydroglucitol (ug/mL)	13	X	X	O	O	O	O	O	O
46	1,5-anhydroglucitol (ug/mL)	14	X	.	X	X	X	X	X	X
47	1,5-anhydroglucitol (ug/mL)	15	X	.	X	X	X	X	X	O
48	1,5-anhydroglucitol (ug/mL)	16	X	O	O	O	O	O	O	O

Obs	Freq	Percent	BASE	visit1400	visit1800	visit2200	visit2600	visit3000	visit3400	visit3600
40	1	0.29	2.800000	-0.100000	-0.700000	3.400000	.	.	.	1.500000
41	4	1.18	2.700000	0.400000	-0.225000	0.025000
42	3	0.88	9.500000	-0.100000	-1.566667	.	-1.200000	-2.233333	-4.000000	-2.833333
43	3	0.88	3.366667	0.833333	.	0.433333	0.466667	0.666667	0.933333	1.466667
44	1	0.29	1.400000	0	.	-0.400000	-0.100000	-0.400000	.	.
45	2	0.59	3.100000	0.200000
46	2	0.59	10.800000	.	0.450000	0.200000	-0.100000	-1.100000	-0.700000	-0.700000
47	1	0.29	5.500000	.	-3.000000	-2.600000	-3.200000	-0.400000	-1.200000	.
48	1	0.29	7.400000

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1,5-anhydroglucitol 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=AG_1_5_S Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM	Description	Value
1	1	1,5-anhydroglucitol (ug/mL)	Data Set	WORK.MONOTONE
2	1	1,5-anhydroglucitol (ug/mL)	Method	Monotone
3	1	1,5-anhydroglucitol (ug/mL)	Number of Imputations	1
4	1	1,5-anhydroglucitol (ug/mL)	Seed for random number generator	17078

Parameter Code=AG_1_5_S Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM	Description	Value
5	1	1,5-anhydroglucitol (ug/mL)	Data Set	WORK.MONOTONE
6	1	1,5-anhydroglucitol (ug/mL)	Method	Monotone
7	1	1,5-anhydroglucitol (ug/mL)	Number of Imputations	1
8	1	1,5-anhydroglucitol (ug/mL)	Seed for random number generator	1099344527

Parameter Code=AG_1_5_S Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM	Description	Value
9	1	1,5-anhydroglucitol (ug/mL)	Data Set	WORK.MONOTONE
10	1	1,5-anhydroglucitol (ug/mL)	Method	Monotone
11	1	1,5-anhydroglucitol (ug/mL)	Number of Imputations	1
12	1	1,5-anhydroglucitol (ug/mL)	Seed for random number generator	173525354

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The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=AG_1_5_S Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM	Group	REGION1_	BOLAD1_	BASE_	visit1400_	visit1800_
				Miss	Miss	Miss	Miss	Miss
1	1	1,5-anhydroglucitol (ug/mL)	1	X	X	X	X	X
2	1	1,5-anhydroglucitol (ug/mL)	2	X	X	X	X	X
3	1	1,5-anhydroglucitol (ug/mL)	3	X	X	X	X	X
4	1	1,5-anhydroglucitol (ug/mL)	4	X	X	X	X	X
5	1	1,5-anhydroglucitol (ug/mL)	5	X	X	X	X	.

Obs	visit2200_	visit2600_	visit3000_	visit3400_	visit3600_	Freq	Percent	BASE	visit1400
	Miss	Miss	Miss	Miss	Miss				
1	X	X	X	X	X	334	97.95	4.704192	0.238537
2	X	X	X	X	.	2	0.59	4.050000	-0.550000
3	X	X	.	.	.	1	0.29	3.400000	2.200000
4	2	0.59	7.400000	-0.650000
5	2	0.59	5.900000	-0.650000

Obs	visit1800	visit2200	visit2600	visit3000	visit3400	visit3600
1	0.293448	0.221240	0.254988	0.314473	0.232123	0.220060
2	0.450000	0.300000	-0.500000	-0.900000	-0.200000	.
3	5.500000	5.000000	6.000000	.	.	.
4	-1.050000
5

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1,5-anhydroglucitol 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=AG_1_5_S Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM	Group	REGION1_ Miss	BOLAD1_ Miss	BASE_ Miss	visit1400_ Miss	visit1800_ Miss
6	1	1,5-anhydroglucitol (ug/mL)	1	X	X	X	X	X
7	1	1,5-anhydroglucitol (ug/mL)	2	X	X	X	X	X
8	1	1,5-anhydroglucitol (ug/mL)	3	X	X	X	X	X
9	1	1,5-anhydroglucitol (ug/mL)	4	X	X	X	X	X
10	1	1,5-anhydroglucitol (ug/mL)	5	X	X	X	X	X
11	1	1,5-anhydroglucitol (ug/mL)	6	X	X	X	X	X

Obs	visit2200_ Miss	visit2600_ Miss	visit3000_ Miss	visit3400_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit1400
6	X	X	X	X	X	326	97.02	4.582822	0.011324
7	X	X	X	X	.	1	0.30	7.400000	-2.100000
8	X	X	X	.	.	2	0.60	5.850000	-3.100000
9	X	X	.	.	.	1	0.30	3.800000	-0.600000
10	X	3	0.89	3.566667	-1.133333
11	1	0.30	2.800000	-1.100000

Obs	visit1800	visit2200	visit2600	visit3000	visit3400	visit3600
6	-0.065932	-0.105279	-0.051010	-0.090335	-0.001804	-0.111350
7	-3.400000	-4.100000	-4.100000	-3.500000	-4.200000	.
8	-3.050000	-1.800000	-0.300000	-3.050000	.	.
9	0.100000	1.500000	-0.100000	.	.	.
10	-1.200000	-1.433333
11	-1.800000

1,5-anhydroglucitol 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=AG_1_5_S Planned Treatment for Period 30 (N)=3

(continued)

Obs	_Imputation_	PARAM	Group	REGION1_	BOLAD1_	BASE_	visit1400_	visit1800_
				Miss	Miss	Miss	Miss	Miss
12	1	1,5-anhydroglucitol (ug/mL)	7	X	X	X	X	.
13	1	1,5-anhydroglucitol (ug/mL)	8	X	X	X	.	.

Obs	visit2200_	visit2600_	visit3000_	visit3400_	visit3600_	Freq	Percent	BASE	visit1400
	Miss	Miss	Miss	Miss	Miss				
12	1	0.30	4.600000	2.800000
13	1	0.30	6.400000	.

Obs	visit1800	visit2200	visit2600	visit3000	visit3400	visit3600
12
13

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The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=AG_1_5_S Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM	Group	REGION1_	BOLAD1_	BASE_	visit1400_	visit1800_
				Miss	Miss	Miss	Miss	Miss
14	1	1,5-anhydroglucitol (ug/mL)	1	X	X	X	X	X
15	1	1,5-anhydroglucitol (ug/mL)	2	X	X	X	X	X
16	1	1,5-anhydroglucitol (ug/mL)	3	X	X	X	X	X
17	1	1,5-anhydroglucitol (ug/mL)	4	X	X	X	X	X
18	1	1,5-anhydroglucitol (ug/mL)	5	X	X	X	X	X
19	1	1,5-anhydroglucitol (ug/mL)	6	X	X	X	X	.

Obs	visit2200_	visit2600_	visit3000_	visit3400_	visit3600_	Freq	Percent	BASE	visit1400
	Miss	Miss	Miss	Miss	Miss				
14	X	X	X	X	X	324	95.58	4.758333	0.151518
15	X	X	X	X	.	6	1.77	4.450000	-0.427047
16	X	X	X	.	.	1	0.29	1.400000	0
17	X	X	.	.	.	1	0.29	1.600000	-0.200000
18	X	4	1.18	2.700000	0.400000
19	2	0.59	3.100000	0.200000

Obs	visit1800	visit2200	visit2600	visit3000	visit3400	visit3600
14	0.148678	0.029305	0.273963	0.244507	0.202356	0.238272
15	-0.650000	-0.766667	-0.533333	0.133333	-0.083333	.
16	-0.604267	-0.400000	-0.100000	-0.400000	.	.
17	-0.300000	0.500000	1.400000	.	.	.
18	-0.225000	0.025000
19

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The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=AG_1_5_S Planned Treatment for Period 30 (N)=4

(continued)

Obs	_Imputation_	PARAM				Group	REGION1_ Miss	BOLAD1_ Miss	BASE_ Miss	visit1400_ Miss	visit1800_ Miss
20	1	1,5-anhydroglucitol (ug/mL)				7	X	X	X	.	.
Obs	visit2200_ Miss	visit2600_ Miss	visit3000_ Miss	visit3400_ Miss	visit3600_ Miss			Freq	Percent	BASE	visit1400
20			1	0.29	7.400000	.
Obs	visit1800	visit2200	visit2600	visit3000	visit3400	visit3600					
20					

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=AG_1_5_S Planned Treatment for Period 30 (N)=2 Imputed Variable=visit1800

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	1,5-anhydroglucitol (ug/mL)	Intercept	
2	1	1,5-anhydroglucitol (ug/mL)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	1,5-anhydroglucitol (ug/mL)	REGION1	EUROPE
4	1	1,5-anhydroglucitol (ug/mL)	REGION1	JAPAN
5	1	1,5-anhydroglucitol (ug/mL)	BOLAD1	
6	1	1,5-anhydroglucitol (ug/mL)	BASE	
7	1	1,5-anhydroglucitol (ug/mL)	visit1400	

Obs		BOLAD1	ObsVal	_1
1			0.00893	0.095817
2			-0.04691	-0.044230
3			-0.08683	-0.103844
4			0.15154	0.218778
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.01315	-0.070568
6			-0.0009819	-0.047475
7			0.59997	0.495436

Parameter Code=AG_1_5_S Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
8	1	1,5-anhydroglucitol (ug/mL)	Intercept			0.00197	0.002456
9	1	1,5-anhydroglucitol (ug/mL)	REGION1	ASIA (EXCLUDING JAPAN)		0.13620	0.099953

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Regression Information

Parameter Code=AG_1_5_S Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2200

(continued)

O b s	_	P A R A M	E f f e c t	R E G I O N	B O L A D	O b s V a l	I
10	1	1,5-anhydroglucitol (ug/mL)	REGION1	EUROPE		-0.00478	0.006336
11	1	1,5-anhydroglucitol (ug/mL)	REGION1	JAPAN		-0.08627	-0.124506
12	1	1,5-anhydroglucitol (ug/mL)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.07635	0.088680
13	1	1,5-anhydroglucitol (ug/mL)	BASE			-0.03575	-0.095593
14	1	1,5-anhydroglucitol (ug/mL)	visit1400			0.15765	0.235390
15	1	1,5-anhydroglucitol (ug/mL)	visit1800			0.59668	0.590778

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=AG_1_5_S Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2600

Obs	_Imputation_	PARAM	Effect	REGION1
16	1	1,5-anhydroglucitol (ug/mL)	Intercept	
17	1	1,5-anhydroglucitol (ug/mL)	REGION1	ASIA (EXCLUDING JAPAN)
18	1	1,5-anhydroglucitol (ug/mL)	REGION1	EUROPE
19	1	1,5-anhydroglucitol (ug/mL)	REGION1	JAPAN
20	1	1,5-anhydroglucitol (ug/mL)	BOLAD1	
21	1	1,5-anhydroglucitol (ug/mL)	BASE	
22	1	1,5-anhydroglucitol (ug/mL)	visit1400	
23	1	1,5-anhydroglucitol (ug/mL)	visit1800	
24	1	1,5-anhydroglucitol (ug/mL)	visit2200	

Obs	BOLAD1	ObsVal	_1
16		0.02967	0.022519
17		0.04490	-0.051714
18		-0.12752	-0.039783
19		0.08244	0.128659
20	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.05253	-0.095053
21		0.0001956	0.077255
22		0.15055	0.240408
23		0.01642	-0.034252
24		0.68187	0.653635

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=AG_1_5_S Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3000

Obs	_Imputation_	PARAM	Effect	REGION1
25	1	1,5-anhydroglucitol (ug/mL)	Intercept	
26	1	1,5-anhydroglucitol (ug/mL)	REGION1	ASIA (EXCLUDING JAPAN)
27	1	1,5-anhydroglucitol (ug/mL)	REGION1	EUROPE
28	1	1,5-anhydroglucitol (ug/mL)	REGION1	JAPAN
29	1	1,5-anhydroglucitol (ug/mL)	BOLAD1	
30	1	1,5-anhydroglucitol (ug/mL)	BASE	
31	1	1,5-anhydroglucitol (ug/mL)	visit1400	
32	1	1,5-anhydroglucitol (ug/mL)	visit1800	
33	1	1,5-anhydroglucitol (ug/mL)	visit2200	
34	1	1,5-anhydroglucitol (ug/mL)	visit2600	

Obs	BOLAD1	ObsVal	_1
25		-0.00850	0.063519
26		-0.12037	0.150276
27		0.00901	-0.120091
28		0.05194	0.029772
29	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.03791	-0.086294
30		-0.11090	-0.141069
31		0.08363	0.067960
32		-0.05018	-0.095623
33		0.21624	0.121804
34		0.52655	0.607878

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=AG_1_5_S Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3400

Obs	_Imputation_	PARAM	Effect	REGION1
35	1	1,5-anhydroglucitol (ug/mL)	Intercept	
36	1	1,5-anhydroglucitol (ug/mL)	REGION1	ASIA (EXCLUDING JAPAN)
37	1	1,5-anhydroglucitol (ug/mL)	REGION1	EUROPE
38	1	1,5-anhydroglucitol (ug/mL)	REGION1	JAPAN
39	1	1,5-anhydroglucitol (ug/mL)	BOLAD1	
40	1	1,5-anhydroglucitol (ug/mL)	BASE	
41	1	1,5-anhydroglucitol (ug/mL)	visit1400	
42	1	1,5-anhydroglucitol (ug/mL)	visit1800	
43	1	1,5-anhydroglucitol (ug/mL)	visit2200	
44	1	1,5-anhydroglucitol (ug/mL)	visit2600	
45	1	1,5-anhydroglucitol (ug/mL)	visit3000	

Obs	BOLAD1	ObsVal	_1
35		0.01201	-0.061258
36		0.02796	0.000752
37		-0.04187	-0.053081
38		-0.02149	0.044347
39	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.03652	-0.003952
40		-0.15595	-0.173132
41		0.06647	0.121019
42		0.12447	0.104185
43		0.11543	0.124336
44		0.11066	-0.048688
45		0.46534	0.568959

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=AG_1_5_S Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1
46	1	1,5-anhydroglucitol (ug/mL)	Intercept	
47	1	1,5-anhydroglucitol (ug/mL)	REGION1	ASIA (EXCLUDING JAPAN)
48	1	1,5-anhydroglucitol (ug/mL)	REGION1	EUROPE
49	1	1,5-anhydroglucitol (ug/mL)	REGION1	JAPAN
50	1	1,5-anhydroglucitol (ug/mL)	BOLAD1	
51	1	1,5-anhydroglucitol (ug/mL)	BASE	
52	1	1,5-anhydroglucitol (ug/mL)	visit1400	
53	1	1,5-anhydroglucitol (ug/mL)	visit1800	
54	1	1,5-anhydroglucitol (ug/mL)	visit2200	
55	1	1,5-anhydroglucitol (ug/mL)	visit2600	
56	1	1,5-anhydroglucitol (ug/mL)	visit3000	
57	1	1,5-anhydroglucitol (ug/mL)	visit3400	

Obs	BOLAD1	ObsVal	_1
46		0.01076	0.060481
47		0.09724	0.134472
48		-0.07075	-0.070256
49		-0.08070	-0.118385
50	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.01123	0.017185
51		-0.14012	-0.172184
52		0.03709	0.016961
53		-0.04171	-0.011125
54		0.00735	0.043698
55		0.11352	0.088093
56		0.02946	0.089602
57		0.70140	0.648437

1,5-anhydroglucitol 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=AG_1_5_S Planned Treatment for Period 30 (N)=3 Imputed Variable=visit1400

Obs	_Imputation_	PARAM	Effect	REGION1
58	1	1,5-anhydroglucitol (ug/mL)	Intercept	
59	1	1,5-anhydroglucitol (ug/mL)	REGION1	ASIA (EXCLUDING JAPAN)
60	1	1,5-anhydroglucitol (ug/mL)	REGION1	EUROPE
61	1	1,5-anhydroglucitol (ug/mL)	REGION1	JAPAN
62	1	1,5-anhydroglucitol (ug/mL)	BOLAD1	
63	1	1,5-anhydroglucitol (ug/mL)	BASE	

Obs	BOLAD1	ObsVal	_1
58		0.00902	0.051000
59		0.03842	-0.163136
60		-0.06654	-0.133568
61		-0.08686	0.097842
62	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.00475	-0.037239
63		-0.13035	-0.075082

Parameter Code=AG_1_5_S Planned Treatment for Period 30 (N)=3 Imputed Variable=visit1800

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
64	1	1,5-anhydroglucitol (ug/mL)	Intercept			0.01059	0.035256
65	1	1,5-anhydroglucitol (ug/mL)	REGION1	ASIA (EXCLUDING JAPAN)		0.01867	-0.004260
66	1	1,5-anhydroglucitol (ug/mL)	REGION1	EUROPE		-0.05863	-0.031370

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The MI Procedure with Monotone Regression Regression Information

Parameter Code=AG 1 5 S Planned Treatment for Period 30 (N)=3 Imputed Variable=visit1800

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67	1	1,5-anhydroglucitol	(ug/mL)	REGION1	JAPAN		-0.04177	-0.117561
68	1	1,5-anhydroglucitol	(ug/mL)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.01942	0.016607
69	1	1,5-anhydroglucitol	(ug/mL)	BASE			-0.13695	-0.084705
70	1	1,5-anhydroglucitol	(ug/mL)	visit1400			0.54018	0.496164

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Regression Information

Parameter Code=AG_1_5_S Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
71	1	1,5-anhydroglucitol (ug/mL)	Intercept	
72	1	1,5-anhydroglucitol (ug/mL)	REGION1	ASIA (EXCLUDING JAPAN)
73	1	1,5-anhydroglucitol (ug/mL)	REGION1	EUROPE
74	1	1,5-anhydroglucitol (ug/mL)	REGION1	JAPAN
75	1	1,5-anhydroglucitol (ug/mL)	BOLAD1	
76	1	1,5-anhydroglucitol (ug/mL)	BASE	
77	1	1,5-anhydroglucitol (ug/mL)	visit1400	
78	1	1,5-anhydroglucitol (ug/mL)	visit1800	

Obs	BOLAD1	ObsVal	_1
71		0.01029	-0.000533
72		0.12792	-0.012020
73		-0.01428	-0.022629
74		-0.10452	0.000222
75	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.06994	0.161415
76		-0.00812	-0.034551
77		0.10035	0.143310
78		0.63848	0.597941

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=AG_1_5_S Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2600

Obs	_Imputation_	PARAM	Effect	REGION1
79	1	1,5-anhydroglucitol (ug/mL)	Intercept	
80	1	1,5-anhydroglucitol (ug/mL)	REGION1	ASIA (EXCLUDING JAPAN)
81	1	1,5-anhydroglucitol (ug/mL)	REGION1	EUROPE
82	1	1,5-anhydroglucitol (ug/mL)	REGION1	JAPAN
83	1	1,5-anhydroglucitol (ug/mL)	BOLAD1	
84	1	1,5-anhydroglucitol (ug/mL)	BASE	
85	1	1,5-anhydroglucitol (ug/mL)	visit1400	
86	1	1,5-anhydroglucitol (ug/mL)	visit1800	
87	1	1,5-anhydroglucitol (ug/mL)	visit2200	

Obs	BOLAD1	ObsVal	_1
79		-0.01359	-0.070776
80		-0.03355	-0.021909
81		-0.05484	0.021142
82		0.07464	-0.010113
83	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.06948	0.099840
84		-0.11322	-0.116107
85		0.14037	0.084186
86		0.11213	0.204123
87		0.54146	0.468937

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=AG_1_5_S Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3000

Obs	_Imputation_	PARAM	Effect	REGION1
88	1	1,5-anhydroglucitol (ug/mL)	Intercept	
89	1	1,5-anhydroglucitol (ug/mL)	REGION1	ASIA (EXCLUDING JAPAN)
90	1	1,5-anhydroglucitol (ug/mL)	REGION1	EUROPE
91	1	1,5-anhydroglucitol (ug/mL)	REGION1	JAPAN
92	1	1,5-anhydroglucitol (ug/mL)	BOLAD1	
93	1	1,5-anhydroglucitol (ug/mL)	BASE	
94	1	1,5-anhydroglucitol (ug/mL)	visit1400	
95	1	1,5-anhydroglucitol (ug/mL)	visit1800	
96	1	1,5-anhydroglucitol (ug/mL)	visit2200	
97	1	1,5-anhydroglucitol (ug/mL)	visit2600	

Obs	BOLAD1	ObsVal	_1
88		-0.0005946	-0.038163
89		-0.01494	-0.035589
90		-0.02930	-0.055784
91		0.03515	0.104417
92	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.00236	-0.004050
93		-0.12732	-0.062113
94		0.04555	0.004600
95		-0.02963	0.011449
96		0.21628	0.218023
97		0.50171	0.502316

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Regression Information

Parameter Code=AG_1_5_S Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3400

Obs	_Imputation_	PARAM	Effect	REGION1
98	1	1,5-anhydroglucitol (ug/mL)	Intercept	
99	1	1,5-anhydroglucitol (ug/mL)	REGION1	ASIA (EXCLUDING JAPAN)
100	1	1,5-anhydroglucitol (ug/mL)	REGION1	EUROPE
101	1	1,5-anhydroglucitol (ug/mL)	REGION1	JAPAN
102	1	1,5-anhydroglucitol (ug/mL)	BOLAD1	
103	1	1,5-anhydroglucitol (ug/mL)	BASE	
104	1	1,5-anhydroglucitol (ug/mL)	visit1400	
105	1	1,5-anhydroglucitol (ug/mL)	visit1800	
106	1	1,5-anhydroglucitol (ug/mL)	visit2200	
107	1	1,5-anhydroglucitol (ug/mL)	visit2600	
108	1	1,5-anhydroglucitol (ug/mL)	visit3000	

Obs		BOLAD1	ObsVal	_1
98			0.03278	0.013805
99			0.14409	0.120492
100			-0.14563	-0.114163
101			0.08462	0.008386
102	BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.05307	-0.049745
103			-0.02294	0.007803
104			0.05570	0.017536
105			0.00871	0.045007
106			0.20179	0.171563
107			0.08740	0.162932
108			0.50957	0.476658

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=AG_1_5_S Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1
109	1	1,5-anhydroglucitol (ug/mL)	Intercept	
110	1	1,5-anhydroglucitol (ug/mL)	REGION1	ASIA (EXCLUDING JAPAN)
111	1	1,5-anhydroglucitol (ug/mL)	REGION1	EUROPE
112	1	1,5-anhydroglucitol (ug/mL)	REGION1	JAPAN
113	1	1,5-anhydroglucitol (ug/mL)	BOLAD1	
114	1	1,5-anhydroglucitol (ug/mL)	BASE	
115	1	1,5-anhydroglucitol (ug/mL)	visit1400	
116	1	1,5-anhydroglucitol (ug/mL)	visit1800	
117	1	1,5-anhydroglucitol (ug/mL)	visit2200	
118	1	1,5-anhydroglucitol (ug/mL)	visit2600	
119	1	1,5-anhydroglucitol (ug/mL)	visit3000	
120	1	1,5-anhydroglucitol (ug/mL)	visit3400	

Obs	BOLAD1	ObsVal	_1
109		0.00609	0.041896
110		0.05451	0.100062
111		-0.00157	0.044508
112		-0.04423	-0.123909
113	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.04564	-0.039486
114		-0.02894	-0.035968
115		0.04702	0.020348
116		0.00334	0.018069
117		0.03429	0.037220
118		0.12070	0.030465
119		0.04556	0.046966
120		0.69185	0.712616

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=AG_1_5_S Planned Treatment for Period 30 (N)=4 Imputed Variable=visit1400

Obs	_Imputation_	PARAM	Effect	REGION1
121	1	1,5-anhydroglucitol (ug/mL)	Intercept	
122	1	1,5-anhydroglucitol (ug/mL)	REGION1	ASIA (EXCLUDING JAPAN)
123	1	1,5-anhydroglucitol (ug/mL)	REGION1	EUROPE
124	1	1,5-anhydroglucitol (ug/mL)	REGION1	JAPAN
125	1	1,5-anhydroglucitol (ug/mL)	BOLAD1	
126	1	1,5-anhydroglucitol (ug/mL)	BASE	

Obs		BOLAD1	ObsVal	_1
121			-0.01212	-0.001971
122			-0.03904	-0.023798
123			-0.05061	-0.178463
124			0.10136	-0.034810
125	BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.06582	0.108199
126			0.03148	0.010169

Parameter Code=AG_1_5_S Planned Treatment for Period 30 (N)=4 Imputed Variable=visit1800

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
127	1	1,5-anhydroglucitol (ug/mL)	Intercept			-0.06140	-0.089773
128	1	1,5-anhydroglucitol (ug/mL)	REGION1	ASIA (EXCLUDING JAPAN)		-0.30347	-0.078122
129	1	1,5-anhydroglucitol (ug/mL)	REGION1	EUROPE		0.01257	-0.023531

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=AG_1_5_S Planned Treatment for Period 30 (N)=4 Imputed Variable=visit1800

(continued)

O b s	I m p u t a t i o n	P A R A M	E f f e c t	R E G I O N	B O L A D	O b s V a l	I
130	1	1,5-anhydroglucitol	(ug/mL)	REGION1	JAPAN	0.08090	-0.034191
131	1	1,5-anhydroglucitol	(ug/mL)	BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.12047	0.109968
132	1	1,5-anhydroglucitol	(ug/mL)	BASE		0.09390	0.060420
133	1	1,5-anhydroglucitol	(ug/mL)	visit1400		0.63145	0.645081

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=AG_1_5_S Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
134	1	1,5-anhydroglucitol (ug/mL)	Intercept	
135	1	1,5-anhydroglucitol (ug/mL)	REGION1	ASIA (EXCLUDING JAPAN)
136	1	1,5-anhydroglucitol (ug/mL)	REGION1	EUROPE
137	1	1,5-anhydroglucitol (ug/mL)	REGION1	JAPAN
138	1	1,5-anhydroglucitol (ug/mL)	BOLAD1	
139	1	1,5-anhydroglucitol (ug/mL)	BASE	
140	1	1,5-anhydroglucitol (ug/mL)	visit1400	
141	1	1,5-anhydroglucitol (ug/mL)	visit1800	

Obs	BOLAD1	ObsVal	_1
134		0.01647	-0.009001
135		0.18895	0.218005
136		-0.06361	-0.065610
137		-0.07596	-0.077337
138	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.04369	0.070564
139		-0.05807	-0.101862
140		0.17102	0.058470
141		0.61497	0.642639

1,5-anhydroglucitol 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=AG_1_5_S Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2600

Obs	_Imputation_	PARAM	Effect	REGION1
142	1	1,5-anhydroglucitol (ug/mL)	Intercept	
143	1	1,5-anhydroglucitol (ug/mL)	REGION1	ASIA (EXCLUDING JAPAN)
144	1	1,5-anhydroglucitol (ug/mL)	REGION1	EUROPE
145	1	1,5-anhydroglucitol (ug/mL)	REGION1	JAPAN
146	1	1,5-anhydroglucitol (ug/mL)	BOLAD1	
147	1	1,5-anhydroglucitol (ug/mL)	BASE	
148	1	1,5-anhydroglucitol (ug/mL)	visit1400	
149	1	1,5-anhydroglucitol (ug/mL)	visit1800	
150	1	1,5-anhydroglucitol (ug/mL)	visit2200	

Obs	BOLAD1	ObsVal	_1
142		0.01611	0.069040
143		0.21401	0.416010
144		-0.10553	-0.231028
145		-0.14738	-0.220038
146	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.05221	-0.018273
147		0.00342	-0.016642
148		-0.01550	0.029928
149		0.11541	0.100539
150		0.70504	0.702966

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=AG_1_5_S Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3000

Obs	_Imputation_	PARAM	Effect	REGION1
151	1	1,5-anhydroglucitol (ug/mL)	Intercept	
152	1	1,5-anhydroglucitol (ug/mL)	REGION1	ASIA (EXCLUDING JAPAN)
153	1	1,5-anhydroglucitol (ug/mL)	REGION1	EUROPE
154	1	1,5-anhydroglucitol (ug/mL)	REGION1	JAPAN
155	1	1,5-anhydroglucitol (ug/mL)	BOLAD1	
156	1	1,5-anhydroglucitol (ug/mL)	BASE	
157	1	1,5-anhydroglucitol (ug/mL)	visit1400	
158	1	1,5-anhydroglucitol (ug/mL)	visit1800	
159	1	1,5-anhydroglucitol (ug/mL)	visit2200	
160	1	1,5-anhydroglucitol (ug/mL)	visit2600	

Obs	BOLAD1	ObsVal	_1
151		0.00190	-0.029987
152		-0.01338	-0.150578
153		-0.09019	-0.136099
154		-0.02415	0.066046
155	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.00135	0.073849
156		0.03231	0.091239
157		0.11795	0.080660
158		0.06791	0.106245
159		0.07638	-0.002603
160		0.58164	0.605766

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=AG_1_5_S Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3400

Obs	_Imputation_	PARAM	Effect	REGION1
161	1	1,5-anhydroglucitol (ug/mL)	Intercept	
162	1	1,5-anhydroglucitol (ug/mL)	REGION1	ASIA (EXCLUDING JAPAN)
163	1	1,5-anhydroglucitol (ug/mL)	REGION1	EUROPE
164	1	1,5-anhydroglucitol (ug/mL)	REGION1	JAPAN
165	1	1,5-anhydroglucitol (ug/mL)	BOLAD1	
166	1	1,5-anhydroglucitol (ug/mL)	BASE	
167	1	1,5-anhydroglucitol (ug/mL)	visit1400	
168	1	1,5-anhydroglucitol (ug/mL)	visit1800	
169	1	1,5-anhydroglucitol (ug/mL)	visit2200	
170	1	1,5-anhydroglucitol (ug/mL)	visit2600	
171	1	1,5-anhydroglucitol (ug/mL)	visit3000	

Obs	BOLAD1	ObsVal	_1
161		0.01347	-0.000178
162		0.12094	0.115326
163		0.02684	0.101829
164		-0.13174	-0.180277
165	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.02507	-0.021734
166		-0.05326	-0.011297
167		-0.08563	-0.053566
168		0.08680	0.026654
169		0.08497	-0.002372
170		0.13340	0.145641
171		0.65671	0.760505

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=AG_1_5_S Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1
172	1	1,5-anhydroglucitol (ug/mL)	Intercept	
173	1	1,5-anhydroglucitol (ug/mL)	REGION1	ASIA (EXCLUDING JAPAN)
174	1	1,5-anhydroglucitol (ug/mL)	REGION1	EUROPE
175	1	1,5-anhydroglucitol (ug/mL)	REGION1	JAPAN
176	1	1,5-anhydroglucitol (ug/mL)	BOLAD1	
177	1	1,5-anhydroglucitol (ug/mL)	BASE	
178	1	1,5-anhydroglucitol (ug/mL)	visit1400	
179	1	1,5-anhydroglucitol (ug/mL)	visit1800	
180	1	1,5-anhydroglucitol (ug/mL)	visit2200	
181	1	1,5-anhydroglucitol (ug/mL)	visit2600	
182	1	1,5-anhydroglucitol (ug/mL)	visit3000	
183	1	1,5-anhydroglucitol (ug/mL)	visit3400	

Obs	BOLAD1	ObsVal	_1
172		0.00653	0.035656
173		0.09231	0.064642
174		-0.0003705	-0.007904
175		-0.04271	-0.029474
176	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.00804	0.009737
177		-0.03263	-0.016872
178		-0.06194	-0.053065
179		0.08730	0.105926
180		0.10091	0.107712
181		-0.09855	-0.118108
182		0.19627	0.186721
183		0.70782	0.723574

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The Mixed procedure
Model Information

Parameter Code=AG_1_5_S Parameter=1,5-anhydroglucitol (ug/mL)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Data Set	WORK.IMPUTE
2	1	NN1218-4131	Dependent Variable	eotVisit
3	1	NN1218-4131	Covariance Structure	Diagonal
4	1	NN1218-4131	Estimation Method	REML
5	1	NN1218-4131	Residual Variance Method	Profile
6	1	NN1218-4131	Fixed Effects SE Method	Model-Based
7	1	NN1218-4131	Degrees of Freedom Method	Residual

1,5-anhydroglucitol 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Class Level Information

Parameter Code=AG_1_5_S Parameter=1,5-anhydroglucitol (ug/mL)

Input				Output			
Source				Statistic			
Model				Variable			
Number				Level			
1	1	NN1218-4131	TRTPN	3	2	3	4
2	1	NN1218-4131	REGION1	4	ASIA (EXCLUDING JAPAN)	EUROPE	JAPAN NORTH AMERICA
3	1	NN1218-4131	BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	CARBOHYDRATE COUNTING (FLEXIBLE)	BOLUS INSULI

1,5-anhydroglucitol 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Dimensions

Parameter Code=AG_1_5_S Parameter=1,5-anhydroglucitol (ug/mL)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Covariance Parameters	1
2	1	NN1218-4131	Columns in X	10
3	1	NN1218-4131	Columns in Z	0
4	1	NN1218-4131	Subjects	1
5	1	NN1218-4131	Max Obs per Subject	1016

1,5-anhydroglucitol 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Number of Observations

Parameter Code=AG_1_5_S Parameter=1,5-anhydroglucitol (ug/mL)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
1	1	NN1218-4131	Number of Observations Read	1016	1016	1016	1016	1016
2	1	NN1218-4131	Number of Observations Used	1016	1016	1016	1016	1016
3	1	NN1218-4131	Number of Observations Not Used	0	1016	1016	1016	1016

1,5-anhydroglucitol 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Covariance Parameter Estimates

Parameter Code=AG_1_5_S Parameter=1,5-anhydroglucitol (ug/mL)

Obs	_Imputation_	STUDYID	CovParm	Estimate
1	1	NN1218-4131	Residual	4.6265

1,5-anhydroglucitol 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Fit Statistics

Parameter Code=AG_1_5_S Parameter=1,5-anhydroglucitol (ug/mL)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	-2 Res Log Likelihood	4451.5
2	1	NN1218-4131	AIC (Smaller is Better)	4453.5
3	1	NN1218-4131	AICC (Smaller is Better)	4453.5
4	1	NN1218-4131	BIC (Smaller is Better)	4458.4

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The Mixed procedure
Solution for Fixed Effects

Parameter Code=AG_1_5_S Parameter=1,5-anhydroglucitol (ug/mL)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
1	1	NN1218-4131	TRTPN	2				
2	1	NN1218-4131	TRTPN	3				
3	1	NN1218-4131	TRTPN	4				
4	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
5	1	NN1218-4131	REGION1	—	EUROPE			
6	1	NN1218-4131	REGION1	—	JAPAN			
7	1	NN1218-4131	REGION1	—	NORTH AMERICA			
8	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
9	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
10	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	1.0629	0.1946	1008	5.46	<.0001	0.05	0.6811	1.4448
2	0.7099	0.1951	1008	3.64	0.0003	0.05	0.3270	1.0927
3	1.1074	0.1967	1008	5.63	<.0001	0.05	0.7214	1.4935
4	0.3556	0.2496	1008	1.42	0.1545	0.05	-0.1342	0.8453
5	-0.5164	0.1736	1008	-2.97	0.0030	0.05	-0.8571	-0.1757
6	-0.3137	0.1938	1008	-1.62	0.1058	0.05	-0.6940	0.06654
7	0
8	0.1454	0.1512	1008	0.96	0.3364	0.05	-0.1513	0.4420
9	0
10	-0.1546	0.02308	1008	-6.70	<.0001	0.05	-0.1999	-0.1093

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The Mixed procedure
Least Squares Means

Obs	_Imputation_	PARAMCD	PARAM	STUDYID	Effect	TRTPN
1	1	AG_1_5_S	1,5-anhydroglucitol (ug/mL)	NN1218-4131	TRTPN	2
2	1	AG_1_5_S	1,5-anhydroglucitol (ug/mL)	NN1218-4131	TRTPN	3
3	1	AG_1_5_S	1,5-anhydroglucitol (ug/mL)	NN1218-4131	TRTPN	4

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	WORK.IMPUTE	0.2210	0.1167	1008	1.89	0.0584	0.05	-0.00790	0.4499
2	WORK.IMPUTE	-0.1320	0.1175	1008	-1.12	0.2613	0.05	-0.3626	0.09851
3	WORK.IMPUTE	0.2655	0.1169	1008	2.27	0.0234	0.05	0.03611	0.4950

1,5-anhydroglucitol 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Least Squares Means Estimate

Parameter Code=AG_1_5_S Parameter=1,5-anhydroglucitol (ug/mL)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
1	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
2	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	WORK.IMPUTE	-0.04453	0.1653	1008	-0.27	0.7876	0.05	-0.3688	0.2798
2	WORK.IMPUTE	-0.3976	0.1658	1008	-2.40	0.0167	0.05	-0.7229	-0.07224

1,5-anhydroglucitol 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=AG_1_5_S Parameter=1,5-anhydroglucitol (ug/mL) Study Identifier=NN1218-4

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	100

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000133	0.013598	0.013733	1.03E6	0.009895	0.009800	0.999902

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.228023	0.117186	-0.00166	0.457704	1.03E6	0.203166	0.256132

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	1.95	0.0517

1,5-anhydroglucitol 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=AG_1_5_S Parameter=1,5-anhydroglucitol (ug/mL) Study Identifier=NN1218-4

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	100

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000217	0.013792	0.014011	405741	0.015868	0.015625	0.999844

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.140053	0.118367	-0.37205	0.091943	405741	-0.188039	-0.104013

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-1.18	0.2367

1,5-anhydroglucitol 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=AG_1_5_S Parameter=1,5-anhydroglucitol (ug/mL) Study Identifier=NN1218-4

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	100

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000329	0.013660	0.013993	175442	0.024333	0.023766	0.999762

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.220890	0.118291	-0.01096	0.452737	175442	0.190084	0.265782

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	1.87	0.0619

1,5-anhydroglucitol 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=AG_1_5_S Label=Faster aspart (meal) - NovoRapid (meal) Parameter=1,5-anhydroglucitol (ug/mL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	100

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000456	0.027291	0.027751	360191	0.016858	0.016584	0.999834

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.007133	0.166586	-0.31937	0.333637	360191	-0.048020	0.060142

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	0.04	0.9658

1,5-anhydroglucitol 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=AG_1_5_S Label=Faster aspart (post) - NovoRapid (meal) Parameter=1,5-anhydroglucitol (ug/mL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	100

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000537	0.027467	0.028010	263715	0.019758	0.019383	0.999806

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.360943	0.167361	-0.68897	-0.03292	263715	-0.430585	-0.317017

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-2.16	0.0310

1,5-anhydroglucitol 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Model Information

Parameter Code=AG_1_5_S Parameter=1,5-anhydroglucitol (ug/mL)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Data Set	WORK.IMPUTE_ABS
2	1	NN1218-4131	Dependent Variable	eotVisitAbs_
3	1	NN1218-4131	Covariance Structure	Diagonal
4	1	NN1218-4131	Estimation Method	REML
5	1	NN1218-4131	Residual Variance Method	Profile
6	1	NN1218-4131	Fixed Effects SE Method	Model-Based
7	1	NN1218-4131	Degrees of Freedom Method	Residual

1,5-anhydroglucitol 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Class Level Information

Parameter Code=AG_1_5_S Parameter=1,5-anhydroglucitol (ug/mL)

Input				Output			
S				T			
U				C			
D				l			
Y				a			
I				s			
D				s			
1	1	NN1218-4131	TRTPN	3	2	3	4
2	1	NN1218-4131	REGION1	4	ASIA (EXCLUDING JAPAN)	EUROPE	JAPAN NORTH AMERICA
3	1	NN1218-4131	BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	CARBOHYDRATE COUNTING (FLEXIBLE)	BOLUS INSULI

1,5-anhydroglucitol 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Dimensions

Parameter Code=AG_1_5_S Parameter=1,5-anhydroglucitol (ug/mL)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Covariance Parameters	1
2	1	NN1218-4131	Columns in X	10
3	1	NN1218-4131	Columns in Z	0
4	1	NN1218-4131	Subjects	1
5	1	NN1218-4131	Max Obs per Subject	1016

1,5-anhydroglucitol 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Number of Observations

Parameter Code=AG_1_5_S Parameter=1,5-anhydroglucitol (ug/mL)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
1	1	NN1218-4131	Number of Observations Read	1016	1016	1016	1016	1016
2	1	NN1218-4131	Number of Observations Used	1016	1016	1016	1016	1016
3	1	NN1218-4131	Number of Observations Not Used	0	1016	1016	1016	1016

1,5-anhydroglucitol 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Covariance Parameter Estimates

Parameter Code=AG_1_5_S Parameter=1,5-anhydroglucitol (ug/mL)

Obs	_Imputation_	STUDYID	CovParm	Estimate
1	1	NN1218-4131	Residual	4.6265

1,5-anhydroglucitol 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Fit Statistics

Parameter Code=AG_1_5_S Parameter=1,5-anhydroglucitol (ug/mL)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	-2 Res Log Likelihood	4451.5
2	1	NN1218-4131	AIC (Smaller is Better)	4453.5
3	1	NN1218-4131	AICC (Smaller is Better)	4453.5
4	1	NN1218-4131	BIC (Smaller is Better)	4458.4

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1,5-anhydroglucitol 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Solution for Fixed Effects

Parameter Code=AG_1_5_S Parameter=1,5-anhydroglucitol (ug/mL)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1		BOLAD1	
1	1	NN1218-4131	TRTPN	2				
2	1	NN1218-4131	TRTPN	3				
3	1	NN1218-4131	TRTPN	4				
4	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
5	1	NN1218-4131	REGION1	—	EUROPE			
6	1	NN1218-4131	REGION1	—	JAPAN			
7	1	NN1218-4131	REGION1	—	NORTH AMERICA			
8	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
9	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
10	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	1.0629	0.1946	1008	5.46	<.0001	0.05	0.6811	1.4448
2	0.7099	0.1951	1008	3.64	0.0003	0.05	0.3270	1.0927
3	1.1074	0.1967	1008	5.63	<.0001	0.05	0.7214	1.4935
4	0.3556	0.2496	1008	1.42	0.1545	0.05	-0.1342	0.8453
5	-0.5164	0.1736	1008	-2.97	0.0030	0.05	-0.8571	-0.1757
6	-0.3137	0.1938	1008	-1.62	0.1058	0.05	-0.6940	0.06654
7	0
8	0.1454	0.1512	1008	0.96	0.3364	0.05	-0.1513	0.4420
9	0
10	0.8454	0.02308	1008	36.63	<.0001	0.05	0.8001	0.8907

nn1218/nn1218-4131/ctr_20180214_er
13FEB2018:22:07:12 - a_lab_stat_diff.sas/a_15an_stat_on_fas_app.txt

1,5-anhydroglucitol 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Least Squares Means

Obs	_Imputation_	PARAMCD	PARAM	STUDYID	Effect	TRTPN
1	1	AG_1_5_S	1,5-anhydroglucitol (ug/mL)	NN1218-4131	TRTPN	2
101	1	AG_1_5_S	1,5-anhydroglucitol (ug/mL)	NN1218-4131	TRTPN	3
201	1	AG_1_5_S	1,5-anhydroglucitol (ug/mL)	NN1218-4131	TRTPN	4

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	WORK.IMPUTE	0.2210	0.1167	1008	1.89	0.0584	0.05	-0.00790	0.4499
101	WORK.IMPUTE	-0.1320	0.1175	1008	-1.12	0.2613	0.05	-0.3626	0.09851
201	WORK.IMPUTE	0.2655	0.1169	1008	2.27	0.0234	0.05	0.03611	0.4950

1,5-anhydroglucitol 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Least Squares Means Estimate

Parameter Code=AG_1_5_S Parameter=1,5-anhydroglucitol (ug/mL)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
1	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
101	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	WORK.IMPUTE	-0.04453	0.1653	1008	-0.27	0.7876	0.05	-0.3688	0.2798
101	WORK.IMPUTE	-0.3976	0.1658	1008	-2.40	0.0167	0.05	-0.7229	-0.07224

1,5-anhydroglucitol 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=AG_1_5_S Parameter=1,5-anhydroglucitol (ug/mL) Study Identifier=NN1218-4

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	100

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000133	0.013598	0.013733	1.03E6	0.009895	0.009800	0.999902

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	4.899775	0.117186	4.670095	5.129456	1.03E6	4.874918	4.927884

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	41.81	<.0001

1,5-anhydroglucitol 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=AG_1_5_S Parameter=1,5-anhydroglucitol (ug/mL) Study Identifier=NN1218-4

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	100

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000217	0.013792	0.014011	405741	0.015868	0.015625	0.999844

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	4.531699	0.118367	4.299704	4.763695	405741	4.483713	4.567739

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	38.29	<.0001

1,5-anhydroglucitol 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=AG_1_5_S Parameter=1,5-anhydroglucitol (ug/mL) Study Identifier=NN1218-4

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	100

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000329	0.013660	0.013993	175442	0.024333	0.023766	0.999762

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	4.892642	0.118291	4.660795	5.124489	175442	4.861836	4.937534

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	41.36	<.0001

18: Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis setThe MI Procedure with MCMC
Model Information

Parameter Code=P9SMPGMU Planned Treatment for Period 30 (N)=2

Obs	PARAM	Description	Value
1	Mean SMPG (mg/dL)	Data Set	WORK.ENDPOINT_PARAM
2	Mean SMPG (mg/dL)	Method	Monotone-data_MCMC
3	Mean SMPG (mg/dL)	Multiple Imputation Chain	Multiple Chains
4	Mean SMPG (mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
5	Mean SMPG (mg/dL)	Start	Starting Value
6	Mean SMPG (mg/dL)	Prior	Jeffreys
7	Mean SMPG (mg/dL)	Number of Imputations	20000
8	Mean SMPG (mg/dL)	Number of Burn-in Iterations	200
9	Mean SMPG (mg/dL)	Seed for random number generator	1234

Parameter Code=P9SMPGMU Planned Treatment for Period 30 (N)=3

Obs	PARAM	Description	Value
10	Mean SMPG (mg/dL)	Data Set	WORK.ENDPOINT_PARAM
11	Mean SMPG (mg/dL)	Method	Monotone-data_MCMC
12	Mean SMPG (mg/dL)	Multiple Imputation Chain	Multiple Chains
13	Mean SMPG (mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
14	Mean SMPG (mg/dL)	Start	Starting Value
15	Mean SMPG (mg/dL)	Prior	Jeffreys
16	Mean SMPG (mg/dL)	Number of Imputations	20000
17	Mean SMPG (mg/dL)	Number of Burn-in Iterations	200
18	Mean SMPG (mg/dL)	Seed for random number generator	950811097

Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=P9SMPGMU Planned Treatment for Period 30 (N)=4

Obs	PARAM	Description	Value
19	Mean SMPG (mg/dL)	Data Set	WORK.ENDPOINT_PARAM
20	Mean SMPG (mg/dL)	Method	Monotone-data_MCMC
21	Mean SMPG (mg/dL)	Multiple Imputation Chain	Multiple Chains
22	Mean SMPG (mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
23	Mean SMPG (mg/dL)	Start	Starting Value
24	Mean SMPG (mg/dL)	Prior	Jeffreys
25	Mean SMPG (mg/dL)	Number of Imputations	20000
26	Mean SMPG (mg/dL)	Number of Burn-in Iterations	200
27	Mean SMPG (mg/dL)	Seed for random number generator	950357174

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Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with MCMC
Missing data pattern

Parameter Code=P9SMPGMU Planned Treatment for Period 30 (N)=2

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
1	Mean SMPG (mg/dL)	1	X	X	X	294	89.36	158.128181	-3.785678	-4.356683
2	Mean SMPG (mg/dL)	2	X	X	O	9	2.74	152.993132	-0.382600	.
3	Mean SMPG (mg/dL)	3	X	.	X	17	5.17	183.091466	.	-27.601635
4	Mean SMPG (mg/dL)	4	X	O	O	9	2.74	151.947761	.	.

Parameter Code=P9SMPGMU Planned Treatment for Period 30 (N)=3

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
5	Mean SMPG (mg/dL)	1	X	X	X	303	91.54	161.272912	-4.795922	-5.264115
6	Mean SMPG (mg/dL)	2	X	X	O	12	3.63	160.718113	6.819953	.
7	Mean SMPG (mg/dL)	3	X	.	X	12	3.63	138.365007	.	12.877421
8	Mean SMPG (mg/dL)	4	X	O	O	4	1.21	170.189045	.	.

Parameter Code=P9SMPGMU Planned Treatment for Period 30 (N)=4

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
9	Mean SMPG (mg/dL)	1	X	X	X	297	90.27	158.493946	0.251688	-5.831923
10	Mean SMPG (mg/dL)	2	X	X	O	11	3.34	146.783872	3.939277	.
11	Mean SMPG (mg/dL)	3	X	.	X	12	3.65	157.575563	.	-7.756297
12	Mean SMPG (mg/dL)	4	X	O	O	9	2.74	161.325755	.	.

Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9SMPGMU Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM	Description	Value
1	1	Mean SMPG (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	Mean SMPG (mg/dL)	Method	Monotone
3	1	Mean SMPG (mg/dL)	Number of Imputations	1
4	1	Mean SMPG (mg/dL)	Seed for random number generator	4321

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Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=P9SMPGMU Planned Treatment for Period 30 (N)=2

O b s	I m p u t a t i o n _	P A R A M	G r o u p	R E G I O N 1	B O L A D 1	B L A S E	v i s i t t 2	v i s i t t 3	F r e q	P e r c e n t	B A S E	v i s i t t 2	v i s i t t 3
1	1	Mean SMPG (mg/dL)	1	X	X	X	X	X	311	94.53	159.492734	-4.490982	-5.627307
2	1	Mean SMPG (mg/dL)	2	X	X	X	X	.	9	2.74	152.993132	-0.382600	.
3	1	Mean SMPG (mg/dL)	3	X	X	X	.	.	9	2.74	151.947761	.	.

Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression Regression Information

Parameter Code=P9SMPGMU Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2200

	O	P	E	R	B	O	
b	A	A	f	E	O	b	
n	R	R	e	G	L	s	
s <th>A</th> <th>A</th> <th>c</th> <th>I</th> <th>A</th> <th>v</th> <th></th>	A	A	c	I	A	v	
_	M	t	t	N	D	a	
				1	1	1	\bar{I}
1	1	Mean	SMPG	(mg/dL)	Intercept	-0.00661	0.025790
2	1	Mean	SMPG	(mg/dL)	REGION1 ASIA (EXCLUDING JAPAN)	-0.23330	-0.202653
3	1	Mean	SMPG	(mg/dL)	REGION1 EUROPE	-0.03349	-0.164116
4	1	Mean	SMPG	(mg/dL)	REGION1 JAPAN	0.11752	0.099894
5	1	Mean	SMPG	(mg/dL)	BOLAD1 BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.13461	-0.180701
6	1	Mean	SMPG	(mg/dL)	BASE	-0.57675	-0.617873

Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression Regression Information

Parameter Code=P9SMPGMU Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

Output	Parameter	Effect	Region	BOLUS	Observation		
				1	1	\bar{I}	
7 1	Mean	SMPG (mg/dL)	Intercept			0.02507	0.019661
8 1	Mean	SMPG (mg/dL)	REGION1 ASIA (EXCLUDING JAPAN)			-0.02128	-0.074567
9 1	Mean	SMPG (mg/dL)	REGION1 EUROPE			-0.12440	-0.145260
10 1	Mean	SMPG (mg/dL)	REGION1 JAPAN			0.10845	0.204348
11 1	Mean	SMPG (mg/dL)	BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.07249	-0.154988
12 1	Mean	SMPG (mg/dL)	BASE			-0.32902	-0.356293
13 1	Mean	SMPG (mg/dL)	visit2200			0.47129	0.506333

Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9SMPGMU Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM	Description	Value
1	1	Mean SMPG (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	Mean SMPG (mg/dL)	Method	Monotone
3	1	Mean SMPG (mg/dL)	Number of Imputations	1
4	1	Mean SMPG (mg/dL)	Seed for random number generator	4322

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Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=P9SMPGMU Planned Treatment for Period 30 (N)=3

O b s	I m p u t a t i o n _	P A R A M _	G r o u p	R E G I O N 1	B O L A L 1	B L A S E	v i s i t 2	v i s i t 3	F r e q	P e r c e n t	B A S E	v i s i t 2	v i s i t 3
1	1	Mean SMPG (mg/dL)	1	X	X	X	X	X	315	95.17	160.400230	-4.010412	-4.573009
2	1	Mean SMPG (mg/dL)	2	X	X	X	X	.	12	3.63	160.718113	6.819953	.
3	1	Mean SMPG (mg/dL)	3	X	X	X	.	.	4	1.21	170.189045	.	.

Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression Regression Information

Parameter Code=P9SMPGMU Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2200

	O	P	E	R	B	O	
b	A	A	f	E	O	b	
n	R	M	e	G	L	s	
s <th>A</th> <th></th> <th>c</th> <th>I</th> <th>A</th> <th>v</th> <th></th>	A		c	I	A	v	
_	M		t	N	D	a	
				1	1	1	\bar{I}
1	1	Mean SMPG (mg/dL)	Intercept			0.01486	0.113834
2	1	Mean SMPG (mg/dL)	REGION1 ASIA (EXCLUDING JAPAN)			-0.07408	0.059664
3	1	Mean SMPG (mg/dL)	REGION1 EUROPE			-0.14178	-0.141982
4	1	Mean SMPG (mg/dL)	REGION1 JAPAN			0.21368	0.122507
5	1	Mean SMPG (mg/dL)	BOLAD1 BOLUS INSULIN ALGORITHM (SLIDING SCALE)			-0.14557	-0.118674
6	1	Mean SMPG (mg/dL)	BASE			-0.50495	-0.549477

Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression Regression Information

Parameter Code=P9SMPGMU Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

Output	Parameter	Effect	Region	Bolus	Observation		
Obs	ARM	Fact	1	1	1	\bar{I}	
7 1	Mean	SMPG (mg/dL)	Intercept			0.00571	0.073650
8 1	Mean	SMPG (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)		-0.07136	-0.129909
9 1	Mean	SMPG (mg/dL)	REGION1	EUROPE		-0.05872	-0.078005
10 1	Mean	SMPG (mg/dL)	REGION1	JAPAN		0.05801	0.082896
11 1	Mean	SMPG (mg/dL)	BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.05868	-0.076911
12 1	Mean	SMPG (mg/dL)	BASE			-0.33401	-0.386207
13 1	Mean	SMPG (mg/dL)	visit2200			0.47537	0.496515

Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9SMPGMU Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM	Description	Value
1	1	Mean SMPG (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	Mean SMPG (mg/dL)	Method	Monotone
3	1	Mean SMPG (mg/dL)	Number of Imputations	1
4	1	Mean SMPG (mg/dL)	Seed for random number generator	4323

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Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=P9SMPGMU Planned Treatment for Period 30 (N)=4

O b s	I m p u t a t i o n _					P A R A M	G r o u p	R E G I O N 1	B O L A L 1	B A L A N C E	v i s i t 2	v i s i t 3	F r e q	P e r c e n t	B A S E	v i s i t 2	v i s i t 3
1	1	Mean	SMPG	(mg/dL)	1	X	X	X	X	X	309	93.92	158.458280	0.008361	-5.906656		
2	1	Mean	SMPG	(mg/dL)	2	X	X	X	X	.	11	3.34	146.783872	3.939277	.		
3	1	Mean	SMPG	(mg/dL)	3	X	X	X	.	.	9	2.74	161.325755	.	.		

Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression Regression Information

Parameter Code=P9SMPGMU Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2200

	Observed	Predicted	Residuals	Standardized Residuals	Bias Accelerated CI	Observed	Expected
	Mean	SE	CI	Lower	Upper	Mean	SE
1	1	Mean	SMPG (mg/dL)	Intercept		0.03400	-0.010891
2	1	Mean	SMPG (mg/dL)	REGION1 ASIA (EXCLUDING JAPAN)		-0.04465	0.006466
3	1	Mean	SMPG (mg/dL)	REGION1 EUROPE		-0.21533	-0.328039
4	1	Mean	SMPG (mg/dL)	REGION1 JAPAN		0.18158	0.220818
5	1	Mean	SMPG (mg/dL)	BOLAD1 BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.16162	-0.165311
6	1	Mean	SMPG (mg/dL)	BASE		-0.57023	-0.651998

Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression Regression Information

Parameter Code=P9SMPGMU Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

Output	Parameter	Effect	REG	BOLD	Obs	
Obs	ARM	Effect	REG	BOLD	Obs	
1	1	1	1	1	1	1
7	1	Mean	SMPG (mg/dL)	Intercept		0.01829
8	1	Mean	SMPG (mg/dL)	REGION1 ASIA (EXCLUDING JAPAN)		-0.00901
9	1	Mean	SMPG (mg/dL)	REGION1 EUROPE		-0.14651
10	1	Mean	SMPG (mg/dL)	REGION1 JAPAN		0.19231
11	1	Mean	SMPG (mg/dL)	BOLAD1		-0.02697
12	1	Mean	SMPG (mg/dL)	BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.48699
13	1	Mean	SMPG (mg/dL)	BASE		0.35191
13	1	Mean	SMPG (mg/dL)	visit2200		0.385449

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Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=P9PSMPGM Planned Treatment for Period 30 (N)=2

Obs	PARAM	Description	Value
1	Mean SMPG (mmol/L)	Data Set	WORK.ENDPOINT_PARAM
2	Mean SMPG (mmol/L)	Method	Monotone-data_MCMC
3	Mean SMPG (mmol/L)	Multiple Imputation Chain	Multiple Chains
4	Mean SMPG (mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
5	Mean SMPG (mmol/L)	Start	Starting Value
6	Mean SMPG (mmol/L)	Prior	Jeffreys
7	Mean SMPG (mmol/L)	Number of Imputations	20000
8	Mean SMPG (mmol/L)	Number of Burn-in Iterations	200
9	Mean SMPG (mmol/L)	Seed for random number generator	1234

Parameter Code=P9PSMPGM Planned Treatment for Period 30 (N)=3

Obs	PARAM	Description	Value
10	Mean SMPG (mmol/L)	Data Set	WORK.ENDPOINT_PARAM
11	Mean SMPG (mmol/L)	Method	Monotone-data_MCMC
12	Mean SMPG (mmol/L)	Multiple Imputation Chain	Multiple Chains
13	Mean SMPG (mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
14	Mean SMPG (mmol/L)	Start	Starting Value
15	Mean SMPG (mmol/L)	Prior	Jeffreys
16	Mean SMPG (mmol/L)	Number of Imputations	20000
17	Mean SMPG (mmol/L)	Number of Burn-in Iterations	200
18	Mean SMPG (mmol/L)	Seed for random number generator	950811097

Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=P9PSMPGM Planned Treatment for Period 30 (N)=4

Obs	PARAM	Description	Value
19	Mean SMPG (mmol/L)	Data Set	WORK.ENDPOINT_PARAM
20	Mean SMPG (mmol/L)	Method	Monotone-data_MCMC
21	Mean SMPG (mmol/L)	Multiple Imputation Chain	Multiple Chains
22	Mean SMPG (mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
23	Mean SMPG (mmol/L)	Start	Starting Value
24	Mean SMPG (mmol/L)	Prior	Jeffreys
25	Mean SMPG (mmol/L)	Number of Imputations	20000
26	Mean SMPG (mmol/L)	Number of Burn-in Iterations	200
27	Mean SMPG (mmol/L)	Seed for random number generator	950357174

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Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with MCMC
Missing data pattern

Parameter Code=P9PSMPGM Planned Treatment for Period 30 (N)=2

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
1	Mean SMPG (mmol/L)	1	X	X	X	294	89.36	8.775149	-0.210082	-0.241769
2	Mean SMPG (mmol/L)	2	X	X	O	9	2.74	8.490185	-0.021232	.
3	Mean SMPG (mmol/L)	3	X	.	X	17	5.17	10.160459	.	-1.531722
4	Mean SMPG (mmol/L)	4	X	O	O	9	2.74	8.432173	.	.

Parameter Code=P9PSMPGM Planned Treatment for Period 30 (N)=3

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
5	Mean SMPG (mmol/L)	1	X	X	X	303	91.54	8.949662	-0.266144	-0.292126
6	Mean SMPG (mmol/L)	2	X	X	O	12	3.63	8.918874	0.378466	.
7	Mean SMPG (mmol/L)	3	X	.	X	12	3.63	7.678413	.	0.714618
8	Mean SMPG (mmol/L)	4	X	O	O	4	1.21	9.444453	.	.

Parameter Code=P9PSMPGM Planned Treatment for Period 30 (N)=4

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
9	Mean SMPG (mmol/L)	1	X	X	X	297	90.27	8.795446	0.013967	-0.323636
10	Mean SMPG (mmol/L)	2	X	X	O	11	3.34	8.145609	0.218606	.
11	Mean SMPG (mmol/L)	3	X	.	X	12	3.65	8.744482	.	-0.430427
12	Mean SMPG (mmol/L)	4	X	O	O	9	2.74	8.952595	.	.

Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PSMPGM Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM	Description	Value
1	1	Mean SMPG (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	Mean SMPG (mmol/L)	Method	Monotone
3	1	Mean SMPG (mmol/L)	Number of Imputations	1
4	1	Mean SMPG (mmol/L)	Seed for random number generator	4321

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nn1218/nn1218-4131/ctr_20180214_er
09FEB2018:20:27:16 - a 797pp stat diff.sas/a 9pp mean stat in_fas app.txt
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Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PSMPGM Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2200

Imputed					Region	Bolus	Ob	
Obs					Region	Bolus	Obs	
Mean					Region	Bolus	Obs	
SMPG (mmol/L)					Region	Bolus	Obs	
Intercept					Region	Bolus	Obs	
REGION1 ASIA (EXCLUDING JAPAN)					Region	Bolus	Obs	
REGION1 EUROPE					Region	Bolus	Obs	
REGION1 JAPAN					Region	Bolus	Obs	
BOLAD1					Region	Bolus	Obs	
BOLUS INSULIN ALGORITHM (SLIDING SCALE)					Region	Bolus	Obs	
BASE					Region	Bolus	Obs	

1	1	Mean	SMPG	(mmol/L)	Intercept			-0.00661	0.025790
2	1	Mean	SMPG	(mmol/L)	REGION1 ASIA (EXCLUDING JAPAN)			-0.23330	-0.202653
3	1	Mean	SMPG	(mmol/L)	REGION1 EUROPE			-0.03349	-0.164116
4	1	Mean	SMPG	(mmol/L)	REGION1 JAPAN			0.11752	0.099894
5	1	Mean	SMPG	(mmol/L)	BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.13461	-0.180701
6	1	Mean	SMPG	(mmol/L)	BASE			-0.57675	-0.617873

Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PSMPGM Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

O b s _	O o b s _	P A R A M	E f f e c t	R E G I O N 1	B O L A D 1	O b s V a l	I
7	1	Mean	SMPG (mmol/L)	Intercept		0.02507	0.019661
8	1	Mean	SMPG (mmol/L)	REGION1 ASIA (EXCLUDING JAPAN)		-0.02128	-0.074567
9	1	Mean	SMPG (mmol/L)	REGION1 EUROPE		-0.12440	-0.145260
10	1	Mean	SMPG (mmol/L)	REGION1 JAPAN		0.10845	0.204348
11	1	Mean	SMPG (mmol/L)	BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.07249	-0.154988
12	1	Mean	SMPG (mmol/L)	BASE		-0.32902	-0.356293
13	1	Mean	SMPG (mmol/L)	visit2200		0.47129	0.506333

Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PSMPGM Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM	Description	Value
1	1	Mean SMPG (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	Mean SMPG (mmol/L)	Method	Monotone
3	1	Mean SMPG (mmol/L)	Number of Imputations	1
4	1	Mean SMPG (mmol/L)	Seed for random number generator	4322

Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression Missing Data Pattern

Parameter Code=P9PSMPGM Planned Treatment for Period 30 (N)=3

O b s	I m p u t a t i o n			P A R A M	G r o u p	R E G I O N 1					F r e q	P e r c e n t	B A S E	v i s i t 2 0 0	v i s i t 3 6 0 0
						R E G I O N 1	B O L A D 1	B A S E	v i s i t 2 0 0	v i s i t 3 6 0 0					
						\bar{M} i s s	\bar{M} i s s	\bar{M} i s s	\bar{M} i s s	\bar{M} i s s					
1	1	Mean	SMPG	(mmol/L)	1	X	X	X	X	X	315	95.17	8.901234	-0.222553	-0.253774
2	1	Mean	SMPG	(mmol/L)	2	X	X	X	X	.	12	3.63	8.918874	0.378466	.
3	1	Mean	SMPG	(mmol/L)	3	X	X	X	.	.	4	1.21	9.444453	.	.

Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression Regression Information

Parameter Code=P9PSMPGM Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2200

O b s _		P A R A M		E f f e c t		R E G I O N		B O L U S		O b s _		I	
1	1	Mean	SMPG	(mmol/L)	Intercept						0.01486		0.113834
2	1	Mean	SMPG	(mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)					-0.07408		0.059664
3	1	Mean	SMPG	(mmol/L)	REGION1	EUROPE					-0.14178		-0.141982
4	1	Mean	SMPG	(mmol/L)	REGION1	JAPAN					0.21368		0.122507
5	1	Mean	SMPG	(mmol/L)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)				-0.14557		-0.118674
6	1	Mean	SMPG	(mmol/L)	BASE						-0.50495		-0.549477

Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression Regression Information

Parameter Code=P9PSMPGM Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

Output variable	Parameter	Effect	Regression coefficient	Bias	Observed	Inter
7 1 Mean	SMPG (mmol/L)	Intercept			0.00571	0.073650
8 1 Mean	SMPG (mmol/L)	REGION1 ASIA (EXCLUDING JAPAN)			-0.07136	-0.129909
9 1 Mean	SMPG (mmol/L)	REGION1 EUROPE			-0.05872	-0.078005
10 1 Mean	SMPG (mmol/L)	REGION1 JAPAN			0.05801	0.082896
11 1 Mean	SMPG (mmol/L)	BOLAD1 BOLUS INSULIN ALGORITHM (SLIDING SCALE)			-0.05868	-0.076911
12 1 Mean	SMPG (mmol/L)	BASE			-0.33401	-0.386207
13 1 Mean	SMPG (mmol/L)	visit2200			0.47537	0.496515

Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PSMPGM Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM	Description	Value
1	1	Mean SMPG (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	Mean SMPG (mmol/L)	Method	Monotone
3	1	Mean SMPG (mmol/L)	Number of Imputations	1
4	1	Mean SMPG (mmol/L)	Seed for random number generator	4323

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nn1218/nn1218-4131/ctr_20180214_er
09FEB2018:20:27:16 - a 797pp stat diff.sas/a 9pp mean stat in_fas app.txt
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Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression Regression Information

Parameter Code=P9PSMPGM Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2200

			P	E	R	B	O	
			A	f	E	O	b	
			R	e	G	L	s	
			A	c	I	A	V	
			M	t	N	D	a	
					1	1	1	\bar{I}
1	1	Mean	SMPG (mmol/L)	Intercept			0.03400	-0.010891
2	1	Mean	SMPG (mmol/L)	REGION1 ASIA (EXCLUDING JAPAN)			-0.04465	0.006466
3	1	Mean	SMPG (mmol/L)	REGION1 EUROPE			-0.21533	-0.328039
4	1	Mean	SMPG (mmol/L)	REGION1 JAPAN			0.18158	0.220818
5	1	Mean	SMPG (mmol/L)	BOLAD1 BOLUS INSULIN ALGORITHM (SLIDING SCALE)			-0.16162	-0.165311
6	1	Mean	SMPG (mmol/L)	BASE			-0.57023	-0.651998

Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression Regression Information

Parameter Code=P9PSMPGM Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

	O b s _	P A R M	E f f e c t	R E G I O N 1	B O L U S D 1	O b s V a l	T
7	1	Mean SMPG (mmol/L)	Intercept			0.01829	0.084915
8	1	Mean SMPG (mmol/L)	REGION1 ASIA (EXCLUDING JAPAN)			-0.00901	-0.001395
9	1	Mean SMPG (mmol/L)	REGION1 EUROPE			-0.14651	-0.192972
10	1	Mean SMPG (mmol/L)	REGION1 JAPAN			0.19231	0.223175
11	1	Mean SMPG (mmol/L)	BOLAD1 BOLUS INSULIN ALGORITHM (SLIDING SCALE)			-0.02697	-0.073826
12	1	Mean SMPG (mmol/L)	BASE			-0.48699	-0.480340
13	1	Mean SMPG (mmol/L)	visit2200			0.35191	0.385449

Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Model Information

Parameter Code=P9PSMPGM Parameter=Mean SMPG (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Data Set	WORK.IMPUTE
2	1	NN1218-4131	Dependent Variable	eotVisit
3	1	NN1218-4131	Covariance Structure	Diagonal
4	1	NN1218-4131	Estimation Method	REML
5	1	NN1218-4131	Residual Variance Method	Profile
6	1	NN1218-4131	Fixed Effects SE Method	Model-Based
7	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=P9SMPGMU Parameter=Mean SMPG (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
8	1	NN1218-4131	Data Set	WORK.IMPUTE
9	1	NN1218-4131	Dependent Variable	eotVisit
10	1	NN1218-4131	Covariance Structure	Diagonal
11	1	NN1218-4131	Estimation Method	REML
12	1	NN1218-4131	Residual Variance Method	Profile
13	1	NN1218-4131	Fixed Effects SE Method	Model-Based
14	1	NN1218-4131	Degrees of Freedom Method	Residual

Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Class Level Information

Parameter Code=P9PSMPGM Parameter=Mean SMPG (mmol/L)

Ob- s	Input ID	STUDY	Class	Level	Values	min
1	1	NN1218-4131	TRTPN	3	2 3 4	5
2	1	NN1218-4131	REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA	49
3	1	NN1218-4131	BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULI	85

Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Class Level Information

Parameter Code=P9SMPGMU Parameter=Mean SMPG (mg/dL)

Ob- s	—	Input ID	STUDY	Class	Level	Values	min
4	1	NN1218-4131	TRTPN		3 2 3 4		5
5	1	NN1218-4131	REGION1		4 ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA		49
6	1	NN1218-4131	BOLAD1		2 BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULI		85

Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Dimensions

Parameter Code=P9PSMPGM Parameter=Mean SMPG (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Covariance Parameters	1
2	1	NN1218-4131	Columns in X	10
3	1	NN1218-4131	Columns in Z	0
4	1	NN1218-4131	Subjects	1
5	1	NN1218-4131	Max Obs per Subject	989

Parameter Code=P9SMPGMU Parameter=Mean SMPG (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
6	1	NN1218-4131	Covariance Parameters	1
7	1	NN1218-4131	Columns in X	10
8	1	NN1218-4131	Columns in Z	0
9	1	NN1218-4131	Subjects	1
10	1	NN1218-4131	Max Obs per Subject	989

Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Number of Observations

Parameter Code=P9PSMPGM Parameter=Mean SMPG (mmol/L)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
1	1	NN1218-4131	Number of Observations Read	989	989	989	989	989
2	1	NN1218-4131	Number of Observations Used	989	989	989	989	989
3	1	NN1218-4131	Number of Observations Not Used	0	989	989	989	989

Parameter Code=P9SMPGMU Parameter=Mean SMPG (mg/dL)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
4	1	NN1218-4131	Number of Observations Read	989	989	989	989	989
5	1	NN1218-4131	Number of Observations Used	989	989	989	989	989
6	1	NN1218-4131	Number of Observations Not Used	0	989	989	989	989

Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Covariance Parameter Estimates

Parameter Code=P9PSMPGM Parameter=Mean SMPG (mmol/L)

Obs	_Imputation_	STUDYID	CovParm	Estimate
1	1	NN1218-4131	Residual	2.3247

Parameter Code=P9SMPGMU Parameter=Mean SMPG (mg/dL)

Obs	_Imputation_	STUDYID	CovParm	Estimate
20001	1	NN1218-4131	Residual	754.88

Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Fit Statistics

Parameter Code=P9PSMPGM Parameter=Mean SMPG (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	-2 Res Log Likelihood	3657.1
2	1	NN1218-4131	AIC (Smaller is Better)	3659.1
3	1	NN1218-4131	AICC (Smaller is Better)	3659.1
4	1	NN1218-4131	BIC (Smaller is Better)	3664.0

Parameter Code=P9SMPGMU Parameter=Mean SMPG (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
5	1	NN1218-4131	-2 Res Log Likelihood	9336.0
6	1	NN1218-4131	AIC (Smaller is Better)	9338.0
7	1	NN1218-4131	AICC (Smaller is Better)	9338.0
8	1	NN1218-4131	BIC (Smaller is Better)	9342.9

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Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Solution for Fixed Effects

Parameter Code=P9PSMPGM Parameter=Mean SMPG (mmol/L)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1
1	1	NN1218-4131	TRTPN	2		
2	1	NN1218-4131	TRTPN	3		
3	1	NN1218-4131	TRTPN	4		
4	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)	
5	1	NN1218-4131	REGION1	—	EUROPE	
6	1	NN1218-4131	REGION1	—	JAPAN	
7	1	NN1218-4131	REGION1	—	NORTH AMERICA	
8	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)
9	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY
10	1	NN1218-4131	BASE	—		

Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	6.2077	0.2770	981	22.41	<.0001	0.05	5.6642	6.7512
2	6.2964	0.2792	981	22.55	<.0001	0.05	5.7485	6.8442
3	6.1087	0.2755	981	22.18	<.0001	0.05	5.5681	6.6493
4	-0.3204	0.1786	981	-1.79	0.0732	0.05	-0.6709	0.03018
5	-0.4521	0.1271	981	-3.56	0.0004	0.05	-0.7016	-0.2027
6	0.2782	0.1408	981	1.98	0.0484	0.05	0.001906	0.5545
7	0
8	-0.4246	0.1097	981	-3.87	0.0001	0.05	-0.6398	-0.2093
9	0
10	-0.6919	0.02786	981	-24.83	<.0001	0.05	-0.7466	-0.6373

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Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Solution for Fixed Effects

Parameter Code=P9SMPGMU Parameter=Mean SMPG (mg/dL)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
11	1	NN1218-4131	TRTPN	2				
12	1	NN1218-4131	TRTPN	3				
13	1	NN1218-4131	TRTPN	4				
14	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
15	1	NN1218-4131	REGION1	—	EUROPE			
16	1	NN1218-4131	REGION1	—	JAPAN			
17	1	NN1218-4131	REGION1	—	NORTH AMERICA			
18	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
19	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
20	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
11	111.86	4.9911	981	22.41	<.0001	0.05	102.07	121.66
12	113.46	5.0304	981	22.55	<.0001	0.05	103.59	123.33
13	110.08	4.9640	981	22.18	<.0001	0.05	100.34	119.82
14	-5.7727	3.2188	981	-1.79	0.0732	0.05	-12.0892	0.5438
15	-8.1475	2.2908	981	-3.56	0.0004	0.05	-12.6429	-3.6521
16	5.0134	2.5372	981	1.98	0.0484	0.05	0.03435	9.9924
17	0
18	-7.6510	1.9767	981	-3.87	0.0001	0.05	-11.5300	-3.7720
19	0
20	-0.6919	0.02786	981	-24.83	<.0001	0.05	-0.7466	-0.6373

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Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Least Squares Means

Obs	_Imputation_	PARAMCD	PARAM		STUDYID	Effect	TRTPN	Margins
1	1	P9PSMPGM	Mean	SMPG (mmol/L)	NN1218-4131	TRTPN	2	WORK.IMPUTE
2	1	P9PSMPGM	Mean	SMPG (mmol/L)	NN1218-4131	TRTPN	3	WORK.IMPUTE
3	1	P9PSMPGM	Mean	SMPG (mmol/L)	NN1218-4131	TRTPN	4	WORK.IMPUTE
4	1	P9SMPGMU	Mean	SMPG (mg/dL)	NN1218-4131	TRTPN	2	WORK.IMPUTE
5	1	P9SMPGMU	Mean	SMPG (mg/dL)	NN1218-4131	TRTPN	3	WORK.IMPUTE
6	1	P9SMPGMU	Mean	SMPG (mg/dL)	NN1218-4131	TRTPN	4	WORK.IMPUTE

Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	-0.2801	0.08418	981	-3.33	0.0009	0.05	-0.4453	-0.1149
2	-0.1915	0.08390	981	-2.28	0.0227	0.05	-0.3561	-0.02681
3	-0.3791	0.08416	981	-4.50	<.0001	0.05	-0.5443	-0.2140
4	-5.0478	1.5170	981	-3.33	0.0009	0.05	-8.0247	-2.0709
5	-3.4501	1.5119	981	-2.28	0.0227	0.05	-6.4171	-0.4831
6	-6.8315	1.5165	981	-4.50	<.0001	0.05	-9.8075	-3.8555

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Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Least Squares Means Estimate

Parameter Code=P9PSMPGM Parameter=Mean SMPG (mmol/L)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
1	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
2	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	WORK.IMPUTE	0.09899	0.1191	981	0.83	0.4062	0.05	-0.1348	0.3328
2	WORK.IMPUTE	0.1876	0.1189	981	1.58	0.1148	0.05	-0.04566	0.4210

Parameter Code=P9SMPGMU Parameter=Mean SMPG (mg/dL)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
3	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
4	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
3	WORK.IMPUTE	1.7837	2.1466	981	0.83	0.4062	0.05	-2.4287	5.9962
4	WORK.IMPUTE	3.3814	2.1424	981	1.58	0.1148	0.05	-0.8228	7.5856

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 1402 of 4425	Novo Nordisk
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Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9PSMPGM Parameter=Mean SMPG (mmol/L) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000373	0.007061	0.007433	7.96E6	0.052775	0.050130	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.299071	0.086217	-0.46805	-0.13009	7.96E6	-0.370558	-0.216750

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-3.47	0.0005

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Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9SMPGMU Parameter=Mean SMPG (mg/dL) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.120995	2.292760	2.413761	7.96E6	0.052775	0.050130	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-5.389258	1.553628	-8.43431	-2.34420	7.96E6	-6.677448	-3.905842

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-3.47	0.0005

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 1404 of 4425	Novo Nordisk
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Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9PSMPGM Parameter=Mean SMPG (mmol/L) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000292	0.007014	0.007306	1.25E7	0.041675	0.040008	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.214200	0.085475	-0.38173	-0.04667	1.25E7	-0.281920	-0.148961

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-2.51	0.0122

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Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9SMPGMU Parameter=Mean SMPG (mg/dL) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.094910	2.277494	2.372408	1.25E7	0.041675	0.040008	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-3.859876	1.540262	-6.87874	-0.84102	1.25E7	-5.080194	-2.684285

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-2.51	0.0122

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Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9PSMPGM Parameter=Mean SMPG (mmol/L) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000419	0.007057	0.007475	6.38E6	0.059329	0.056007	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.364279	0.086460	-0.53374	-0.19482	6.38E6	-0.439006	-0.274399

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-4.21	<.0001

nn1218/nn1218-4131/ctr_20180214_er
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Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 1407 of 4425	Novo Nordisk
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Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9SMPGMU Parameter=Mean SMPG (mg/dL) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.135943	2.291434	2.427383	6.38E6	0.059329	0.056007	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-6.564312	1.558006	-9.61795	-3.51068	6.38E6	-7.910895	-4.944676

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-4.21	<.0001

nn1218/nn1218-4131/ctr_20180214_er
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Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 1408 of 4425	Novo Nordisk
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Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=P9PSMPGM Label=Faster aspart (meal) - NovoRapid (meal) Parameter=Mean SMPG (mmol/L) Study Identifier=NN1218-41

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000790	0.014138	0.014928	7.14E6	0.055867	0.052911	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.065208	0.122181	-0.17426	0.304678	7.14E6	-0.049526	0.168208

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	0.53	0.5935

nn1218/nn1218-4131/ctr_20180214_er
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Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 1409 of 4425	Novo Nordisk
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Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=P9PSMPGM Label=Faster aspart (post) - NovoRapid (meal) Parameter=Mean SMPG (mmol/L) Study Identifier=NN1218-41

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000710	0.014083	0.014793	8.67E6	0.050437	0.048015	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.150080	0.121626	-0.08830	0.388462	8.67E6	0.044210	0.248466

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	1.23	0.2172

nn1218/nn1218-4131/ctr_20180214_er
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Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 1410 of 4425	Novo Nordisk
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Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=P9SMPGMU Label=Faster aspart (meal) - NovoRapid (meal) Parameter=Mean SMPG (mg/dL) Study Identifier=NN1218-413

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.256470	4.590984	4.847466	7.14E6	0.055867	0.052911	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	1.175054	2.201696	-3.14019	5.490300	7.14E6	-0.892453	3.031109

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	0.53	0.5935

nn1218/nn1218-4131/ctr_20180214_er
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Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 1411 of 4425	Novo Nordisk
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Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=P9SMPGMU Label=Faster aspart (post) - NovoRapid (meal) Parameter=Mean SMPG (mg/dL) Study Identifier=NN1218-413

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.230631	4.572915	4.803558	8.67E6	0.050437	0.048015	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits	DF	Minimum	Maximum
Estimate	2.704435	2.191702	-1.59122 7.000093	8.67E6	0.796670	4.477360

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	1.23	0.2172

nn1218/nn1218-4131/ctr_20180214_er
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Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Model Information

Parameter Code=P9PSMPGM Parameter=Mean SMPG (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Data Set	WORK.IMPUTE_ABS
2	1	NN1218-4131	Dependent Variable	eotVisitAbs
3	1	NN1218-4131	Covariance Structure	Diagonal
4	1	NN1218-4131	Estimation Method	REML
5	1	NN1218-4131	Residual Variance Method	Profile
6	1	NN1218-4131	Fixed Effects SE Method	Model-Based
7	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=P9SMPGMU Parameter=Mean SMPG (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
8	1	NN1218-4131	Data Set	WORK.IMPUTE_ABS
9	1	NN1218-4131	Dependent Variable	eotVisitAbs
10	1	NN1218-4131	Covariance Structure	Diagonal
11	1	NN1218-4131	Estimation Method	REML
12	1	NN1218-4131	Residual Variance Method	Profile
13	1	NN1218-4131	Fixed Effects SE Method	Model-Based
14	1	NN1218-4131	Degrees of Freedom Method	Residual

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Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Class Level Information

Parameter Code=P9PSMPGM Parameter=Mean SMPG (mmol/L)

O b s		I n s		D		S		C		L		V		m	
p		u		t		a		t		i		a		l	
e		e		s		e		l		e		u		g	
t		h													
1	1	NN1218-4131	TRTPN	3	2	3	4							5	
2	1	NN1218-4131	REGION1	4	ASIA (EXCLUDING JAPAN)	EUROPE	JAPAN	NORTH AMERICA						49	
3	1	NN1218-4131	BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	CARBOHYDRATE COUNTING (FLEXIBLE)	BOLUS INSULI	85							

Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Class Level Information

Parameter Code=P9SMPGMU Parameter=Mean SMPG (mg/dL)

Ob- s	—	Input on ID	STUDY ID	Class s	Le- vel s	Val- ues	mi- n le- gt h
4	1	NN1218-4131	TRTPN		3 2 3 4		5
5	1	NN1218-4131	REGION1		4 ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA		49
6	1	NN1218-4131	BOLAD1		2 BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULI		85

Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Dimensions

Parameter Code=P9PSMPGM Parameter=Mean SMPG (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Covariance Parameters	1
2	1	NN1218-4131	Columns in X	10
3	1	NN1218-4131	Columns in Z	0
4	1	NN1218-4131	Subjects	1
5	1	NN1218-4131	Max Obs per Subject	989

Parameter Code=P9SMPGMU Parameter=Mean SMPG (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
6	1	NN1218-4131	Covariance Parameters	1
7	1	NN1218-4131	Columns in X	10
8	1	NN1218-4131	Columns in Z	0
9	1	NN1218-4131	Subjects	1
10	1	NN1218-4131	Max Obs per Subject	989

Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Number of Observations

Parameter Code=P9PSMPGM Parameter=Mean SMPG (mmol/L)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
1	1	NN1218-4131	Number of Observations Read	989	989	989	989	989
2	1	NN1218-4131	Number of Observations Used	989	989	989	989	989
3	1	NN1218-4131	Number of Observations Not Used	0	989	989	989	989

Parameter Code=P9SMPGMU Parameter=Mean SMPG (mg/dL)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
4	1	NN1218-4131	Number of Observations Read	989	989	989	989	989
5	1	NN1218-4131	Number of Observations Used	989	989	989	989	989
6	1	NN1218-4131	Number of Observations Not Used	0	989	989	989	989

Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Covariance Parameter Estimates

Parameter Code=P9PSMPGM Parameter=Mean SMPG (mmol/L)

Obs	_Imputation_	STUDYID	CovParm	Estimate
1	1	NN1218-4131	Residual	2.3247

Parameter Code=P9SMPGMU Parameter=Mean SMPG (mg/dL)

Obs	_Imputation_	STUDYID	CovParm	Estimate
20001	1	NN1218-4131	Residual	754.88

Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Fit Statistics

Parameter Code=P9PSMPGM Parameter=Mean SMPG (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	-2 Res Log Likelihood	3657.1
2	1	NN1218-4131	AIC (Smaller is Better)	3659.1
3	1	NN1218-4131	AICC (Smaller is Better)	3659.1
4	1	NN1218-4131	BIC (Smaller is Better)	3664.0

Parameter Code=P9SMPGMU Parameter=Mean SMPG (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
5	1	NN1218-4131	-2 Res Log Likelihood	9336.0
6	1	NN1218-4131	AIC (Smaller is Better)	9338.0
7	1	NN1218-4131	AICC (Smaller is Better)	9338.0
8	1	NN1218-4131	BIC (Smaller is Better)	9342.9

Fast-acting insulin aspart
NN1218-4131

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Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Solution for Fixed Effects

Parameter Code=P9PSMPGM Parameter=Mean SMPG (mmol/L)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1
1	1	NN1218-4131	TRTPN	2		
2	1	NN1218-4131	TRTPN	3		
3	1	NN1218-4131	TRTPN	4		
4	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)	
5	1	NN1218-4131	REGION1	—	EUROPE	
6	1	NN1218-4131	REGION1	—	JAPAN	
7	1	NN1218-4131	REGION1	—	NORTH AMERICA	
8	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)
9	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY
10	1	NN1218-4131	BASE	—		

Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	6.2077	0.2770	981	22.41	<.0001	0.05	5.6642	6.7512
2	6.2964	0.2792	981	22.55	<.0001	0.05	5.7485	6.8442
3	6.1087	0.2755	981	22.18	<.0001	0.05	5.5681	6.6493
4	-0.3204	0.1786	981	-1.79	0.0732	0.05	-0.6709	0.03018
5	-0.4521	0.1271	981	-3.56	0.0004	0.05	-0.7016	-0.2027
6	0.2782	0.1408	981	1.98	0.0484	0.05	0.001906	0.5545
7	0
8	-0.4246	0.1097	981	-3.87	0.0001	0.05	-0.6398	-0.2093
9	0
10	0.3081	0.02786	981	11.06	<.0001	0.05	0.2534	0.3627

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Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Solution for Fixed Effects

Parameter Code=P9SMPGMU Parameter=Mean SMPG (mg/dL)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
11	1	NN1218-4131	TRTPN	2				
12	1	NN1218-4131	TRTPN	3				
13	1	NN1218-4131	TRTPN	4				
14	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
15	1	NN1218-4131	REGION1	—	EUROPE			
16	1	NN1218-4131	REGION1	—	JAPAN			
17	1	NN1218-4131	REGION1	—	NORTH AMERICA			
18	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
19	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
20	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
11	111.86	4.9911	981	22.41	<.0001	0.05	102.07	121.66
12	113.46	5.0304	981	22.55	<.0001	0.05	103.59	123.33
13	110.08	4.9640	981	22.18	<.0001	0.05	100.34	119.82
14	-5.7727	3.2188	981	-1.79	0.0732	0.05	-12.0892	0.5438
15	-8.1475	2.2908	981	-3.56	0.0004	0.05	-12.6429	-3.6521
16	5.0134	2.5372	981	1.98	0.0484	0.05	0.03435	9.9924
17	0
18	-7.6510	1.9767	981	-3.87	0.0001	0.05	-11.5300	-3.7720
19	0
20	0.3081	0.02786	981	11.06	<.0001	0.05	0.2534	0.3627

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Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Least Squares Means

Obs	_Imputation_	PARAMCD	PARAM	STUDYID	Effect	TRTPN	Margins
1	1	P9PSMPGM	Mean SMPG (mmol/L)	NN1218-4131	TRTPN	2	WORK.IMPUTE
20001	1	P9SMPGMU	Mean SMPG (mg/dL)	NN1218-4131	TRTPN	2	WORK.IMPUTE
40001	1	P9PSMPGM	Mean SMPG (mmol/L)	NN1218-4131	TRTPN	3	WORK.IMPUTE
60001	1	P9SMPGMU	Mean SMPG (mg/dL)	NN1218-4131	TRTPN	3	WORK.IMPUTE
80001	1	P9PSMPGM	Mean SMPG (mmol/L)	NN1218-4131	TRTPN	4	WORK.IMPUTE
100001	1	P9SMPGMU	Mean SMPG (mg/dL)	NN1218-4131	TRTPN	4	WORK.IMPUTE

Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	-0.2801	0.08418	981	-3.33	0.0009	0.05	-0.4453	-0.1149
20001	-5.0478	1.5170	981	-3.33	0.0009	0.05	-8.0247	-2.0709
40001	-0.1915	0.08390	981	-2.28	0.0227	0.05	-0.3561	-0.02681
60001	-3.4501	1.5119	981	-2.28	0.0227	0.05	-6.4171	-0.4831
80001	-0.3791	0.08416	981	-4.50	<.0001	0.05	-0.5443	-0.2140
100001	-6.8315	1.5165	981	-4.50	<.0001	0.05	-9.8075	-3.8555

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Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Least Squares Means Estimate

Parameter Code=P9PSMPGM Parameter=Mean SMPG (mmol/L)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
1	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
20001	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	WORK.IMPUTE	0.09899	0.1191	981	0.83	0.4062	0.05	-0.1348	0.3328
20001	WORK.IMPUTE	0.1876	0.1189	981	1.58	0.1148	0.05	-0.04566	0.4210

Parameter Code=P9SMPGMU Parameter=Mean SMPG (mg/dL)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
40001	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
60001	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
40001	WORK.IMPUTE	1.7837	2.1466	981	0.83	0.4062	0.05	-2.4287	5.9962
60001	WORK.IMPUTE	3.3814	2.1424	981	1.58	0.1148	0.05	-0.8228	7.5856

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Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9PSMPGM Parameter=Mean SMPG (mmol/L) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000373	0.007061	0.007433	7.96E6	0.052775	0.050130	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	8.539121	0.086217	8.370139	8.708103	7.96E6	8.467635	8.621442

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	99.04	<.0001

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Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9SMPGMU Parameter=Mean SMPG (mg/dL) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.120995	2.292760	2.413761	7.96E6	0.052775	0.050130	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	153.874966	1.553628	150.8299	156.9200	7.96E6	152.586776	155.358381

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	99.04	<.0001

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Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9PSMPGM Parameter=Mean SMPG (mmol/L) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000292	0.007014	0.007306	1.25E7	0.041675	0.040008	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	8.623993	0.085475	8.456464	8.791521	1.25E7	8.556272	8.689231

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	100.89	<.0001

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Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9SMPGMU Parameter=Mean SMPG (mg/dL) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.094910	2.277494	2.372408	1.25E7	0.041675	0.040008	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	155.404348	1.540262	152.3855	158.4232	1.25E7	154.184030	156.579939

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	100.89	<.0001

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Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9PSMPGM Parameter=Mean SMPG (mmol/L) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000419	0.007057	0.007475	6.38E6	0.059329	0.056007	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	8.473913	0.086460	8.304455	8.643371	6.38E6	8.399186	8.563793

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	98.01	<.0001

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Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9SMPGMU Parameter=Mean SMPG (mg/dL) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.135943	2.291434	2.427383	6.38E6	0.059329	0.056007	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	152.699912	1.558006	149.6463	155.7535	6.38E6	151.353329	154.319548

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	98.01	<.0001

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Model Information

Parameter Code=P9SMPGMU Planned Treatment for Period 30 (N)=2

Obs	PARAM	Description	Value
1	Mean SMPG (mg/dL)	Data Set	WORK.ENDPOINT_PARAM
2	Mean SMPG (mg/dL)	Method	Monotone-data_MCMC
3	Mean SMPG (mg/dL)	Multiple Imputation Chain	Multiple Chains
4	Mean SMPG (mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
5	Mean SMPG (mg/dL)	Start	Starting Value
6	Mean SMPG (mg/dL)	Prior	Jeffreys
7	Mean SMPG (mg/dL)	Number of Imputations	20000
8	Mean SMPG (mg/dL)	Number of Burn-in Iterations	200
9	Mean SMPG (mg/dL)	Seed for random number generator	1234

Parameter Code=P9SMPGMU Planned Treatment for Period 30 (N)=3

Obs	PARAM	Description	Value
10	Mean SMPG (mg/dL)	Data Set	WORK.ENDPOINT_PARAM
11	Mean SMPG (mg/dL)	Method	Monotone-data_MCMC
12	Mean SMPG (mg/dL)	Multiple Imputation Chain	Multiple Chains
13	Mean SMPG (mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
14	Mean SMPG (mg/dL)	Start	Starting Value
15	Mean SMPG (mg/dL)	Prior	Jeffreys
16	Mean SMPG (mg/dL)	Number of Imputations	20000
17	Mean SMPG (mg/dL)	Number of Burn-in Iterations	200
18	Mean SMPG (mg/dL)	Seed for random number generator	1280580680

Fast-acting insulin aspart
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Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment
- full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=P9SMPGMU Planned Treatment for Period 30 (N)=4

Obs	PARAM	Description	Value
19	Mean SMPG (mg/dL)	Data Set	WORK.ENDPOINT_PARAM
20	Mean SMPG (mg/dL)	Method	Monotone-data_MCMC
21	Mean SMPG (mg/dL)	Multiple Imputation Chain	Multiple Chains
22	Mean SMPG (mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
23	Mean SMPG (mg/dL)	Start	Starting Value
24	Mean SMPG (mg/dL)	Prior	Jeffreys
25	Mean SMPG (mg/dL)	Number of Imputations	20000
26	Mean SMPG (mg/dL)	Number of Burn-in Iterations	200
27	Mean SMPG (mg/dL)	Seed for random number generator	663706498

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Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC
Missing data pattern

Parameter Code=P9SMPGMU Planned Treatment for Period 30 (N)=2

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
1	Mean SMPG (mg/dL)	1	X	X	X	294	89.36	158.128181	-3.785678	-4.392977
2	Mean SMPG (mg/dL)	2	X	X	O	9	2.74	152.993132	-0.382600	.
3	Mean SMPG (mg/dL)	3	X	.	X	16	4.86	185.610502	.	-29.984869
4	Mean SMPG (mg/dL)	4	X	O	O	10	3.04	151.031674	.	.

Parameter Code=P9SMPGMU Planned Treatment for Period 30 (N)=3

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
5	Mean SMPG (mg/dL)	1	X	X	X	302	91.24	161.343079	-4.873679	-5.279685
6	Mean SMPG (mg/dL)	2	X	X	O	12	3.63	160.718113	6.819953	.
7	Mean SMPG (mg/dL)	3	X	.	X	12	3.63	138.365007	.	12.877421
8	Mean SMPG (mg/dL)	4	X	O	O	5	1.51	164.167725	.	.

Parameter Code=P9SMPGMU Planned Treatment for Period 30 (N)=4

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
9	Mean SMPG (mg/dL)	1	X	X	X	295	89.67	158.727953	0.217769	-6.063895
10	Mean SMPG (mg/dL)	2	X	X	O	12	3.65	144.712319	6.332085	.
11	Mean SMPG (mg/dL)	3	X	.	X	11	3.34	158.080196	.	-8.059039
12	Mean SMPG (mg/dL)	4	X	O	O	11	3.34	157.271521	.	.

Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9SMPGMU Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM	Description	Value
1	1	Mean SMPG (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	Mean SMPG (mg/dL)	Method	Monotone
3	1	Mean SMPG (mg/dL)	Number of Imputations	1
4	1	Mean SMPG (mg/dL)	Seed for random number generator	4321

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Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment
- full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=P9SMPGMU Planned Treatment for Period 30 (N)=2

O b s	I m p u t a t i o n _	P A R A M _	G r o u p	R E G I O N 1	B O L A D 1	B L A S E	v i s i t t 2	v i s i t t 3	F r e q	P e r c e n t	B A S E	v i s i t t 2	v i s i t t 3
1	1	Mean SMPG (mg/dL)	1	X	X	X	X	X	310	94.22	159.546624	-5.125468	-5.713848
2	1	Mean SMPG (mg/dL)	2	X	X	X	X	.	9	2.74	152.993132	-0.382600	.
3	1	Mean SMPG (mg/dL)	3	X	X	X	.	.	10	3.04	151.031674	.	.

Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression Regression Information

Parameter Code=P9SMPGMU Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2200

	Observed	Predicted	Residuals	Standardized Residuals	Cook's Distance	Leverage	Observed vs Predicted
1 1 Mean SMPG (mg/dL) Intercept	-0.01033	0.022125					
2 1 Mean SMPG (mg/dL) REGION1 ASIA (EXCLUDING JAPAN)	-0.24312	-0.212520					
3 1 Mean SMPG (mg/dL) REGION1 EUROPE	-0.03161	-0.162460					
4 1 Mean SMPG (mg/dL) REGION1 JAPAN	0.11184	0.093731					
5 1 Mean SMPG (mg/dL) BOLAD1 BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.11391	-0.160507					
6 1 Mean SMPG (mg/dL) BASE	-0.57946	-0.621005					

Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression Regression Information

Parameter Code=P9SMPGMU Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

Output	Parameter	Effect	REG1	BOLUS	Observation	
7 1	Mean	SMPG (mg/dL)	Intercept			0.02911
8 1	Mean	SMPG (mg/dL)	REGION1 ASIA (EXCLUDING JAPAN)			-0.01294
9 1	Mean	SMPG (mg/dL)	REGION1 EUROPE			-0.12373
10 1	Mean	SMPG (mg/dL)	REGION1 JAPAN			0.10625
11 1	Mean	SMPG (mg/dL)	BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.08248
12 1	Mean	SMPG (mg/dL)	BASE			-0.32071
13 1	Mean	SMPG (mg/dL)	visit2200			0.48063

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Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment
- full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9SMPGMU Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM	Description	Value
1	1	Mean SMPG (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	Mean SMPG (mg/dL)	Method	Monotone
3	1	Mean SMPG (mg/dL)	Number of Imputations	1
4	1	Mean SMPG (mg/dL)	Seed for random number generator	4322

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Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment
- full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=P9SMPGMU Planned Treatment for Period 30 (N)=3

O b s	I m p u t a t i o n _	P A R A M _	G r o u p	R E G I S T E R E D I T I O N _					F r e q	P e r c e n t	B A S E	v i s i t e s	v i s i t e s
				M	M	M	M	M					
1	1	Mean SMPG (mg/dL)	1	X	X	X	X	X	314	94.86	160.464937	-4.549172	-4.585782
2	1	Mean SMPG (mg/dL)	2	X	X	X	X	.	12	3.63	160.718113	6.819953	.
3	1	Mean SMPG (mg/dL)	3	X	X	X	.	.	5	1.51	164.167725	.	.

Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression Regression Information

Parameter Code=P9SMPGMU Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2200

Output		Parameter		Region	Baseline	Observed	Mean	
Line	Item	Unit	Effect	Estimate	Estimate	Estimate	Estimate	
1	Mean	SMPG (mg/dL)	Intercept			0.01280	0.112542	
2	Mean	SMPG (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)		-0.09199	0.042414	
3	Mean	SMPG (mg/dL)	REGION1	EUROPE		-0.13522	-0.135491	
4	Mean	SMPG (mg/dL)	REGION1	JAPAN		0.20572	0.114047	
5	Mean	SMPG (mg/dL)	BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)			-0.14333	-0.116188
6	Mean	SMPG (mg/dL)	BASE			-0.49122	-0.536161	

Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression Regression Information

Parameter Code=P9SMPGMU Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

Obs	Time point	Parameter	Effect	Region	Bolus	Ob	Val	Intercept
7	1	Mean SMPG (mg/dL)	Intercept				0.00831	-0.048644
8	1	Mean SMPG (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)			-0.06188	-0.151362
9	1	Mean SMPG (mg/dL)	REGION1	EUROPE			-0.06162	-0.040390
10	1	Mean SMPG (mg/dL)	REGION1	JAPAN			0.06180	0.059984
11	1	Mean SMPG (mg/dL)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.05775	-0.070783
12	1	Mean SMPG (mg/dL)	BASE				-0.33677	-0.277998
13	1	Mean SMPG (mg/dL)	visit2200				0.48444	0.484426

Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9SMPGMU Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM	Description	Value
1	1	Mean SMPG (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	Mean SMPG (mg/dL)	Method	Monotone
3	1	Mean SMPG (mg/dL)	Number of Imputations	1
4	1	Mean SMPG (mg/dL)	Seed for random number generator	4323

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Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment
- full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=P9SMPGMU Planned Treatment for Period 30 (N)=4

O b s	I m p u t a t i o n _	P A R A M _	G r o u p	R E G I O N 1	B O L A D 1	B L A S E	v i s i t t 2	v i s i t t 3	F r e q	P e r c e n t	B A S E	v i s i t t 2	v i s i t t 3
1	1	Mean SMPG (mg/dL)	1	X	X	X	X	X	306	93.01	158.704668	0.539645	-6.135616
2	1	Mean SMPG (mg/dL)	2	X	X	X	X	.	12	3.65	144.712319	6.332085	.
3	1	Mean SMPG (mg/dL)	3	X	X	X	.	.	11	3.34	157.271521	.	.

Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression Regression Information

Parameter Code=P9SMPGMU Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2200

		O b s _		P A R A M		E f f e c t		R E G I O N		B O L U S		O b s _		I	
1	1	Mean	SMPG	(mg/dL)	Intercept								0.03292	-0.011802	
2	1	Mean	SMPG	(mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)							-0.03941	0.012046	
3	1	Mean	SMPG	(mg/dL)	REGION1	EUROPE							-0.20794	-0.319966	
4	1	Mean	SMPG	(mg/dL)	REGION1	JAPAN							0.17341	0.212241	
5	1	Mean	SMPG	(mg/dL)	BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)							-0.14146	-0.145328	
6	1	Mean	SMPG	(mg/dL)	BASE								-0.58213	-0.663604	

Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression Regression Information

Parameter Code=P9SMPGMU Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

O o b s _	P A R A M	E f f e c t	R E G I O N 1	B O L A D 1	O b s V a l	\bar{I}
7 1	Mean SMPG (mg/dL)	Intercept			0.02531	-0.000279
8 1	Mean SMPG (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)		-0.01133	-0.018915
9 1	Mean SMPG (mg/dL)	REGION1	EUROPE		-0.15317	-0.198134
10 1	Mean SMPG (mg/dL)	REGION1	JAPAN		0.19803	0.246675
11 1	Mean SMPG (mg/dL)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.03665	0.007525
12 1	Mean SMPG (mg/dL)	BASE			-0.49198	-0.497061
13 1	Mean SMPG (mg/dL)	visit2200			0.33372	0.389399

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Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=P9PSMPGM Planned Treatment for Period 30 (N)=2

Obs	PARAM	Description	Value
1	Mean SMPG (mmol/L)	Data Set	WORK.ENDPOINT_PARAM
2	Mean SMPG (mmol/L)	Method	Monotone-data_MCMC
3	Mean SMPG (mmol/L)	Multiple Imputation Chain	Multiple Chains
4	Mean SMPG (mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
5	Mean SMPG (mmol/L)	Start	Starting Value
6	Mean SMPG (mmol/L)	Prior	Jeffreys
7	Mean SMPG (mmol/L)	Number of Imputations	20000
8	Mean SMPG (mmol/L)	Number of Burn-in Iterations	200
9	Mean SMPG (mmol/L)	Seed for random number generator	1234

Parameter Code=P9PSMPGM Planned Treatment for Period 30 (N)=3

Obs	PARAM	Description	Value
10	Mean SMPG (mmol/L)	Data Set	WORK.ENDPOINT_PARAM
11	Mean SMPG (mmol/L)	Method	Monotone-data_MCMC
12	Mean SMPG (mmol/L)	Multiple Imputation Chain	Multiple Chains
13	Mean SMPG (mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
14	Mean SMPG (mmol/L)	Start	Starting Value
15	Mean SMPG (mmol/L)	Prior	Jeffreys
16	Mean SMPG (mmol/L)	Number of Imputations	20000
17	Mean SMPG (mmol/L)	Number of Burn-in Iterations	200
18	Mean SMPG (mmol/L)	Seed for random number generator	1280580680

Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=P9PSMPGM Planned Treatment for Period 30 (N)=4

Obs	PARAM	Description	Value
19	Mean SMPG (mmol/L)	Data Set	WORK.ENDPOINT_PARAM
20	Mean SMPG (mmol/L)	Method	Monotone-data_MCMC
21	Mean SMPG (mmol/L)	Multiple Imputation Chain	Multiple Chains
22	Mean SMPG (mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
23	Mean SMPG (mmol/L)	Start	Starting Value
24	Mean SMPG (mmol/L)	Prior	Jeffreys
25	Mean SMPG (mmol/L)	Number of Imputations	20000
26	Mean SMPG (mmol/L)	Number of Burn-in Iterations	200
27	Mean SMPG (mmol/L)	Seed for random number generator	663706498

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Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC
Missing data pattern

Parameter Code=P9PSMPGM Planned Treatment for Period 30 (N)=2

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
1	Mean SMPG (mmol/L)	1	X	X	X	294	89.36	8.775149	-0.210082	-0.243783
2	Mean SMPG (mmol/L)	2	X	X	O	9	2.74	8.490185	-0.021232	.
3	Mean SMPG (mmol/L)	3	X	.	X	16	4.86	10.300250	.	-1.663977
4	Mean SMPG (mmol/L)	4	X	O	O	10	3.04	8.381336	.	.

Parameter Code=P9PSMPGM Planned Treatment for Period 30 (N)=3

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
5	Mean SMPG (mmol/L)	1	X	X	X	302	91.24	8.953556	-0.270459	-0.292990
6	Mean SMPG (mmol/L)	2	X	X	O	12	3.63	8.918874	0.378466	.
7	Mean SMPG (mmol/L)	3	X	.	X	12	3.63	7.678413	.	0.714618
8	Mean SMPG (mmol/L)	4	X	O	O	5	1.51	9.110307	.	.

Parameter Code=P9PSMPGM Planned Treatment for Period 30 (N)=4

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
9	Mean SMPG (mmol/L)	1	X	X	X	295	89.67	8.808432	0.012085	-0.336509
10	Mean SMPG (mmol/L)	2	X	X	O	12	3.65	8.030650	0.351392	.
11	Mean SMPG (mmol/L)	3	X	.	X	11	3.34	8.772486	.	-0.447227
12	Mean SMPG (mmol/L)	4	X	O	O	11	3.34	8.727609	.	.

Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PSMPGM Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM	Description	Value
1	1	Mean SMPG (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	Mean SMPG (mmol/L)	Method	Monotone
3	1	Mean SMPG (mmol/L)	Number of Imputations	1
4	1	Mean SMPG (mmol/L)	Seed for random number generator	4321

Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression Missing Data Pattern

Parameter Code=P9PSMPGM Planned Treatment for Period 30 (N)=2

Obs	Inputation	PARAM	Group	REGIONS					Frequency	Percentage	BASIS	visits	visits
				REGION 1	REGION 2	REGION 3	REGION 4	REGION 5					
1	1	Mean SMPG (mmol/L)	1	X	X	X	X	X	310	94.22	8.853864	-0.284432	-0.317084
2	1	Mean SMPG (mmol/L)	2	X	X	X	X	.	9	2.74	8.490185	-0.021232	.
3	1	Mean SMPG (mmol/L)	3	X	X	X	.	.	10	3.04	8.381336	.	.

Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression Regression Information

Parameter Code=P9PSMPGM Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2200

	O	P	E	R	B	O	
I	b	A	f	E	O	b	
m	n	R	e	G	L	s	
p	s	A	c	I	A	V	
u	_	M	t	N	D	a	
t				1	1	l	I
a							
t							
i							
1	1	Mean	SMPG (mmol/L)	Intercept		-0.01033	0.022125
2	1	Mean	SMPG (mmol/L)	REGION1 ASIA (EXCLUDING JAPAN)		-0.24312	-0.212520
3	1	Mean	SMPG (mmol/L)	REGION1 EUROPE		-0.03161	-0.162460
4	1	Mean	SMPG (mmol/L)	REGION1 JAPAN		0.11184	0.093731
5	1	Mean	SMPG (mmol/L)	BOLAD1 BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.11391	-0.160507
6	1	Mean	SMPG (mmol/L)	BASE		-0.57946	-0.621005

Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression Regression Information

Parameter Code=P9PSMPGM Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

Output variable	Parameter	Effect	Regression coefficient	BOLUS	Observation	
7	1	Mean	SMPG (mmol/L)	Intercept		0.02911
8	1	Mean	SMPG (mmol/L)	REGION1 ASIA (EXCLUDING JAPAN)		-0.01294
9	1	Mean	SMPG (mmol/L)	REGION1 EUROPE		-0.12373
10	1	Mean	SMPG (mmol/L)	REGION1 JAPAN		0.10625
11	1	Mean	SMPG (mmol/L)	BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.08248
12	1	Mean	SMPG (mmol/L)	BASE		-0.32071
13	1	Mean	SMPG (mmol/L)	visit2200		0.48063

Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PSMPGM Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM	Description	Value
1	1	Mean SMPG (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	Mean SMPG (mmol/L)	Method	Monotone
3	1	Mean SMPG (mmol/L)	Number of Imputations	1
4	1	Mean SMPG (mmol/L)	Seed for random number generator	4322

Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression Missing Data Pattern

Parameter Code=P9PSMPGM Planned Treatment for Period 30 (N)=3

Obs	Impu- tation	PAR AM	Group	REGIONS			VISIT23		Freq	Percent	BASIS	VISIT23	VISIT23	VISIT23
				REGIONS	REGIONS	REGIONS	REGIONS	REGIONS						
1	1	Mean SMPG (mmol/L)	1	X	X	X	X	X	314	94.86	8.904824	-0.252451	-0.254483	
2	1	Mean SMPG (mmol/L)	2	X	X	X	X	.	12	3.63	8.918874	0.378466	.	
3	1	Mean SMPG (mmol/L)	3	X	X	X	.	.	5	1.51	9.110307	.	.	

Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression Regression Information

Parameter Code=P9PSMPGM Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2200

O b s _		P A R A M		E f f e c t		R E G I O N		B O L U S		O b s _		I	
1	1	Mean	SMPG	(mmol/L)	Intercept						0.01280		0.112542
2	1	Mean	SMPG	(mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)					-0.09199		0.042414
3	1	Mean	SMPG	(mmol/L)	REGION1	EUROPE					-0.13522		-0.135491
4	1	Mean	SMPG	(mmol/L)	REGION1	JAPAN					0.20572		0.114047
5	1	Mean	SMPG	(mmol/L)	BOLAD1				BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.14333		-0.116188
6	1	Mean	SMPG	(mmol/L)	BASE						-0.49122		-0.536161

Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression Regression Information

Parameter Code=P9PSMPGM Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

Output variable	Parameter	Effect	Regression	BOLUS	Observation	
			Estimate	Estimate	Estimate	
7 1 Mean	SMPG (mmol/L)	Intercept			0.00831	-0.048644
8 1 Mean	SMPG (mmol/L)	REGION1 ASIA (EXCLUDING JAPAN)			-0.06188	-0.151362
9 1 Mean	SMPG (mmol/L)	REGION1 EUROPE			-0.06162	-0.040390
10 1 Mean	SMPG (mmol/L)	REGION1 JAPAN			0.06180	0.059984
11 1 Mean	SMPG (mmol/L)	BOLAD1 BOLUS INSULIN ALGORITHM (SLIDING SCALE)			-0.05775	-0.070783
12 1 Mean	SMPG (mmol/L)	BASE			-0.33677	-0.277998
13 1 Mean	SMPG (mmol/L)	visit2200			0.48444	0.484426

Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PSMPGM Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM	Description	Value
1	1	Mean SMPG (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	Mean SMPG (mmol/L)	Method	Monotone
3	1	Mean SMPG (mmol/L)	Number of Imputations	1
4	1	Mean SMPG (mmol/L)	Seed for random number generator	4323

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NN1218-4131

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Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment
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The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=P9PSMPGM Planned Treatment for Period 30 (N)=4

O b s	I m p u t a t i o n _					G r o u p	R E G I O N 1					F r e q	P e r c e n t	B A S E	v i s i t 2	v i s i t 3
							\bar{M}	\bar{M}	\bar{M}	\bar{M}	\bar{M}					
1	1	Mean	SMPG	(mmol/L)	1	X	X	X	X	X	306	93.01	8.807140	0.029947	-0.340489	
2	1	Mean	SMPG	(mmol/L)	2	X	X	X	X	.	12	3.65	8.030650	0.351392	.	
3	1	Mean	SMPG	(mmol/L)	3	X	X	X	.	.	11	3.34	8.727609	.	.	

Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression Regression Information

Parameter Code=P9PSMPGM Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2200

O b s _		P A R A M	E f f e c t	R E G I O N	B O L U S	O b s	\bar{I}
1	1	Mean SMPG (mmol/L)	Intercept			0.03292	-0.011802
2	1	Mean SMPG (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)		-0.03941	0.012046
3	1	Mean SMPG (mmol/L)	REGION1	EUROPE		-0.20794	-0.319966
4	1	Mean SMPG (mmol/L)	REGION1	JAPAN		0.17341	0.212241
5	1	Mean SMPG (mmol/L)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.14146	-0.145328
6	1	Mean SMPG (mmol/L)	BASE			-0.58213	-0.663604

Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression Regression Information

Parameter Code=P9PSMPGM Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

Output variable	Parameter	Effect	Regression coefficient	Observation	Observed value	Target
7 1 Mean	SMPG (mmol/L)	Intercept			0.02531	-0.000279
8 1 Mean	SMPG (mmol/L)	REGION1 ASIA (EXCLUDING JAPAN)			-0.01133	-0.018915
9 1 Mean	SMPG (mmol/L)	REGION1 EUROPE			-0.15317	-0.198134
10 1 Mean	SMPG (mmol/L)	REGION1 JAPAN			0.19803	0.246675
11 1 Mean	SMPG (mmol/L)	BOLAD1 BOLUS INSULIN ALGORITHM (SLIDING SCALE)			-0.03665	0.007525
12 1 Mean	SMPG (mmol/L)	BASE			-0.49198	-0.497061
13 1 Mean	SMPG (mmol/L)	visit2200			0.33372	0.389399

Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Model Information

Parameter Code=P9PSMPGM Parameter=Mean SMPG (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Data Set	WORK.IMPUTE
2	1	NN1218-4131	Dependent Variable	eotVisit
3	1	NN1218-4131	Covariance Structure	Diagonal
4	1	NN1218-4131	Estimation Method	REML
5	1	NN1218-4131	Residual Variance Method	Profile
6	1	NN1218-4131	Fixed Effects SE Method	Model-Based
7	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=P9SMPGMU Parameter=Mean SMPG (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
8	1	NN1218-4131	Data Set	WORK.IMPUTE
9	1	NN1218-4131	Dependent Variable	eotVisit
10	1	NN1218-4131	Covariance Structure	Diagonal
11	1	NN1218-4131	Estimation Method	REML
12	1	NN1218-4131	Residual Variance Method	Profile
13	1	NN1218-4131	Fixed Effects SE Method	Model-Based
14	1	NN1218-4131	Degrees of Freedom Method	Residual

Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Class Level Information

Parameter Code=P9PSMPGM Parameter=Mean SMPG (mmol/L)

Ob- s	—	Input ID	STUDY	Class	Level	Values	min
1	1	NN1218-4131	TRTPN		3 2 3 4		5
2	1	NN1218-4131	REGION1		4 ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA		49
3	1	NN1218-4131	BOLAD1		2 BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULI		85

Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Class Level Information

Parameter Code=P9SMPGMU Parameter=Mean SMPG (mg/dL)

Ob- s	—	Input ID	STUDY	Class	Level	Values	Unit
4	1	NN1218-4131	TRTPN		3 2 3 4		5
5	1	NN1218-4131	REGION1		4 ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA		49
6	1	NN1218-4131	BOLAD1		2 BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULI		85

Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Dimensions

Parameter Code=P9PSMPGM Parameter=Mean SMPG (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Covariance Parameters	1
2	1	NN1218-4131	Columns in X	10
3	1	NN1218-4131	Columns in Z	0
4	1	NN1218-4131	Subjects	1
5	1	NN1218-4131	Max Obs per Subject	989

Parameter Code=P9SMPGMU Parameter=Mean SMPG (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
6	1	NN1218-4131	Covariance Parameters	1
7	1	NN1218-4131	Columns in X	10
8	1	NN1218-4131	Columns in Z	0
9	1	NN1218-4131	Subjects	1
10	1	NN1218-4131	Max Obs per Subject	989

Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Number of Observations

Parameter Code=P9PSMPGM Parameter=Mean SMPG (mmol/L)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
1	1	NN1218-4131	Number of Observations Read	989	989	989	989	989
2	1	NN1218-4131	Number of Observations Used	989	989	989	989	989
3	1	NN1218-4131	Number of Observations Not Used	0	989	989	989	989

Parameter Code=P9SMPGMU Parameter=Mean SMPG (mg/dL)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
4	1	NN1218-4131	Number of Observations Read	989	989	989	989	989
5	1	NN1218-4131	Number of Observations Used	989	989	989	989	989
6	1	NN1218-4131	Number of Observations Not Used	0	989	989	989	989

Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Covariance Parameter Estimates

Parameter Code=P9PSMPGM Parameter=Mean SMPG (mmol/L)

Obs	_Imputation_	STUDYID	CovParm	Estimate
1	1	NN1218-4131	Residual	2.3452

Parameter Code=P9SMPGMU Parameter=Mean SMPG (mg/dL)

Obs	_Imputation_	STUDYID	CovParm	Estimate
20001	1	NN1218-4131	Residual	761.55

Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Fit Statistics

Parameter Code=P9PSMPGM Parameter=Mean SMPG (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	-2 Res Log Likelihood	3665.7
2	1	NN1218-4131	AIC (Smaller is Better)	3667.7
3	1	NN1218-4131	AICC (Smaller is Better)	3667.7
4	1	NN1218-4131	BIC (Smaller is Better)	3672.6

Parameter Code=P9SMPGMU Parameter=Mean SMPG (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
5	1	NN1218-4131	-2 Res Log Likelihood	9344.6
6	1	NN1218-4131	AIC (Smaller is Better)	9346.6
7	1	NN1218-4131	AICC (Smaller is Better)	9346.6
8	1	NN1218-4131	BIC (Smaller is Better)	9351.5

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Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment
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The Mixed procedure
Solution for Fixed Effects

Parameter Code=P9PSMPGM Parameter=Mean SMPG (mmol/L)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1
1	1	NN1218-4131	TRTPN	2		
2	1	NN1218-4131	TRTPN	3		
3	1	NN1218-4131	TRTPN	4		
4	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)	
5	1	NN1218-4131	REGION1	—	EUROPE	
6	1	NN1218-4131	REGION1	—	JAPAN	
7	1	NN1218-4131	REGION1	—	NORTH AMERICA	
8	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)
9	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY
10	1	NN1218-4131	BASE	—		

Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	6.1815	0.2782	981	22.22	<.0001	0.05	5.6356	6.7275
2	6.2578	0.2804	981	22.32	<.0001	0.05	5.7076	6.8080
3	6.0653	0.2767	981	21.92	<.0001	0.05	5.5223	6.6083
4	-0.2878	0.1794	981	-1.60	0.1090	0.05	-0.6398	0.06430
5	-0.4931	0.1277	981	-3.86	0.0001	0.05	-0.7437	-0.2425
6	0.2130	0.1414	981	1.51	0.1324	0.05	-0.06456	0.4905
7	0
8	-0.4376	0.1102	981	-3.97	<.0001	0.05	-0.6538	-0.2214
9	0
10	-0.6848	0.02799	981	-24.47	<.0001	0.05	-0.7397	-0.6299

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Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment
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The Mixed procedure
Solution for Fixed Effects

Parameter Code=P9SMPGMU Parameter=Mean SMPG (mg/dL)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
11	1	NN1218-4131	TRTPN	2				
12	1	NN1218-4131	TRTPN	3				
13	1	NN1218-4131	TRTPN	4				
14	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
15	1	NN1218-4131	REGION1	—	EUROPE			
16	1	NN1218-4131	REGION1	—	JAPAN			
17	1	NN1218-4131	REGION1	—	NORTH AMERICA			
18	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
19	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
20	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
11	111.39	5.0131	981	22.22	<.0001	0.05	101.55	121.23
12	112.77	5.0526	981	22.32	<.0001	0.05	102.85	122.68
13	109.30	4.9859	981	21.92	<.0001	0.05	99.5122	119.08
14	-5.1857	3.2330	981	-1.60	0.1090	0.05	-11.5300	1.1587
15	-8.8854	2.3009	981	-3.86	0.0001	0.05	-13.4006	-4.3702
16	3.8375	2.5484	981	1.51	0.1324	0.05	-1.1634	8.8385
17	0
18	-7.8856	1.9854	981	-3.97	<.0001	0.05	-11.7817	-3.9895
19	0
20	-0.6848	0.02799	981	-24.47	<.0001	0.05	-0.7397	-0.6299

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Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment
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The Mixed procedure
Least Squares Means

Obs	_Imputation_	PARAMCD	PARAM	STUDYID	Effect	TRTPN	Margins
1	1	P9PSMPGM	Mean SMPG (mmol/L)	NN1218-4131	TRTPN	2	WORK.IMPUTE
2	1	P9PSMPGM	Mean SMPG (mmol/L)	NN1218-4131	TRTPN	3	WORK.IMPUTE
3	1	P9PSMPGM	Mean SMPG (mmol/L)	NN1218-4131	TRTPN	4	WORK.IMPUTE
4	1	P9SMPGMU	Mean SMPG (mg/dL)	NN1218-4131	TRTPN	2	WORK.IMPUTE
5	1	P9SMPGMU	Mean SMPG (mg/dL)	NN1218-4131	TRTPN	3	WORK.IMPUTE
6	1	P9SMPGMU	Mean SMPG (mg/dL)	NN1218-4131	TRTPN	4	WORK.IMPUTE

Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	-0.2766	0.08455	981	-3.27	0.0011	0.05	-0.4425	-0.1107
2	-0.2003	0.08427	981	-2.38	0.0176	0.05	-0.3657	-0.03495
3	-0.3928	0.08453	981	-4.65	<.0001	0.05	-0.5587	-0.2270
4	-4.9841	1.5237	981	-3.27	0.0011	0.05	-7.9741	-1.9941
5	-3.6098	1.5186	981	-2.38	0.0176	0.05	-6.5899	-0.6298
6	-7.0788	1.5232	981	-4.65	<.0001	0.05	-10.0680	-4.0897

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The Mixed procedure
Least Squares Means Estimate

Parameter Code=P9PSMPGM Parameter=Mean SMPG (mmol/L)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
1	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
2	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	WORK.IMPUTE	0.1162	0.1196	981	0.97	0.3315	0.05	-0.1186	0.3510
2	WORK.IMPUTE	0.1925	0.1194	981	1.61	0.1073	0.05	-0.04183	0.4268

Parameter Code=P9SMPGMU Parameter=Mean SMPG (mg/dL)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
3	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
4	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
3	WORK.IMPUTE	2.0948	2.1561	981	0.97	0.3315	0.05	-2.1363	6.3258
4	WORK.IMPUTE	3.4690	2.1518	981	1.61	0.1073	0.05	-0.7537	7.6917

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Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9PSMPGM Parameter=Mean SMPG (mmol/L) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000407	0.007093	0.007500	6.78E6	0.057441	0.054321	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.300143	0.086604	-0.46988	-0.13040	6.78E6	-0.393126	-0.221181

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-3.47	0.0005

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Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9SMPGMU Parameter=Mean SMPG (mg/dL) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.132289	2.303166	2.435462	6.78E6	0.057441	0.054321	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-5.408586	1.560597	-8.46730	-2.34987	6.78E6	-7.084129	-3.985678

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-3.47	0.0005

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Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9PSMPGM Parameter=Mean SMPG (mmol/L) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000313	0.007046	0.007359	1.1E7	0.044477	0.042584	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.212613	0.085784	-0.38075	-0.04448	1.1E7	-0.286751	-0.134369

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-2.48	0.0132

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Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9SMPGMU Parameter=Mean SMPG (mg/dL) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.101752	2.287831	2.389587	1.1E7	0.044477	0.042584	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-3.831288	1.545829	-6.86106	-0.80152	1.1E7	-5.167257	-2.421337

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-2.48	0.0132

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Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9PSMPGM Parameter=Mean SMPG (mmol/L) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000496	0.007089	0.007585	4.68E6	0.069963	0.065389	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.364066	0.087090	-0.53476	-0.19337	4.68E6	-0.452535	-0.274843

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-4.18	<.0001

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Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9SMPGMU Parameter=Mean SMPG (mg/dL) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.161036	2.301834	2.462878	4.68E6	0.069963	0.065389	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-6.560461	1.569356	-9.63634	-3.48458	4.68E6	-8.154677	-4.952673

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-4.18	<.0001

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Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=P9PSMPGM Label=Faster aspart (meal) - NovoRapid (meal) Parameter=Mean SMPG (mmol/L) Study Identifier=NN1218-41

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000914	0.014202	0.015117	5.47E6	0.064385	0.060491	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.063922	0.122951	-0.17706	0.304901	5.47E6	-0.064917	0.185230

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	0.52	0.6031

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Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=P9PSMPGM Label=Faster aspart (post) - NovoRapid (meal) Parameter=Mean SMPG (mmol/L) Study Identifier=NN1218-41

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000798	0.014147	0.014945	7.01E6	0.056410	0.053398	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.151452	0.122248	-0.08815	0.391054	7.01E6	0.043579	0.266407

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	1.24	0.2154

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Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=P9SMPGMU Label=Faster aspart (meal) - NovoRapid (meal) Parameter=Mean SMPG (mg/dL) Study Identifier=NN1218-413

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.296918	4.611820	4.908753	5.47E6	0.064385	0.060491	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	1.151875	2.215570	-3.19056	5.494314	5.47E6	-1.169804	3.337847

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	0.52	0.6031

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Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=P9SMPGMU Label=Faster aspart (post) - NovoRapid (meal) Parameter=Mean SMPG (mg/dL) Study Identifier=NN1218-413

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.259115	4.593670	4.852798	7.01E6	0.056410	0.053398	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	2.729172	2.202907	-1.58845	7.046791	7.01E6	0.785302	4.800662

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	1.24	0.2154

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Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Model Information

Parameter Code=P9PSMPGM Parameter=Mean SMPG (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Data Set	WORK.IMPUTE_ABS
2	1	NN1218-4131	Dependent Variable	eotVisitAbs
3	1	NN1218-4131	Covariance Structure	Diagonal
4	1	NN1218-4131	Estimation Method	REML
5	1	NN1218-4131	Residual Variance Method	Profile
6	1	NN1218-4131	Fixed Effects SE Method	Model-Based
7	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=P9SMPGMU Parameter=Mean SMPG (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
8	1	NN1218-4131	Data Set	WORK.IMPUTE_ABS
9	1	NN1218-4131	Dependent Variable	eotVisitAbs
10	1	NN1218-4131	Covariance Structure	Diagonal
11	1	NN1218-4131	Estimation Method	REML
12	1	NN1218-4131	Residual Variance Method	Profile
13	1	NN1218-4131	Fixed Effects SE Method	Model-Based
14	1	NN1218-4131	Degrees of Freedom Method	Residual

Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Class Level Information

Parameter Code=P9PSMPGM Parameter=Mean SMPG (mmol/L)

Obs	Input	STUDY ID	Class	Level	Values	Unit
1	1	NN1218-4131	TRTPN	3	2 3 4	5
2	1	NN1218-4131	REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA	49
3	1	NN1218-4131	BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULI	85

Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Dimensions

Parameter Code=P9PSMPGM Parameter=Mean SMPG (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Covariance Parameters	1
2	1	NN1218-4131	Columns in X	10
3	1	NN1218-4131	Columns in Z	0
4	1	NN1218-4131	Subjects	1
5	1	NN1218-4131	Max Obs per Subject	989

Parameter Code=P9SMPGMU Parameter=Mean SMPG (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
6	1	NN1218-4131	Covariance Parameters	1
7	1	NN1218-4131	Columns in X	10
8	1	NN1218-4131	Columns in Z	0
9	1	NN1218-4131	Subjects	1
10	1	NN1218-4131	Max Obs per Subject	989

Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Number of Observations

Parameter Code=P9PSMPGM Parameter=Mean SMPG (mmol/L)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
1	1	NN1218-4131	Number of Observations Read	989	989	989	989	989
2	1	NN1218-4131	Number of Observations Used	989	989	989	989	989
3	1	NN1218-4131	Number of Observations Not Used	0	989	989	989	989

Parameter Code=P9SMPGMU Parameter=Mean SMPG (mg/dL)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
4	1	NN1218-4131	Number of Observations Read	989	989	989	989	989
5	1	NN1218-4131	Number of Observations Used	989	989	989	989	989
6	1	NN1218-4131	Number of Observations Not Used	0	989	989	989	989

Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Covariance Parameter Estimates

Parameter Code=P9PSMPGM Parameter=Mean SMPG (mmol/L)

Obs	_Imputation_	STUDYID	CovParm	Estimate
1	1	NN1218-4131	Residual	2.3452

Parameter Code=P9SMPGMU Parameter=Mean SMPG (mg/dL)

Obs	_Imputation_	STUDYID	CovParm	Estimate
20001	1	NN1218-4131	Residual	761.55

Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Fit Statistics

Parameter Code=P9PSMPGM Parameter=Mean SMPG (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	-2 Res Log Likelihood	3665.7
2	1	NN1218-4131	AIC (Smaller is Better)	3667.7
3	1	NN1218-4131	AICC (Smaller is Better)	3667.7
4	1	NN1218-4131	BIC (Smaller is Better)	3672.6

Parameter Code=P9SMPGMU Parameter=Mean SMPG (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
5	1	NN1218-4131	-2 Res Log Likelihood	9344.6
6	1	NN1218-4131	AIC (Smaller is Better)	9346.6
7	1	NN1218-4131	AICC (Smaller is Better)	9346.6
8	1	NN1218-4131	BIC (Smaller is Better)	9351.5

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Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment
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The Mixed procedure
Solution for Fixed Effects

Parameter Code=P9PSMPGM Parameter=Mean SMPG (mmol/L)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1
1	1	NN1218-4131	TRTPN	2		
2	1	NN1218-4131	TRTPN	3		
3	1	NN1218-4131	TRTPN	4		
4	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)	
5	1	NN1218-4131	REGION1	—	EUROPE	
6	1	NN1218-4131	REGION1	—	JAPAN	
7	1	NN1218-4131	REGION1	—	NORTH AMERICA	
8	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)
9	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY
10	1	NN1218-4131	BASE	—		

Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	6.1815	0.2782	981	22.22	<.0001	0.05	5.6356	6.7275
2	6.2578	0.2804	981	22.32	<.0001	0.05	5.7076	6.8080
3	6.0653	0.2767	981	21.92	<.0001	0.05	5.5223	6.6083
4	-0.2878	0.1794	981	-1.60	0.1090	0.05	-0.6398	0.06430
5	-0.4931	0.1277	981	-3.86	0.0001	0.05	-0.7437	-0.2425
6	0.2130	0.1414	981	1.51	0.1324	0.05	-0.06456	0.4905
7	0
8	-0.4376	0.1102	981	-3.97	<.0001	0.05	-0.6538	-0.2214
9	0
10	0.3152	0.02799	981	11.26	<.0001	0.05	0.2603	0.3701

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Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment
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The Mixed procedure
Solution for Fixed Effects

Parameter Code=P9SMPGMU Parameter=Mean SMPG (mg/dL)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
11	1	NN1218-4131	TRTPN	2				
12	1	NN1218-4131	TRTPN	3				
13	1	NN1218-4131	TRTPN	4				
14	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
15	1	NN1218-4131	REGION1	—	EUROPE			
16	1	NN1218-4131	REGION1	—	JAPAN			
17	1	NN1218-4131	REGION1	—	NORTH AMERICA			
18	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
19	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
20	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
11	111.39	5.0131	981	22.22	<.0001	0.05	101.55	121.23
12	112.77	5.0526	981	22.32	<.0001	0.05	102.85	122.68
13	109.30	4.9859	981	21.92	<.0001	0.05	99.5122	119.08
14	-5.1857	3.2330	981	-1.60	0.1090	0.05	-11.5300	1.1587
15	-8.8854	2.3009	981	-3.86	0.0001	0.05	-13.4006	-4.3702
16	3.8375	2.5484	981	1.51	0.1324	0.05	-1.1634	8.8385
17	0
18	-7.8856	1.9854	981	-3.97	<.0001	0.05	-11.7817	-3.9895
19	0
20	0.3152	0.02799	981	11.26	<.0001	0.05	0.2603	0.3701

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Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment
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The Mixed procedure
Least Squares Means

Obs	_Imputation_	PARAMCD	PARAM		STUDYID	Effect	TRTPN	Margins
1	1	P9PSMPGM	Mean	SMPG (mmol/L)	NN1218-4131	TRTPN	2	WORK.IMPUTE
20001	1	P9SMPGMU	Mean	SMPG (mg/dL)	NN1218-4131	TRTPN	2	WORK.IMPUTE
40001	1	P9PSMPGM	Mean	SMPG (mmol/L)	NN1218-4131	TRTPN	3	WORK.IMPUTE
60001	1	P9SMPGMU	Mean	SMPG (mg/dL)	NN1218-4131	TRTPN	3	WORK.IMPUTE
80001	1	P9PSMPGM	Mean	SMPG (mmol/L)	NN1218-4131	TRTPN	4	WORK.IMPUTE
100001	1	P9SMPGMU	Mean	SMPG (mg/dL)	NN1218-4131	TRTPN	4	WORK.IMPUTE

Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	-0.2766	0.08455	981	-3.27	0.0011	0.05	-0.4425	-0.1107
20001	-4.9841	1.5237	981	-3.27	0.0011	0.05	-7.9741	-1.9941
40001	-0.2003	0.08427	981	-2.38	0.0176	0.05	-0.3657	-0.03495
60001	-3.6098	1.5186	981	-2.38	0.0176	0.05	-6.5899	-0.6298
80001	-0.3928	0.08453	981	-4.65	<.0001	0.05	-0.5587	-0.2270
100001	-7.0788	1.5232	981	-4.65	<.0001	0.05	-10.0680	-4.0897

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Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Least Squares Means Estimate

Parameter Code=P9PSMPGM Parameter=Mean SMPG (mmol/L)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
1	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
20001	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	WORK.IMPUTE	0.1162	0.1196	981	0.97	0.3315	0.05	-0.1186	0.3510
20001	WORK.IMPUTE	0.1925	0.1194	981	1.61	0.1073	0.05	-0.04183	0.4268

Parameter Code=P9SMPGMU Parameter=Mean SMPG (mg/dL)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
40001	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
60001	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
40001	WORK.IMPUTE	2.0948	2.1561	981	0.97	0.3315	0.05	-2.1363	6.3258
60001	WORK.IMPUTE	3.4690	2.1518	981	1.61	0.1073	0.05	-0.7537	7.6917

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Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9PSMPGM Parameter=Mean SMPG (mmol/L) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000407	0.007093	0.007500	6.78E6	0.057441	0.054321	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	8.538049	0.086604	8.368309	8.707789	6.78E6	8.445066	8.617011

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	98.59	<.0001

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Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9SMPGMU Parameter=Mean SMPG (mg/dL) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.132289	2.303166	2.435462	6.78E6	0.057441	0.054321	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	153.855638	1.560597	150.7969	156.9144	6.78E6	152.180095	155.278546

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	98.59	<.0001

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Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9PSMPGM Parameter=Mean SMPG (mmol/L) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000313	0.007046	0.007359	1.1E7	0.044477	0.042584	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	8.625579	0.085784	8.457445	8.793713	1.1E7	8.551441	8.703823

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	100.55	<.0001

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Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9SMPGMU Parameter=Mean SMPG (mg/dL) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.101752	2.287831	2.389587	1.1E7	0.044477	0.042584	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	155.432935	1.545829	152.4032	158.4627	1.1E7	154.096967	156.842886

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	100.55	<.0001

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Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9PSMPGM Parameter=Mean SMPG (mmol/L) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000496	0.007089	0.007585	4.68E6	0.069963	0.065389	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	8.474127	0.087090	8.303434	8.644819	4.68E6	8.385657	8.563349

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	97.30	<.0001

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Mean of 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9SMPGMU Parameter=Mean SMPG (mg/dL) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.161036	2.301834	2.462878	4.68E6	0.069963	0.065389	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	152.703763	1.569356	149.6279	155.7796	4.68E6	151.109547	154.311551

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	97.30	<.0001

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20: Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis setThe MI Procedure with MCMC
Model Information

Parameter Code=P9PFLUCU Planned Treatment for Period 30 (N)=2

Obs	PARAM		Description	Value
1	Fluctuation	(SMPG) (mg/dL)	Data Set	WORK.ENDPOINT_PARAM
2	Fluctuation	(SMPG) (mg/dL)	Method	Monotone-data_MCMC
3	Fluctuation	(SMPG) (mg/dL)	Multiple Imputation Chain	Multiple Chains
4	Fluctuation	(SMPG) (mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
5	Fluctuation	(SMPG) (mg/dL)	Start	Starting Value
6	Fluctuation	(SMPG) (mg/dL)	Prior	Jeffreys
7	Fluctuation	(SMPG) (mg/dL)	Number of Imputations	20000
8	Fluctuation	(SMPG) (mg/dL)	Number of Burn-in Iterations	200
9	Fluctuation	(SMPG) (mg/dL)	Seed for random number generator	1234

Parameter Code=P9PFLUCU Planned Treatment for Period 30 (N)=3

Obs	PARAM		Description	Value
10	Fluctuation	(SMPG) (mg/dL)	Data Set	WORK.ENDPOINT_PARAM
11	Fluctuation	(SMPG) (mg/dL)	Method	Monotone-data_MCMC
12	Fluctuation	(SMPG) (mg/dL)	Multiple Imputation Chain	Multiple Chains
13	Fluctuation	(SMPG) (mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
14	Fluctuation	(SMPG) (mg/dL)	Start	Starting Value
15	Fluctuation	(SMPG) (mg/dL)	Prior	Jeffreys
16	Fluctuation	(SMPG) (mg/dL)	Number of Imputations	20000
17	Fluctuation	(SMPG) (mg/dL)	Number of Burn-in Iterations	200
18	Fluctuation	(SMPG) (mg/dL)	Seed for random number generator	950811097

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The MI Procedure with MCMC
Model Information

Parameter Code=P9PFLUCU Planned Treatment for Period 30 (N)=4

Obs	PARAM	Description	Value
19	Fluctuation (SMPG) (mg/dL)	Data Set	WORK.ENDPOINT_PARAM
20	Fluctuation (SMPG) (mg/dL)	Method	Monotone-data_MCMC
21	Fluctuation (SMPG) (mg/dL)	Multiple Imputation Chain	Multiple Chains
22	Fluctuation (SMPG) (mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
23	Fluctuation (SMPG) (mg/dL)	Start	Starting Value
24	Fluctuation (SMPG) (mg/dL)	Prior	Jeffreys
25	Fluctuation (SMPG) (mg/dL)	Number of Imputations	20000
26	Fluctuation (SMPG) (mg/dL)	Number of Burn-in Iterations	200
27	Fluctuation (SMPG) (mg/dL)	Seed for random number generator	950357174

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The MI Procedure with MCMC
Missing data pattern

Parameter Code=P9PFLUCU Planned Treatment for Period 30 (N)=2

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
1	Fluctuation (SMPG) (mg/dL)	1	X	X	X	294	89.36	3.565678	-0.085374	-0.129163
2	Fluctuation (SMPG) (mg/dL)	2	X	X	O	9	2.74	3.518092	0.068401	.
3	Fluctuation (SMPG) (mg/dL)	3	X	.	X	17	5.17	3.584368	.	-0.289537
4	Fluctuation (SMPG) (mg/dL)	4	X	O	O	9	2.74	3.519117	.	.

Parameter Code=P9PFLUCU Planned Treatment for Period 30 (N)=3

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
5	Fluctuation (SMPG) (mg/dL)	1	X	X	X	303	91.54	3.589437	-0.129108	-0.140601
6	Fluctuation (SMPG) (mg/dL)	2	X	X	O	12	3.63	3.598043	-0.009609	.
7	Fluctuation (SMPG) (mg/dL)	3	X	.	X	12	3.63	3.471679	.	-0.082594
8	Fluctuation (SMPG) (mg/dL)	4	X	O	O	4	1.21	3.642353	.	.

Parameter Code=P9PFLUCU Planned Treatment for Period 30 (N)=4

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
9	Fluctuation (SMPG) (mg/dL)	1	X	X	X	297	90.27	3.560927	-0.051299	-0.106319
10	Fluctuation (SMPG) (mg/dL)	2	X	X	O	11	3.34	3.581550	-0.110797	.
11	Fluctuation (SMPG) (mg/dL)	3	X	.	X	12	3.65	3.574985	.	-0.371274
12	Fluctuation (SMPG) (mg/dL)	4	X	O	O	9	2.74	3.667663	.	.

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Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PFLUCU Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM	Description	Value
1	1	Fluctuation (SMPG) (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	Fluctuation (SMPG) (mg/dL)	Method	Monotone
3	1	Fluctuation (SMPG) (mg/dL)	Number of Imputations	1
4	1	Fluctuation (SMPG) (mg/dL)	Seed for random number generator	4321

Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression Missing Data Pattern

Parameter Code=P9PFLUCU Planned Treatment for Period 30 (N)=2

O	b	s				P	G	R E G I O N 1	B O L A D 1	B A S E	V I S I T 2	V I S I T 3	F	P	B	V	V
			A	M				M	M	M	M	M	r	e	E	i	i
			S	M				s	s	s	s	s	q	c	n	t	t
1	1	Fluctuation	(SMPG)	(mg/dL)	1	X	X	X	X	X	.	.	311	94.53	3.566700	-0.085417	-0.137929
2	1	Fluctuation	(SMPG)	(mg/dL)	2	X	X	X	X	X	.	.	9	2.74	3.518092	0.068401	.
3	1	Fluctuation	(SMPG)	(mg/dL)	3	X	X	X	9	2.74	3.519117	.	.

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PFLUCU Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	Fluctuation (SMPG) (mg/dL)	Intercept	
2	1	Fluctuation (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	Fluctuation (SMPG) (mg/dL)	REGION1	EUROPE
4	1	Fluctuation (SMPG) (mg/dL)	REGION1	JAPAN
5	1	Fluctuation (SMPG) (mg/dL)	BOLAD1	
6	1	Fluctuation (SMPG) (mg/dL)	BASE	

Obs	BOLAD1	ObsVal	_1
1		0.02011	0.057986
2		-0.12622	-0.089824
3		-0.31639	-0.471279
4		0.15745	0.139678
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.11227	-0.166279
6		-0.25843	-0.308815

Parameter Code=P9PFLUCU Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	Fluctuation (SMPG) (mg/dL)	Intercept			0.04640	0.040370
8	1	Fluctuation (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)		0.07066	0.011511
9	1	Fluctuation (SMPG) (mg/dL)	REGION1	EUROPE		-0.08967	-0.113915

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PFLUCU Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
10	1	Fluctuation (SMPG) (mg/dL)	REGION1	JAPAN		0.06104	0.167947
11	1	Fluctuation (SMPG) (mg/dL)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.12769	-0.218031
12	1	Fluctuation (SMPG) (mg/dL)	BASE			-0.11620	-0.134886
13	1	Fluctuation (SMPG) (mg/dL)	visit2200			0.56925	0.619752

Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PFLUCU Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM	Description	Value
1	1	Fluctuation (SMPG) (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	Fluctuation (SMPG) (mg/dL)	Method	Monotone
3	1	Fluctuation (SMPG) (mg/dL)	Number of Imputations	1
4	1	Fluctuation (SMPG) (mg/dL)	Seed for random number generator	4322

Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression Missing Data Pattern

Parameter Code=P9PFLUCU Planned Treatment for Period 30 (N)=3

O b s		I m p u t a t i o n —	P A R A M	G r o u p	R E G I O N 1 1					B O L A S E		F r e q	P e r c e n t	B A S E	v i s i t 2 2 0 0	v i s i t 3 6 0 0
					M	M	M	M	M	M	M					
1	1	Fluctuation	(SMPG)	(mg/dL)	1	X	X	X	X	X	315	95.17	3.584951	-0.122618	-0.138391	
2	1	Fluctuation	(SMPG)	(mg/dL)	2	X	X	X	X	.	12	3.63	3.598043	-0.009609	.	
3	1	Fluctuation	(SMPG)	(mg/dL)	3	X	X	X	.	.	4	1.21	3.642353	.	.	

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PFLUCU Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	Fluctuation (SMPG) (mg/dL)	Intercept	
2	1	Fluctuation (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	Fluctuation (SMPG) (mg/dL)	REGION1	EUROPE
4	1	Fluctuation (SMPG) (mg/dL)	REGION1	JAPAN
5	1	Fluctuation (SMPG) (mg/dL)	BOLAD1	
6	1	Fluctuation (SMPG) (mg/dL)	BASE	

Obs		BOLAD1	ObsVal	_1
1			0.00897	0.119821
2			-0.12270	0.026716
3			-0.16978	-0.169683
4			0.27038	0.167965
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.12887	-0.098652
6			-0.20863	-0.257153

Parameter Code=P9PFLUCU Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	Fluctuation (SMPG) (mg/dL)	Intercept			-0.05542	0.023289
8	1	Fluctuation (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)		-0.33294	-0.400941
9	1	Fluctuation (SMPG) (mg/dL)	REGION1	EUROPE		0.11932	0.096175

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PFLUCU Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
10	1	Fluctuation (SMPG) (mg/dL)	REGION1	JAPAN		0.19295	0.222670
11	1	Fluctuation (SMPG) (mg/dL)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.00599	-0.015015
12	1	Fluctuation (SMPG) (mg/dL)	BASE			-0.02218	-0.075409
13	1	Fluctuation (SMPG) (mg/dL)	visit2200			0.51671	0.559142

Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PFLUCU Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM	Description	Value
1	1	Fluctuation (SMPG) (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	Fluctuation (SMPG) (mg/dL)	Method	Monotone
3	1	Fluctuation (SMPG) (mg/dL)	Number of Imputations	1
4	1	Fluctuation (SMPG) (mg/dL)	Seed for random number generator	4323

Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression Missing Data Pattern

Parameter Code=P9PFLUCU Planned Treatment for Period 30 (N)=4

	O b s	I m p u t a t i o n _	P A R A M	G r o u p	R E G I O N 1	B O L A D 1	B A S E	V i s i t 2	V i s i t 3	F r e q	P e r c e n t	B A S E	V i s i t 2	V i s i t 3
1	1	Fluctuation	(SMPG)	(mg/dL)	1	X	X	X	X	309	93.92	3.561473	-0.058392	-0.116608
2	1	Fluctuation	(SMPG)	(mg/dL)	2	X	X	X	X	11	3.34	3.581550	-0.110797	.
3	1	Fluctuation	(SMPG)	(mg/dL)	3	X	X	X	.	9	2.74	3.667663	.	.

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PFLUCU Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	Fluctuation (SMPG) (mg/dL)	Intercept	
2	1	Fluctuation (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	Fluctuation (SMPG) (mg/dL)	REGION1	EUROPE
4	1	Fluctuation (SMPG) (mg/dL)	REGION1	JAPAN
5	1	Fluctuation (SMPG) (mg/dL)	BOLAD1	
6	1	Fluctuation (SMPG) (mg/dL)	BASE	

Obs		BOLAD1	ObsVal	_1
1			0.01633	-0.035548
2			-0.08041	-0.021101
3			-0.19792	-0.329497
4			0.19862	0.247175
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.08866	-0.095232
6			-0.39019	-0.490105

Parameter Code=P9PFLUCU Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	Fluctuation (SMPG) (mg/dL)	Intercept			0.01179	0.088797
8	1	Fluctuation (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)		0.03798	0.045795
9	1	Fluctuation (SMPG) (mg/dL)	REGION1	EUROPE		-0.17124	-0.225721

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PFLUCU Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
10	1	Fluctuation (SMPG) (mg/dL)	REGION1	JAPAN		0.21340	0.251072
11	1	Fluctuation (SMPG) (mg/dL)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.01499	-0.068401
12	1	Fluctuation (SMPG) (mg/dL)	BASE			-0.30639	-0.302498
13	1	Fluctuation (SMPG) (mg/dL)	visit2200			0.48945	0.533054

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The MI Procedure with MCMC
Model Information

Parameter Code=P9P_FLUC Planned Treatment for Period 30 (N)=2

Obs	PARAM	Description	Value
1	Fluctuation (SMPG) (mmol/L)	Data Set	WORK.ENDPOINT_PARAM
2	Fluctuation (SMPG) (mmol/L)	Method	Monotone-data_MCMC
3	Fluctuation (SMPG) (mmol/L)	Multiple Imputation Chain	Multiple Chains
4	Fluctuation (SMPG) (mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
5	Fluctuation (SMPG) (mmol/L)	Start	Starting Value
6	Fluctuation (SMPG) (mmol/L)	Prior	Jeffreys
7	Fluctuation (SMPG) (mmol/L)	Number of Imputations	20000
8	Fluctuation (SMPG) (mmol/L)	Number of Burn-in Iterations	200
9	Fluctuation (SMPG) (mmol/L)	Seed for random number generator	1234

Parameter Code=P9P_FLUC Planned Treatment for Period 30 (N)=3

Obs	PARAM	Description	Value
10	Fluctuation (SMPG) (mmol/L)	Data Set	WORK.ENDPOINT_PARAM
11	Fluctuation (SMPG) (mmol/L)	Method	Monotone-data_MCMC
12	Fluctuation (SMPG) (mmol/L)	Multiple Imputation Chain	Multiple Chains
13	Fluctuation (SMPG) (mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
14	Fluctuation (SMPG) (mmol/L)	Start	Starting Value
15	Fluctuation (SMPG) (mmol/L)	Prior	Jeffreys
16	Fluctuation (SMPG) (mmol/L)	Number of Imputations	20000
17	Fluctuation (SMPG) (mmol/L)	Number of Burn-in Iterations	200
18	Fluctuation (SMPG) (mmol/L)	Seed for random number generator	950811097

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The MI Procedure with MCMC
Model Information

Parameter Code=P9P_FLUC Planned Treatment for Period 30 (N)=4

Obs	PARAM		Description	Value
19	Fluctuation	(SMPG) (mmol/L)	Data Set	WORK.ENDPOINT_PARAM
20	Fluctuation	(SMPG) (mmol/L)	Method	Monotone-data_MCMC
21	Fluctuation	(SMPG) (mmol/L)	Multiple Imputation Chain	Multiple Chains
22	Fluctuation	(SMPG) (mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
23	Fluctuation	(SMPG) (mmol/L)	Start	Starting Value
24	Fluctuation	(SMPG) (mmol/L)	Prior	Jeffreys
25	Fluctuation	(SMPG) (mmol/L)	Number of Imputations	20000
26	Fluctuation	(SMPG) (mmol/L)	Number of Burn-in Iterations	200
27	Fluctuation	(SMPG) (mmol/L)	Seed for random number generator	950357174

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The MI Procedure with MCMC
Missing data pattern

Parameter Code=P9P_FLUC Planned Treatment for Period 30 (N)=2

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
1	Fluctuation (SMPG) (mmol/L)	1	X	X	X	294	89.36	0.674196	-0.085374	-0.129163
2	Fluctuation (SMPG) (mmol/L)	2	X	X	O	9	2.74	0.626610	0.068401	.
3	Fluctuation (SMPG) (mmol/L)	3	X	.	X	17	5.17	0.692886	.	-0.289537
4	Fluctuation (SMPG) (mmol/L)	4	X	O	O	9	2.74	0.627635	.	.

Parameter Code=P9P_FLUC Planned Treatment for Period 30 (N)=3

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
5	Fluctuation (SMPG) (mmol/L)	1	X	X	X	303	91.54	0.697954	-0.129108	-0.140601
6	Fluctuation (SMPG) (mmol/L)	2	X	X	O	12	3.63	0.706561	-0.009609	.
7	Fluctuation (SMPG) (mmol/L)	3	X	.	X	12	3.63	0.580197	.	-0.082594
8	Fluctuation (SMPG) (mmol/L)	4	X	O	O	4	1.21	0.750871	.	.

Parameter Code=P9P_FLUC Planned Treatment for Period 30 (N)=4

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
9	Fluctuation (SMPG) (mmol/L)	1	X	X	X	297	90.27	0.669445	-0.051299	-0.106319
10	Fluctuation (SMPG) (mmol/L)	2	X	X	O	11	3.34	0.690067	-0.110797	.
11	Fluctuation (SMPG) (mmol/L)	3	X	.	X	12	3.65	0.683503	.	-0.371274
12	Fluctuation (SMPG) (mmol/L)	4	X	O	O	9	2.74	0.776181	.	.

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The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9P_FLUC Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM	Description	Value
1	1	Fluctuation (SMPG) (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	Fluctuation (SMPG) (mmol/L)	Method	Monotone
3	1	Fluctuation (SMPG) (mmol/L)	Number of Imputations	1
4	1	Fluctuation (SMPG) (mmol/L)	Seed for random number generator	4321

Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression Missing Data Pattern

Parameter Code=P9P FLUC Planned Treatment for Period 30 (N)=2

	O b s	I m p u t a t i o n _	P A R A M	G r o u p	R E G I O N 1	B O L A D 1	B A S E	V i s i t 2	V i s i t 3	F r e q	P e r c e n t	B A S E	v i s i t 2	v i s i t 3
	1	1	Fluctuation (SMPG) (mmol/L)	1	X	X	X	X	X	311	94.53	0.675218	-0.085417	-0.137929
	2	1	Fluctuation (SMPG) (mmol/L)	2	X	X	X	X	.	9	2.74	0.626610	0.068401	.
	3	1	Fluctuation (SMPG) (mmol/L)	3	X	X	X	.	.	9	2.74	0.627635	.	.

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Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis -
in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9P_FLUC Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	Fluctuation (SMPG) (mmol/L)	Intercept	
2	1	Fluctuation (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	Fluctuation (SMPG) (mmol/L)	REGION1	EUROPE
4	1	Fluctuation (SMPG) (mmol/L)	REGION1	JAPAN
5	1	Fluctuation (SMPG) (mmol/L)	BOLAD1	
6	1	Fluctuation (SMPG) (mmol/L)	BASE	

Obs	BOLAD1	ObsVal	_1
1		0.02011	0.057986
2		-0.12622	-0.089824
3		-0.31639	-0.471279
4		0.15745	0.139678
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.11227	-0.166279
6		-0.25843	-0.308815

Parameter Code=P9P_FLUC Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	Fluctuation (SMPG) (mmol/L)	Intercept			0.04640	0.040370
8	1	Fluctuation (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)		0.07066	0.011511
9	1	Fluctuation (SMPG) (mmol/L)	REGION1	EUROPE		-0.08967	-0.113915

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9P_FLUC Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

(continued)

O b s —		P A R M		E f f e c t		R E G I O N		B O L U S		O b s e r v e d		I m p u t e d	
10	1	Fluctuation	(SMPG)	(mmol/L)	REGION1	JAPAN				0.06104	0.167947		
11	1	Fluctuation	(SMPG)	(mmol/L)	BOLAD1		BOLUS	INSULIN	ALGORITHM (SLIDING SCALE)	-0.12769	-0.218031		
12	1	Fluctuation	(SMPG)	(mmol/L)	BASE					-0.11620	-0.134886		
13	1	Fluctuation	(SMPG)	(mmol/L)	visit2200					0.56925	0.619752		

Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9P_FLUC Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM	Description	Value
1	1	Fluctuation (SMPG) (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	Fluctuation (SMPG) (mmol/L)	Method	Monotone
3	1	Fluctuation (SMPG) (mmol/L)	Number of Imputations	1
4	1	Fluctuation (SMPG) (mmol/L)	Seed for random number generator	4322

Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression Missing Data Pattern

Parameter Code=P9P_FLUC Planned Treatment for Period 30 (N)=3

	O b s		I m p u t a t i o n _	P A R A M	G r o u p	R E G I O N \bar{M} s	B O L D \bar{M} s	B A S E \bar{M} s	V I S I T 2 2 0 \bar{M} s	V I S I T 3 6 0 \bar{M} s	F r e q	P e r c e n t	B A S E	v i s i t 2 0 0	v i s i t 3 6 0 0
1	1	Fluctuation	(SMPG)	(mmol/L)	1	X	X	X	X	X	315	95.17	0.693468	-0.122618	-0.138391
2	1	Fluctuation	(SMPG)	(mmol/L)	2	X	X	X	X	.	12	3.63	0.706561	-0.009609	.
3	1	Fluctuation	(SMPG)	(mmol/L)	3	X	X	X	.	.	4	1.21	0.750871	.	.

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in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9P_FLUC Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	Fluctuation (SMPG) (mmol/L)	Intercept	
2	1	Fluctuation (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	Fluctuation (SMPG) (mmol/L)	REGION1	EUROPE
4	1	Fluctuation (SMPG) (mmol/L)	REGION1	JAPAN
5	1	Fluctuation (SMPG) (mmol/L)	BOLAD1	
6	1	Fluctuation (SMPG) (mmol/L)	BASE	

Obs		BOLAD1	ObsVal	_1
1			0.00897	0.119821
2			-0.12270	0.026716
3			-0.16978	-0.169683
4			0.27038	0.167965
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.12887	-0.098652
6			-0.20863	-0.257153

Parameter Code=P9P_FLUC Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	Fluctuation (SMPG) (mmol/L)	Intercept			-0.05542	0.023289
8	1	Fluctuation (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)		-0.33294	-0.400941
9	1	Fluctuation (SMPG) (mmol/L)	REGION1	EUROPE		0.11932	0.096175

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The MI Procedure with Monotone Regression Regression Information

Parameter Code=P9P FLUC Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

(continued)

	O	b	s		P	E	R	B	O	
				A	f	E		O	b	
				R	f	G		L	s	
				A	e	I		A	V	
				M	c	N		D	a	
					t	1		1	l	\bar{I}
10	1	Fluctuation	(SMPG)	(mmol/L)	REGION1	JAPAN			0.19295	0.222670
11	1	Fluctuation	(SMPG)	(mmol/L)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.00599	-0.015015
12	1	Fluctuation	(SMPG)	(mmol/L)	BASE				-0.02218	-0.075409
13	1	Fluctuation	(SMPG)	(mmol/L)	visit2200				0.51671	0.559142

Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9P_FLUC Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM	Description	Value
1	1	Fluctuation (SMPG) (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	Fluctuation (SMPG) (mmol/L)	Method	Monotone
3	1	Fluctuation (SMPG) (mmol/L)	Number of Imputations	1
4	1	Fluctuation (SMPG) (mmol/L)	Seed for random number generator	4323

Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression Missing Data Pattern

Parameter Code=P9P FLUC Planned Treatment for Period 30 (N)=4

	O b s	I m p u t a t i o n _	P A R A M	G r o u p	R E G I O N l	B O L A D l	B A S E	V i s i t 2	V i s i t 3	F r e q	P e r c e n t	B A S E	v i s i t 2	v i s i t 3
1	1	Fluctuation	(SMPG)	(mmol/L)	1	X	X	X	X	309	93.92	0.669991	-0.058392	-0.116608
2	1	Fluctuation	(SMPG)	(mmol/L)	2	X	X	X	X	11	3.34	0.690067	-0.110797	.
3	1	Fluctuation	(SMPG)	(mmol/L)	3	X	X	X	.	9	2.74	0.776181	.	.

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9P_FLUC Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	Fluctuation (SMPG) (mmol/L)	Intercept	
2	1	Fluctuation (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	Fluctuation (SMPG) (mmol/L)	REGION1	EUROPE
4	1	Fluctuation (SMPG) (mmol/L)	REGION1	JAPAN
5	1	Fluctuation (SMPG) (mmol/L)	BOLAD1	
6	1	Fluctuation (SMPG) (mmol/L)	BASE	

Obs	BOLAD1	ObsVal	_1
1		0.01633	-0.035548
2		-0.08041	-0.021101
3		-0.19792	-0.329497
4		0.19862	0.247175
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.08866	-0.095232
6		-0.39019	-0.490105

Parameter Code=P9P_FLUC Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	Fluctuation (SMPG) (mmol/L)	Intercept			0.01179	0.088797
8	1	Fluctuation (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)		0.03798	0.045795
9	1	Fluctuation (SMPG) (mmol/L)	REGION1	EUROPE		-0.17124	-0.225721

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The MI Procedure with Monotone Regression Regression Information

Parameter Code=P9P FLUC Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

(continued)

	O	b	s		P	E	R	B	O	
					A	f	E	O	b	
					R	e	G	A	s	
					A	c	I	D	V	
					M	t	N	1	a	
							1	1	l	\bar{I}
10	1	Fluctuation	(SMPG)	(mmol/L)	REGION1	JAPAN			0.21340	0.251072
11	1	Fluctuation	(SMPG)	(mmol/L)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.01499	-0.068401
12	1	Fluctuation	(SMPG)	(mmol/L)	BASE				-0.30639	-0.302498
13	1	Fluctuation	(SMPG)	(mmol/L)	visit2200				0.48945	0.533054

Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Model Information

Parameter Code=P9PFLUCU Parameter=Fluctuation (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Data Set	WORK.IMPUTE
2	1	NN1218-4131	Dependent Variable	eotVisit
3	1	NN1218-4131	Covariance Structure	Diagonal
4	1	NN1218-4131	Estimation Method	REML
5	1	NN1218-4131	Residual Variance Method	Profile
6	1	NN1218-4131	Fixed Effects SE Method	Model-Based
7	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=P9P_FLUC Parameter=Fluctuation (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
8	1	NN1218-4131	Data Set	WORK.IMPUTE
9	1	NN1218-4131	Dependent Variable	eotVisit
10	1	NN1218-4131	Covariance Structure	Diagonal
11	1	NN1218-4131	Estimation Method	REML
12	1	NN1218-4131	Residual Variance Method	Profile
13	1	NN1218-4131	Fixed Effects SE Method	Model-Based
14	1	NN1218-4131	Degrees of Freedom Method	Residual

Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Class Level Information

Parameter Code=P9PFLUCU Parameter=Fluctuation (SMPG) (mg/dL)

Ob- s	Input ID	STUDY	Class	Level	Values	min
1	1	NN1218-4131	TRTPN	3	2 3 4	5
2	1	NN1218-4131	REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA	49
3	1	NN1218-4131	BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULI	85

Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Class Level Information

Parameter Code=P9P_FLUC Parameter=Fluctuation (SMPG) (mmol/L)

		I m p u t a t i o n s		S T U D Y I D		C l a s s		L e v e l s		V a r i a n c e s		m i n i m u m v a l u e s	
4	1	NN1218-4131	TRTPN					3	2	3	4		5
5	1	NN1218-4131	REGION1					4	ASIA (EXCLUDING JAPAN)	EUROPE	JAPAN	NORTH AMERICA	49
6	1	NN1218-4131	BOLAD1					2	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	CARBOHYDRATE COUNTING (FLEXIBLE)	BOLUS INSULI		85

Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Dimensions

Parameter Code=P9PFLUCU Parameter=Fluctuation (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Covariance Parameters	1
2	1	NN1218-4131	Columns in X	10
3	1	NN1218-4131	Columns in Z	0
4	1	NN1218-4131	Subjects	1
5	1	NN1218-4131	Max Obs per Subject	989

Parameter Code=P9P_FLUC Parameter=Fluctuation (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
6	1	NN1218-4131	Covariance Parameters	1
7	1	NN1218-4131	Columns in X	10
8	1	NN1218-4131	Columns in Z	0
9	1	NN1218-4131	Subjects	1
10	1	NN1218-4131	Max Obs per Subject	989

Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Number of Observations

Parameter Code=P9PFLUCU Parameter=Fluctuation (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
1	1	NN1218-4131	Number of Observations Read	989	989	989	989	989
2	1	NN1218-4131	Number of Observations Used	989	989	989	989	989
3	1	NN1218-4131	Number of Observations Not Used	0	989	989	989	989

Parameter Code=P9P_FLUC Parameter=Fluctuation (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
4	1	NN1218-4131	Number of Observations Read	989	989	989	989	989
5	1	NN1218-4131	Number of Observations Used	989	989	989	989	989
6	1	NN1218-4131	Number of Observations Not Used	0	989	989	989	989

Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Covariance Parameter Estimates

Parameter Code=P9PFLUCU Parameter=Fluctuation (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	CovParm	Estimate
1	1	NN1218-4131	Residual	0.1758

Parameter Code=P9P_FLUC Parameter=Fluctuation (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	CovParm	Estimate
20001	1	NN1218-4131	Residual	0.1758

Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Fit Statistics

Parameter Code=P9PFLUCU Parameter=Fluctuation (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	-2 Res Log Likelihood	1121.2
2	1	NN1218-4131	AIC (Smaller is Better)	1123.2
3	1	NN1218-4131	AICC (Smaller is Better)	1123.2
4	1	NN1218-4131	BIC (Smaller is Better)	1128.1

Parameter Code=P9P_FLUC Parameter=Fluctuation (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
5	1	NN1218-4131	-2 Res Log Likelihood	1121.2
6	1	NN1218-4131	AIC (Smaller is Better)	1123.2
7	1	NN1218-4131	AICC (Smaller is Better)	1123.2
8	1	NN1218-4131	BIC (Smaller is Better)	1128.1

Fast-acting insulin aspart
NN1218-4131

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Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis -
in-trial - full analysis set

The Mixed procedure
Solution for Fixed Effects

Parameter Code=P9PFLUCU Parameter=Fluctuation (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
1	1	NN1218-4131	TRTPN	2				
2	1	NN1218-4131	TRTPN	3				
3	1	NN1218-4131	TRTPN	4				
4	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
5	1	NN1218-4131	REGION1	—	EUROPE			
6	1	NN1218-4131	REGION1	—	JAPAN			
7	1	NN1218-4131	REGION1	—	NORTH AMERICA			
8	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
9	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
10	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	1.1087	0.1268	981	8.75	<.0001	0.05	0.8599	1.3575
2	1.1090	0.1274	981	8.71	<.0001	0.05	0.8590	1.3589
3	1.1123	0.1266	981	8.78	<.0001	0.05	0.8638	1.3609
4	-0.07527	0.04898	981	-1.54	0.1247	0.05	-0.1714	0.02085
5	-0.09793	0.03522	981	-2.78	0.0055	0.05	-0.1670	-0.02880
6	0.09589	0.03884	981	2.47	0.0137	0.05	0.01968	0.1721
7	0
8	-0.08371	0.03019	981	-2.77	0.0057	0.05	-0.1430	-0.02446
9	0
10	-0.3278	0.03376	981	-9.71	<.0001	0.05	-0.3940	-0.2615

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Fast-acting insulin aspart
NN1218-4131

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Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis -
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The Mixed procedure
Solution for Fixed Effects

Parameter Code=P9P_FLUC Parameter=Fluctuation (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
11	1	NN1218-4131	TRTPN	2				
12	1	NN1218-4131	TRTPN	3				
13	1	NN1218-4131	TRTPN	4				
14	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
15	1	NN1218-4131	REGION1	—	EUROPE			
16	1	NN1218-4131	REGION1	—	JAPAN			
17	1	NN1218-4131	REGION1	—	NORTH AMERICA			
18	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
19	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
20	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
11	0.1610	0.04092	981	3.93	<.0001	0.05	0.08070	0.2413
12	0.1612	0.04160	981	3.88	0.0001	0.05	0.07960	0.2429
13	0.1646	0.04117	981	4.00	<.0001	0.05	0.08383	0.2454
14	-0.07527	0.04898	981	-1.54	0.1247	0.05	-0.1714	0.02085
15	-0.09793	0.03522	981	-2.78	0.0055	0.05	-0.1670	-0.02880
16	0.09589	0.03884	981	2.47	0.0137	0.05	0.01968	0.1721
17	0
18	-0.08371	0.03019	981	-2.77	0.0057	0.05	-0.1430	-0.02446
19	0
20	-0.3278	0.03376	981	-9.71	<.0001	0.05	-0.3940	-0.2615

nn1218/nn1218-4131/ctr_20180214_er
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Fast-acting insulin aspart
NN1218-4131

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Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis -
in-trial - full analysis set

The Mixed procedure
Least Squares Means

Obs	_Imputation_	PARAMCD	PARAM	STUDYID	Effect	TRTPN
1	1	P9PFLUCU	Fluctuation (SMPG) (mg/dL)	NN1218-4131	TRTPN	2
2	1	P9PFLUCU	Fluctuation (SMPG) (mg/dL)	NN1218-4131	TRTPN	3
3	1	P9PFLUCU	Fluctuation (SMPG) (mg/dL)	NN1218-4131	TRTPN	4
4	1	P9P_FLUC	Fluctuation (SMPG) (mmol/L)	NN1218-4131	TRTPN	2
5	1	P9P_FLUC	Fluctuation (SMPG) (mmol/L)	NN1218-4131	TRTPN	3
6	1	P9P_FLUC	Fluctuation (SMPG) (mmol/L)	NN1218-4131	TRTPN	4

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	WORK.IMPUTE	-0.1299	0.02315	981	-5.61	<.0001	0.05	-0.1753	-0.08443
2	WORK.IMPUTE	-0.1296	0.02307	981	-5.62	<.0001	0.05	-0.1749	-0.08434
3	WORK.IMPUTE	-0.1262	0.02314	981	-5.46	<.0001	0.05	-0.1716	-0.08082
4	WORK.IMPUTE	-0.1299	0.02315	981	-5.61	<.0001	0.05	-0.1753	-0.08443
5	WORK.IMPUTE	-0.1296	0.02307	981	-5.62	<.0001	0.05	-0.1749	-0.08434
6	WORK.IMPUTE	-0.1262	0.02314	981	-5.46	<.0001	0.05	-0.1716	-0.08082

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Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Least Squares Means Estimate

Parameter Code=P9PFLUCU Parameter=Fluctuation (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
1	1	NN1218-4131	1	TRTPN	Faster aspart (meal) / NovoRapid (meal)
2	1	NN1218-4131	2	TRTPN	Faster aspart (post) / NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	WORK.IMPUTE	-0.00363	0.03275	981	-0.11	0.9118	0.05	-0.06790	0.06064
2	WORK.IMPUTE	-0.00338	0.03268	981	-0.10	0.9176	0.05	-0.06752	0.06075

Parameter Code=P9P_FLUC Parameter=Fluctuation (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
3	1	NN1218-4131	1	TRTPN	Faster aspart (meal) / NovoRapid (meal)
4	1	NN1218-4131	2	TRTPN	Faster aspart (post) / NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
3	WORK.IMPUTE	-0.00363	0.03275	981	-0.11	0.9118	0.05	-0.06790	0.06064
4	WORK.IMPUTE	-0.00338	0.03268	981	-0.10	0.9176	0.05	-0.06752	0.06075

Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9PFLUCU Parameter=Fluctuation (SMPG) (mg/dL) Study Identifier=NN1218-41

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000027383	0.000533	0.000560	8.37E6	0.051386	0.048875	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.135657	0.023671	-0.18205	-0.08926	8.37E6	-0.154185	-0.113192

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-5.73	<.0001

Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9P_FLUC Parameter=Fluctuation (SMPG) (mmol/L) Study Identifier=NN1218-4

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000027383	0.000533	0.000560	8.37E6	0.051386	0.048875	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.135657	0.023671	-0.18205	-0.08926	8.37E6	-0.154185	-0.113192

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-5.73	<.0001

Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9PFLUCU Parameter=Fluctuation (SMPG) (mg/dL) Study Identifier=NN1218-41

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000023644	0.000529	0.000553	1.09E7	0.044676	0.042765	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.136286	0.023514	-0.18237	-0.09020	1.09E7	-0.155609	-0.117977

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-5.80	<.0001

Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9P_FLUC Parameter=Fluctuation (SMPG) (mmol/L) Study Identifier=NN1218-4

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000023644	0.000529	0.000553	1.09E7	0.044676	0.042765	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.136286	0.023514	-0.18237	-0.09020	1.09E7	-0.155609	-0.117977

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-5.80	<.0001

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 1542 of 4425	Novo Nordisk
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Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9PFLUCU Parameter=Fluctuation (SMPG) (mg/dL) Study Identifier=NN1218-41

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000024042	0.000532	0.000556	1.07E7	0.045164	0.043212	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.122735	0.023588	-0.16897	-0.07650	1.07E7	-0.141312	-0.100524

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-5.20	<.0001

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Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9P_FLUC Parameter=Fluctuation (SMPG) (mmol/L) Study Identifier=NN1218-4

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000024042	0.000532	0.000556	1.07E7	0.045164	0.043212	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.122735	0.023588	-0.16897	-0.07650	1.07E7	-0.141312	-0.100524

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-5.20	<.0001

Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=P9PFLUCU Label=Faster aspart (meal) / NovoRapid (meal) Parameter=Fluctuation (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000051118	0.001067	0.001118	9.56E6	0.047926	0.045734	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.012922	0.033433	-0.07845	0.052606	9.56E6	-0.042312	0.013406

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-0.39	0.6991

Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=P9PFLUCU Label=Faster aspart (post) / NovoRapid (meal) Parameter=Fluctuation (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000047878	0.001062	0.001110	1.07E7	0.045077	0.043133	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.013551	0.033318	-0.07885	0.051751	1.07E7	-0.041002	0.012287

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-0.41	0.6842

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Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=P9P_FLUC Label=Faster aspart (meal) / NovoRapid (meal) Parameter=Fluctuation (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000051118	0.001067	0.001118	9.56E6	0.047926	0.045734	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.012922	0.033433	-0.07845	0.052606	9.56E6	-0.042312	0.013406

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-0.39	0.6991

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Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 1547 of 4425	Novo Nordisk
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Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=P9P_FLUC Label=Faster aspart (post) / NovoRapid (meal) Parameter=Fluctuation (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000047878	0.001062	0.001110	1.07E7	0.045077	0.043133	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.013551	0.033318	-0.07885	0.051751	1.07E7	-0.041002	0.012287

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-0.41	0.6842

nn1218/nn1218-4131/ctr_20180214_er
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Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Model Information

Parameter Code=P9PFLUCU Parameter=Fluctuation (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Data Set	WORK.IMPUTE_ABS
2	1	NN1218-4131	Dependent Variable	eotVisitAbs
3	1	NN1218-4131	Covariance Structure	Diagonal
4	1	NN1218-4131	Estimation Method	REML
5	1	NN1218-4131	Residual Variance Method	Profile
6	1	NN1218-4131	Fixed Effects SE Method	Model-Based
7	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=P9P_FLUC Parameter=Fluctuation (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
8	1	NN1218-4131	Data Set	WORK.IMPUTE_ABS
9	1	NN1218-4131	Dependent Variable	eotVisitAbs
10	1	NN1218-4131	Covariance Structure	Diagonal
11	1	NN1218-4131	Estimation Method	REML
12	1	NN1218-4131	Residual Variance Method	Profile
13	1	NN1218-4131	Fixed Effects SE Method	Model-Based
14	1	NN1218-4131	Degrees of Freedom Method	Residual

Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Class Level Information

Parameter Code=P9PFLUCU Parameter=Fluctuation (SMPG) (mg/dL)

Ob- s	—	Input ID	STUDY	Class	Level	Values	min
1	1	NN1218-4131	TRTPN		3 2 3 4		5
2	1	NN1218-4131	REGION1		4 ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA		49
3	1	NN1218-4131	BOLAD1		2 BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULI		85

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Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Dimensions

Parameter Code=P9PFLUCU Parameter=Fluctuation (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Covariance Parameters	1
2	1	NN1218-4131	Columns in X	10
3	1	NN1218-4131	Columns in Z	0
4	1	NN1218-4131	Subjects	1
5	1	NN1218-4131	Max Obs per Subject	989

Parameter Code=P9P_FLUC Parameter=Fluctuation (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
6	1	NN1218-4131	Covariance Parameters	1
7	1	NN1218-4131	Columns in X	10
8	1	NN1218-4131	Columns in Z	0
9	1	NN1218-4131	Subjects	1
10	1	NN1218-4131	Max Obs per Subject	989

Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Number of Observations

Parameter Code=P9PFLUCU Parameter=Fluctuation (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
1	1	NN1218-4131	Number of Observations Read	989	989	989	989	989
2	1	NN1218-4131	Number of Observations Used	989	989	989	989	989
3	1	NN1218-4131	Number of Observations Not Used	0	989	989	989	989

Parameter Code=P9P_FLUC Parameter=Fluctuation (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
4	1	NN1218-4131	Number of Observations Read	989	989	989	989	989
5	1	NN1218-4131	Number of Observations Used	989	989	989	989	989
6	1	NN1218-4131	Number of Observations Not Used	0	989	989	989	989

Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Covariance Parameter Estimates

Parameter Code=P9PFLUCU Parameter=Fluctuation (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	CovParm	Estimate
1	1	NN1218-4131	Residual	0.1758

Parameter Code=P9P_FLUC Parameter=Fluctuation (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	CovParm	Estimate
20001	1	NN1218-4131	Residual	0.1758

Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Fit Statistics

Parameter Code=P9PFLUCU Parameter=Fluctuation (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	-2 Res Log Likelihood	1121.2
2	1	NN1218-4131	AIC (Smaller is Better)	1123.2
3	1	NN1218-4131	AICC (Smaller is Better)	1123.2
4	1	NN1218-4131	BIC (Smaller is Better)	1128.1

Parameter Code=P9P_FLUC Parameter=Fluctuation (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
5	1	NN1218-4131	-2 Res Log Likelihood	1121.2
6	1	NN1218-4131	AIC (Smaller is Better)	1123.2
7	1	NN1218-4131	AICC (Smaller is Better)	1123.2
8	1	NN1218-4131	BIC (Smaller is Better)	1128.1

Fast-acting insulin aspart
NN1218-4131

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The Mixed procedure
Solution for Fixed Effects

Parameter Code=P9PFLUCU Parameter=Fluctuation (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1
1	1	NN1218-4131	TRTPN	2		
2	1	NN1218-4131	TRTPN	3		
3	1	NN1218-4131	TRTPN	4		
4	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)	
5	1	NN1218-4131	REGION1	—	EUROPE	
6	1	NN1218-4131	REGION1	—	JAPAN	
7	1	NN1218-4131	REGION1	—	NORTH AMERICA	
8	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)
9	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY
10	1	NN1218-4131	BASE	—		

Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	1.1087	0.1268	981	8.75	<.0001	0.05	0.8599	1.3575
2	1.1090	0.1274	981	8.71	<.0001	0.05	0.8590	1.3589
3	1.1123	0.1266	981	8.78	<.0001	0.05	0.8638	1.3609
4	-0.07527	0.04898	981	-1.54	0.1247	0.05	-0.1714	0.02085
5	-0.09793	0.03522	981	-2.78	0.0055	0.05	-0.1670	-0.02880
6	0.09589	0.03884	981	2.47	0.0137	0.05	0.01968	0.1721
7	0
8	-0.08371	0.03019	981	-2.77	0.0057	0.05	-0.1430	-0.02446
9	0
10	0.6722	0.03376	981	19.91	<.0001	0.05	0.6060	0.7385

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The Mixed procedure
Solution for Fixed Effects

Parameter Code=P9P_FLUC Parameter=Fluctuation (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1
11	1	NN1218-4131	TRTPN	2		
12	1	NN1218-4131	TRTPN	3		
13	1	NN1218-4131	TRTPN	4		
14	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)	
15	1	NN1218-4131	REGION1	—	EUROPE	
16	1	NN1218-4131	REGION1	—	JAPAN	
17	1	NN1218-4131	REGION1	—	NORTH AMERICA	
18	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)
19	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY
20	1	NN1218-4131	BASE	—		

Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
11	0.1610	0.04092	981	3.93	<.0001	0.05	0.08070	0.2413
12	0.1612	0.04160	981	3.88	0.0001	0.05	0.07960	0.2429
13	0.1646	0.04117	981	4.00	<.0001	0.05	0.08383	0.2454
14	-0.07527	0.04898	981	-1.54	0.1247	0.05	-0.1714	0.02085
15	-0.09793	0.03522	981	-2.78	0.0055	0.05	-0.1670	-0.02880
16	0.09589	0.03884	981	2.47	0.0137	0.05	0.01968	0.1721
17	0
18	-0.08371	0.03019	981	-2.77	0.0057	0.05	-0.1430	-0.02446
19	0
20	0.6722	0.03376	981	19.91	<.0001	0.05	0.6060	0.7385

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Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis -
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The Mixed procedure
Least Squares Means

Obs	_Imputation_	PARAMCD	PARAM	STUDYID	Effect	TRTPN
1	1	P9PFLUCU	Fluctuation (SMPG) (mg/dL)	NN1218-4131	TRTPN	2
20001	1	P9P_FLUC	Fluctuation (SMPG) (mmol/L)	NN1218-4131	TRTPN	2
40001	1	P9PFLUCU	Fluctuation (SMPG) (mg/dL)	NN1218-4131	TRTPN	3
60001	1	P9P_FLUC	Fluctuation (SMPG) (mmol/L)	NN1218-4131	TRTPN	3
80001	1	P9PFLUCU	Fluctuation (SMPG) (mg/dL)	NN1218-4131	TRTPN	4
100001	1	P9P_FLUC	Fluctuation (SMPG) (mmol/L)	NN1218-4131	TRTPN	4

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	WORK.IMPUTE	-0.1299	0.02315	981	-5.61	<.0001	0.05	-0.1753	-0.08443
20001	WORK.IMPUTE	-0.1299	0.02315	981	-5.61	<.0001	0.05	-0.1753	-0.08443
40001	WORK.IMPUTE	-0.1296	0.02307	981	-5.62	<.0001	0.05	-0.1749	-0.08434
60001	WORK.IMPUTE	-0.1296	0.02307	981	-5.62	<.0001	0.05	-0.1749	-0.08434
80001	WORK.IMPUTE	-0.1262	0.02314	981	-5.46	<.0001	0.05	-0.1716	-0.08082
100001	WORK.IMPUTE	-0.1262	0.02314	981	-5.46	<.0001	0.05	-0.1716	-0.08082

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Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Least Squares Means Estimate

Parameter Code=P9PFLUCU Parameter=Fluctuation (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
1	1	NN1218-4131	1	TRTPN	Faster aspart (meal) / NovoRapid (meal)
20001	1	NN1218-4131	2	TRTPN	Faster aspart (post) / NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	WORK.IMPUTE	-0.00363	0.03275	981	-0.11	0.9118	0.05	-0.06790	0.06064
20001	WORK.IMPUTE	-0.00338	0.03268	981	-0.10	0.9176	0.05	-0.06752	0.06075

Parameter Code=P9P_FLUC Parameter=Fluctuation (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
40001	1	NN1218-4131	1	TRTPN	Faster aspart (meal) / NovoRapid (meal)
60001	1	NN1218-4131	2	TRTPN	Faster aspart (post) / NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
40001	WORK.IMPUTE	-0.00363	0.03275	981	-0.11	0.9118	0.05	-0.06790	0.06064
60001	WORK.IMPUTE	-0.00338	0.03268	981	-0.10	0.9176	0.05	-0.06752	0.06075

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Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9PFLUCU Parameter=Fluctuation (SMPG) (mg/dL) Study Identifier=NN1218-41

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000027383	0.000533	0.000560	8.37E6	0.051386	0.048875	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	3.436118	0.023671	3.389724	3.482511	8.37E6	3.417589	3.458583

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	145.16	<.0001

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Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9P_FLUC Parameter=Fluctuation (SMPG) (mmol/L) Study Identifier=NN1218-4

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000027383	0.000533	0.000560	8.37E6	0.051386	0.048875	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.544635	0.023671	0.498242	0.591029	8.37E6	0.526107	0.567101

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	23.01	<.0001

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Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9PFLUCU Parameter=Fluctuation (SMPG) (mg/dL) Study Identifier=NN1218-41

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000023644	0.000529	0.000553	1.09E7	0.044676	0.042765	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	3.435489	0.023514	3.389402	3.481576	1.09E7	3.416166	3.453798

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	146.10	<.0001

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Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9P_FLUC Parameter=Fluctuation (SMPG) (mmol/L) Study Identifier=NN1218-4

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000023644	0.000529	0.000553	1.09E7	0.044676	0.042765	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.544007	0.023514	0.497920	0.590094	1.09E7	0.524683	0.562316

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	23.14	<.0001

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Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9PFLUCU Parameter=Fluctuation (SMPG) (mg/dL) Study Identifier=NN1218-41

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000024042	0.000532	0.000556	1.07E7	0.045164	0.043212	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	3.449040	0.023588	3.402808	3.495271	1.07E7	3.430462	3.471250

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	146.22	<.0001

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Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9P_FLUC Parameter=Fluctuation (SMPG) (mmol/L) Study Identifier=NN1218-4

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000024042	0.000532	0.000556	1.07E7	0.045164	0.043212	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.557557	0.023588	0.511326	0.603789	1.07E7	0.538980	0.579768

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	23.64	<.0001

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21: Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=P9PFLUCU Planned Treatment for Period 30 (N)=2

Obs	PARAM	Description	Value
1	Fluctuation (SMPG) (mg/dL)	Data Set	WORK.ENDPOINT_PARAM
2	Fluctuation (SMPG) (mg/dL)	Method	Monotone-data_MCMC
3	Fluctuation (SMPG) (mg/dL)	Multiple Imputation Chain	Multiple Chains
4	Fluctuation (SMPG) (mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
5	Fluctuation (SMPG) (mg/dL)	Start	Starting Value
6	Fluctuation (SMPG) (mg/dL)	Prior	Jeffreys
7	Fluctuation (SMPG) (mg/dL)	Number of Imputations	20000
8	Fluctuation (SMPG) (mg/dL)	Number of Burn-in Iterations	200
9	Fluctuation (SMPG) (mg/dL)	Seed for random number generator	1234

Parameter Code=P9PFLUCU Planned Treatment for Period 30 (N)=3

Obs	PARAM	Description	Value
10	Fluctuation (SMPG) (mg/dL)	Data Set	WORK.ENDPOINT_PARAM
11	Fluctuation (SMPG) (mg/dL)	Method	Monotone-data_MCMC
12	Fluctuation (SMPG) (mg/dL)	Multiple Imputation Chain	Multiple Chains
13	Fluctuation (SMPG) (mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
14	Fluctuation (SMPG) (mg/dL)	Start	Starting Value
15	Fluctuation (SMPG) (mg/dL)	Prior	Jeffreys
16	Fluctuation (SMPG) (mg/dL)	Number of Imputations	20000
17	Fluctuation (SMPG) (mg/dL)	Number of Burn-in Iterations	200
18	Fluctuation (SMPG) (mg/dL)	Seed for random number generator	1280580680

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Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=P9PFLUCU Planned Treatment for Period 30 (N)=4

Obs	PARAM	Description	Value
19	Fluctuation (SMPG) (mg/dL)	Data Set	WORK.ENDPOINT_PARAM
20	Fluctuation (SMPG) (mg/dL)	Method	Monotone-data_MCMC
21	Fluctuation (SMPG) (mg/dL)	Multiple Imputation Chain	Multiple Chains
22	Fluctuation (SMPG) (mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
23	Fluctuation (SMPG) (mg/dL)	Start	Starting Value
24	Fluctuation (SMPG) (mg/dL)	Prior	Jeffreys
25	Fluctuation (SMPG) (mg/dL)	Number of Imputations	20000
26	Fluctuation (SMPG) (mg/dL)	Number of Burn-in Iterations	200
27	Fluctuation (SMPG) (mg/dL)	Seed for random number generator	663706498

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The MI Procedure with MCMC
Missing data pattern

Parameter Code=P9PFLUCU Planned Treatment for Period 30 (N)=2

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
1	Fluctuation (SMPG) (mg/dL)	1	X	X	X	294	89.36	3.565678	-0.085374	-0.127628
2	Fluctuation (SMPG) (mg/dL)	2	X	X	O	9	2.74	3.518092	0.068401	.
3	Fluctuation (SMPG) (mg/dL)	3	X	.	X	16	4.86	3.580619	.	-0.318652
4	Fluctuation (SMPG) (mg/dL)	4	X	O	O	10	3.04	3.531641	.	.

Parameter Code=P9PFLUCU Planned Treatment for Period 30 (N)=3

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
5	Fluctuation (SMPG) (mg/dL)	1	X	X	X	302	91.24	3.589227	-0.128060	-0.138335
6	Fluctuation (SMPG) (mg/dL)	2	X	X	O	12	3.63	3.598043	-0.009609	.
7	Fluctuation (SMPG) (mg/dL)	3	X	.	X	12	3.63	3.471679	.	-0.082594
8	Fluctuation (SMPG) (mg/dL)	4	X	O	O	5	1.51	3.644410	.	.

Parameter Code=P9PFLUCU Planned Treatment for Period 30 (N)=4

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
9	Fluctuation (SMPG) (mg/dL)	1	X	X	X	295	89.67	3.560496	-0.050843	-0.106132
10	Fluctuation (SMPG) (mg/dL)	2	X	X	O	12	3.65	3.575880	-0.118377	.
11	Fluctuation (SMPG) (mg/dL)	3	X	.	X	11	3.34	3.563244	.	-0.318211
12	Fluctuation (SMPG) (mg/dL)	4	X	O	O	11	3.34	3.677152	.	.

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Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PFLUCU Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM	Description	Value
1	1	Fluctuation (SMPG) (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	Fluctuation (SMPG) (mg/dL)	Method	Monotone
3	1	Fluctuation (SMPG) (mg/dL)	Number of Imputations	1
4	1	Fluctuation (SMPG) (mg/dL)	Seed for random number generator	4321

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PFLUCU Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	Fluctuation (SMPG) (mg/dL)	Intercept	
2	1	Fluctuation (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	Fluctuation (SMPG) (mg/dL)	REGION1	EUROPE
4	1	Fluctuation (SMPG) (mg/dL)	REGION1	JAPAN
5	1	Fluctuation (SMPG) (mg/dL)	BOLAD1	
6	1	Fluctuation (SMPG) (mg/dL)	BASE	

Obs	BOLAD1	ObsVal	_1
1		0.01378	0.051823
2		-0.14174	-0.105301
3		-0.30756	-0.463076
4		0.15086	0.132496
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.08837	-0.143050
6		-0.25296	-0.303404

Parameter Code=P9PFLUCU Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	Fluctuation (SMPG) (mg/dL)	Intercept			0.05102	0.024475
8	1	Fluctuation (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)		0.07704	-0.002385
9	1	Fluctuation (SMPG) (mg/dL)	REGION1	EUROPE		-0.09474	0.001224

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Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PFLUCU Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
10	1	Fluctuation (SMPG) (mg/dL)	REGION1	JAPAN		0.07504	-0.057990
11	1	Fluctuation (SMPG) (mg/dL)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.13787	-0.104953
12	1	Fluctuation (SMPG) (mg/dL)	BASE			-0.12039	-0.032876
13	1	Fluctuation (SMPG) (mg/dL)	visit2200			0.57846	0.633975

Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PFLUCU Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM	Description	Value
1	1	Fluctuation (SMPG) (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	Fluctuation (SMPG) (mg/dL)	Method	Monotone
3	1	Fluctuation (SMPG) (mg/dL)	Number of Imputations	1
4	1	Fluctuation (SMPG) (mg/dL)	Seed for random number generator	4322

Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression Missing Data Pattern

Parameter Code=P9PFLUCU Planned Treatment for Period 30 (N)=3

O b s	I m p u t a t i o n —	P A R A M	G r o u p	R E G I O N 1					B O L A S E					F r e q	P e r c e n t	B A S E	v i s i t 2 0 0	v i s i t 3 6 0 0
				\bar{M} i s s	\bar{M} i s s	\bar{M} i s s	\bar{M} i s s	\bar{M} i s s										
1	1	Fluctuation (SMPG) (mg/dL)	1	X	X	X	X	X	314	94.86	3.584735	-0.129049	-0.136205					
2	1	Fluctuation (SMPG) (mg/dL)	2	X	X	X	X	.	12	3.63	3.598043	-0.009609	.					
3	1	Fluctuation (SMPG) (mg/dL)	3	X	X	X	.	.	5	1.51	3.644410	.	.					

Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PFLUCU Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	Fluctuation (SMPG) (mg/dL)	Intercept	
2	1	Fluctuation (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	Fluctuation (SMPG) (mg/dL)	REGION1	EUROPE
4	1	Fluctuation (SMPG) (mg/dL)	REGION1	JAPAN
5	1	Fluctuation (SMPG) (mg/dL)	BOLAD1	
6	1	Fluctuation (SMPG) (mg/dL)	BASE	

Obs	BOLAD1	ObsVal	_1
1		0.00579	0.116762
2		-0.14360	0.005578
3		-0.17015	-0.170078
4		0.27415	0.171837
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.12439	-0.094101
6		-0.20111	-0.249640

Parameter Code=P9PFLUCU Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	Fluctuation (SMPG) (mg/dL)	Intercept			-0.05437	-0.120896
8	1	Fluctuation (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)		-0.33112	-0.435283
9	1	Fluctuation (SMPG) (mg/dL)	REGION1	EUROPE		0.11445	0.138931

Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PFLUCU Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
10	1	Fluctuation (SMPG) (mg/dL)	REGION1	JAPAN		0.20707	0.205649
11	1	Fluctuation (SMPG) (mg/dL)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.00747	-0.007716
12	1	Fluctuation (SMPG) (mg/dL)	BASE			-0.02763	0.032930
13	1	Fluctuation (SMPG) (mg/dL)	visit2200			0.51425	0.496452

Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PFLUCU Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM	Description	Value
1	1	Fluctuation (SMPG) (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	Fluctuation (SMPG) (mg/dL)	Method	Monotone
3	1	Fluctuation (SMPG) (mg/dL)	Number of Imputations	1
4	1	Fluctuation (SMPG) (mg/dL)	Seed for random number generator	4323

Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression Missing Data Pattern

Parameter Code=P9PFLUCU Planned Treatment for Period 30 (N)=4

O b s	I m p u t a t i o n —	P A R A M	G r o u p	R E G I O N 1 1					B O L A S E	v i s i t 2 2 0	v i s i t 3 6 0	F r e q	P e r c e n t	B A S E	v i s i t 2 0 0	v i s i t 3 6 0
				\bar{M}	\bar{M}	\bar{M}	\bar{M}	\bar{M}								
1	1	Fluctuation (SMPG) (mg/dL)	1	X	X	X	X	X	306	93.01	3.560595	-0.051017	-0.113756			
2	1	Fluctuation (SMPG) (mg/dL)	2	X	X	X	X	.	12	3.65	3.575880	-0.118377	.			
3	1	Fluctuation (SMPG) (mg/dL)	3	X	X	X	.	.	11	3.34	3.677152	.	.			

Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PFLUCU Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	Fluctuation (SMPG) (mg/dL)	Intercept	
2	1	Fluctuation (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	Fluctuation (SMPG) (mg/dL)	REGION1	EUROPE
4	1	Fluctuation (SMPG) (mg/dL)	REGION1	JAPAN
5	1	Fluctuation (SMPG) (mg/dL)	BOLAD1	
6	1	Fluctuation (SMPG) (mg/dL)	BASE	

Obs	BOLAD1	ObsVal	_1
1		0.01100	-0.040737
2		-0.08431	-0.024486
3		-0.19034	-0.321279
4		0.18011	0.228222
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.06574	-0.072612
6		-0.40101	-0.500596

Parameter Code=P9PFLUCU Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	Fluctuation (SMPG) (mg/dL)	Intercept			0.01094	-0.018855
8	1	Fluctuation (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)		0.02154	0.013130
9	1	Fluctuation (SMPG) (mg/dL)	REGION1	EUROPE		-0.18600	-0.240221

Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PFLUCU Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
10	1	Fluctuation (SMPG) (mg/dL)	REGION1	JAPAN		0.22233	0.281169
11	1	Fluctuation (SMPG) (mg/dL)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.01515	0.035386
12	1	Fluctuation (SMPG) (mg/dL)	BASE			-0.31196	-0.323567
13	1	Fluctuation (SMPG) (mg/dL)	visit2200			0.45880	0.521827

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The MI Procedure with MCMC
Model Information

Parameter Code=P9P_FLUC Planned Treatment for Period 30 (N)=2

Obs	PARAM	Description	Value
1	Fluctuation (SMPG) (mmol/L)	Data Set	WORK.ENDPOINT_PARAM
2	Fluctuation (SMPG) (mmol/L)	Method	Monotone-data_MCMC
3	Fluctuation (SMPG) (mmol/L)	Multiple Imputation Chain	Multiple Chains
4	Fluctuation (SMPG) (mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
5	Fluctuation (SMPG) (mmol/L)	Start	Starting Value
6	Fluctuation (SMPG) (mmol/L)	Prior	Jeffreys
7	Fluctuation (SMPG) (mmol/L)	Number of Imputations	20000
8	Fluctuation (SMPG) (mmol/L)	Number of Burn-in Iterations	200
9	Fluctuation (SMPG) (mmol/L)	Seed for random number generator	1234

Parameter Code=P9P_FLUC Planned Treatment for Period 30 (N)=3

Obs	PARAM	Description	Value
10	Fluctuation (SMPG) (mmol/L)	Data Set	WORK.ENDPOINT_PARAM
11	Fluctuation (SMPG) (mmol/L)	Method	Monotone-data_MCMC
12	Fluctuation (SMPG) (mmol/L)	Multiple Imputation Chain	Multiple Chains
13	Fluctuation (SMPG) (mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
14	Fluctuation (SMPG) (mmol/L)	Start	Starting Value
15	Fluctuation (SMPG) (mmol/L)	Prior	Jeffreys
16	Fluctuation (SMPG) (mmol/L)	Number of Imputations	20000
17	Fluctuation (SMPG) (mmol/L)	Number of Burn-in Iterations	200
18	Fluctuation (SMPG) (mmol/L)	Seed for random number generator	1280580680

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The MI Procedure with MCMC
Model Information

Parameter Code=P9P_FLUC Planned Treatment for Period 30 (N)=4

Obs	PARAM		Description	Value
19	Fluctuation	(SMPG) (mmol/L)	Data Set	WORK.ENDPOINT_PARAM
20	Fluctuation	(SMPG) (mmol/L)	Method	Monotone-data_MCMC
21	Fluctuation	(SMPG) (mmol/L)	Multiple Imputation Chain	Multiple Chains
22	Fluctuation	(SMPG) (mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
23	Fluctuation	(SMPG) (mmol/L)	Start	Starting Value
24	Fluctuation	(SMPG) (mmol/L)	Prior	Jeffreys
25	Fluctuation	(SMPG) (mmol/L)	Number of Imputations	20000
26	Fluctuation	(SMPG) (mmol/L)	Number of Burn-in Iterations	200
27	Fluctuation	(SMPG) (mmol/L)	Seed for random number generator	663706498

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on-treatment - full analysis set

The MI Procedure with MCMC
Missing data pattern

Parameter Code=P9P_FLUC Planned Treatment for Period 30 (N)=2

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
1	Fluctuation (SMPG) (mmol/L)	1	X	X	X	294	89.36	0.674196	-0.085374	-0.127628
2	Fluctuation (SMPG) (mmol/L)	2	X	X	O	9	2.74	0.626610	0.068401	.
3	Fluctuation (SMPG) (mmol/L)	3	X	.	X	16	4.86	0.689137	.	-0.318652
4	Fluctuation (SMPG) (mmol/L)	4	X	O	O	10	3.04	0.640159	.	.

Parameter Code=P9P_FLUC Planned Treatment for Period 30 (N)=3

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
5	Fluctuation (SMPG) (mmol/L)	1	X	X	X	302	91.24	0.697745	-0.128060	-0.138335
6	Fluctuation (SMPG) (mmol/L)	2	X	X	O	12	3.63	0.706561	-0.009609	.
7	Fluctuation (SMPG) (mmol/L)	3	X	.	X	12	3.63	0.580197	.	-0.082594
8	Fluctuation (SMPG) (mmol/L)	4	X	O	O	5	1.51	0.752928	.	.

Parameter Code=P9P_FLUC Planned Treatment for Period 30 (N)=4

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
9	Fluctuation (SMPG) (mmol/L)	1	X	X	X	295	89.67	0.669014	-0.050843	-0.106132
10	Fluctuation (SMPG) (mmol/L)	2	X	X	O	12	3.65	0.684398	-0.118377	.
11	Fluctuation (SMPG) (mmol/L)	3	X	.	X	11	3.34	0.671762	.	-0.318211
12	Fluctuation (SMPG) (mmol/L)	4	X	O	O	11	3.34	0.785670	.	.

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Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9P_FLUC Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM	Description	Value
1	1	Fluctuation (SMPG) (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	Fluctuation (SMPG) (mmol/L)	Method	Monotone
3	1	Fluctuation (SMPG) (mmol/L)	Number of Imputations	1
4	1	Fluctuation (SMPG) (mmol/L)	Seed for random number generator	4321

Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression Missing Data Pattern

Parameter Code=P9P FLUC Planned Treatment for Period 30 (N)=2

	O b s	I m p u t a t i o n _	P A R A M	G r o u p	R E G I O N l	B O L A D l	B A S E	V i s i t 2	V i s i t 3	F r e q	P e r c e n t	B A S E	v i s i t 2	v i s i t 3
1	1	Fluctuation	(SMPG)	(mmol/L)	1	X	X	X	X	310	94.22	0.674967	-0.092845	-0.137487
2	1	Fluctuation	(SMPG)	(mmol/L)	2	X	X	X	X	9	2.74	0.626610	0.068401	.
3	1	Fluctuation	(SMPG)	(mmol/L)	3	X	X	X	.	10	3.04	0.640159	.	.

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9P_FLUC Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	Fluctuation (SMPG) (mmol/L)	Intercept	
2	1	Fluctuation (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	Fluctuation (SMPG) (mmol/L)	REGION1	EUROPE
4	1	Fluctuation (SMPG) (mmol/L)	REGION1	JAPAN
5	1	Fluctuation (SMPG) (mmol/L)	BOLAD1	
6	1	Fluctuation (SMPG) (mmol/L)	BASE	

Obs	BOLAD1	ObsVal	_1
1		0.01378	0.051823
2		-0.14174	-0.105301
3		-0.30756	-0.463076
4		0.15086	0.132496
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.08837	-0.143050
6		-0.25296	-0.303404

Parameter Code=P9P_FLUC Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	Fluctuation (SMPG) (mmol/L)	Intercept			0.05102	0.024475
8	1	Fluctuation (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)		0.07704	-0.002385
9	1	Fluctuation (SMPG) (mmol/L)	REGION1	EUROPE		-0.09474	0.001224

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The MI Procedure with Monotone Regression Regression Information

Parameter Code=P9P FLUC Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

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	O	b	s		P	E	R	B	O	
					A	f	E	O	b	
					R	e	G	L	s	
					A	c	I	A	V	
					M	t	N	D	a	
							1	1	l	\bar{I}
10	1	Fluctuation	(SMPG)	(mmol/L)	REGION1	JAPAN			0.07504	-0.057990
11	1	Fluctuation	(SMPG)	(mmol/L)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.13787	-0.104953
12	1	Fluctuation	(SMPG)	(mmol/L)	BASE				-0.12039	-0.032876
13	1	Fluctuation	(SMPG)	(mmol/L)	visit2200				0.57846	0.633975

Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9P_FLUC Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM	Description	Value
1	1	Fluctuation (SMPG) (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	Fluctuation (SMPG) (mmol/L)	Method	Monotone
3	1	Fluctuation (SMPG) (mmol/L)	Number of Imputations	1
4	1	Fluctuation (SMPG) (mmol/L)	Seed for random number generator	4322

Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression Missing Data Pattern

Parameter Code=P9P_FLUC Planned Treatment for Period 30 (N)=3

O b s	I m p u t a t i o n _	P A R A M	G r o u p	R E G I O N 1 1 1 1 1					B O L A S E		F r e q	P e r c e n t	B A S E	v i s i t 2 0 0	v i s i t 3 6 0 0
				\bar{M}	\bar{M}	\bar{M}	\bar{M}	\bar{M}	\bar{M}	\bar{M}					
				i s s s s	i s s s s	i s s s s	i s s s s	i s s s s	i s s s s	i s s s s					
1	1	Fluctuation (SMPG)	(mmol/L)	1	X	X	X	X	X	X	314	94.86	0.693253	-0.129049	-0.136205
2	1	Fluctuation (SMPG)	(mmol/L)	2	X	X	X	X	X	.	12	3.63	0.706561	-0.009609	.
3	1	Fluctuation (SMPG)	(mmol/L)	3	X	X	X	X	.	.	5	1.51	0.752928	.	.

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9P_FLUC Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	Fluctuation (SMPG) (mmol/L)	Intercept	
2	1	Fluctuation (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	Fluctuation (SMPG) (mmol/L)	REGION1	EUROPE
4	1	Fluctuation (SMPG) (mmol/L)	REGION1	JAPAN
5	1	Fluctuation (SMPG) (mmol/L)	BOLAD1	
6	1	Fluctuation (SMPG) (mmol/L)	BASE	

Obs		BOLAD1	ObsVal	_1
1			0.00579	0.116762
2			-0.14360	0.005578
3			-0.17015	-0.170078
4			0.27415	0.171837
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.12439	-0.094101
6			-0.20111	-0.249640

Parameter Code=P9P_FLUC Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	Fluctuation (SMPG) (mmol/L)	Intercept			-0.05437	-0.120896
8	1	Fluctuation (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)		-0.33112	-0.435283
9	1	Fluctuation (SMPG) (mmol/L)	REGION1	EUROPE		0.11445	0.138931

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Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9P_FLUC Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

(continued)

O b s —		P A R M		E f f e c t		R E G I O N		B O L U S		O b s e r v e d		I m p u t e d	
10	1	Fluctuation	(SMPG)	(mmol/L)	REGION1	JAPAN				0.20707	0.205649		
11	1	Fluctuation	(SMPG)	(mmol/L)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)			0.00747	-0.007716		
12	1	Fluctuation	(SMPG)	(mmol/L)	BASE					-0.02763	0.032930		
13	1	Fluctuation	(SMPG)	(mmol/L)	visit2200					0.51425	0.496452		

Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9P_FLUC Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM	Description	Value
1	1	Fluctuation (SMPG) (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	Fluctuation (SMPG) (mmol/L)	Method	Monotone
3	1	Fluctuation (SMPG) (mmol/L)	Number of Imputations	1
4	1	Fluctuation (SMPG) (mmol/L)	Seed for random number generator	4323

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Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9P_FLUC Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	Fluctuation (SMPG) (mmol/L)	Intercept	
2	1	Fluctuation (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	Fluctuation (SMPG) (mmol/L)	REGION1	EUROPE
4	1	Fluctuation (SMPG) (mmol/L)	REGION1	JAPAN
5	1	Fluctuation (SMPG) (mmol/L)	BOLAD1	
6	1	Fluctuation (SMPG) (mmol/L)	BASE	

Obs		BOLAD1	ObsVal	_1
1			0.01100	-0.040737
2			-0.08431	-0.024486
3			-0.19034	-0.321279
4			0.18011	0.228222
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.06574	-0.072612
6			-0.40101	-0.500596

Parameter Code=P9P_FLUC Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	Fluctuation (SMPG) (mmol/L)	Intercept			0.01094	-0.018855
8	1	Fluctuation (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)		0.02154	0.013130
9	1	Fluctuation (SMPG) (mmol/L)	REGION1	EUROPE		-0.18600	-0.240221

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9P_FLUC Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

(continued)

O b s —		P A R M		E f f e c t		R E G I O N		B O L U S		O b s e r v e d		T	
10	1	Fluctuation	(SMPG)	(mmol/L)	REGION1	JAPAN				0.22233		0.281169	
11	1	Fluctuation	(SMPG)	(mmol/L)	BOLAD1		BOLUS	INSULIN	ALGORITHM (SLIDING SCALE)	-0.01515		0.035386	
12	1	Fluctuation	(SMPG)	(mmol/L)	BASE					-0.31196		-0.323567	
13	1	Fluctuation	(SMPG)	(mmol/L)	visit2200					0.45880		0.521827	

Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Model Information

Parameter Code=P9PFLUCU Parameter=Fluctuation (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Data Set	WORK.IMPUTE
2	1	NN1218-4131	Dependent Variable	eotVisit
3	1	NN1218-4131	Covariance Structure	Diagonal
4	1	NN1218-4131	Estimation Method	REML
5	1	NN1218-4131	Residual Variance Method	Profile
6	1	NN1218-4131	Fixed Effects SE Method	Model-Based
7	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=P9P_FLUC Parameter=Fluctuation (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
8	1	NN1218-4131	Data Set	WORK.IMPUTE
9	1	NN1218-4131	Dependent Variable	eotVisit
10	1	NN1218-4131	Covariance Structure	Diagonal
11	1	NN1218-4131	Estimation Method	REML
12	1	NN1218-4131	Residual Variance Method	Profile
13	1	NN1218-4131	Fixed Effects SE Method	Model-Based
14	1	NN1218-4131	Degrees of Freedom Method	Residual

Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Class Level Information

Parameter Code=P9PFLUCU Parameter=Fluctuation (SMPG) (mg/dL)

Ob- s	Input ID	STUDY	Class	Level	Values	min
1	1	NN1218-4131	TRTPN	3	2 3 4	5
2	1	NN1218-4131	REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA	49
3	1	NN1218-4131	BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULI	85

Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Class Level Information

Parameter Code=P9P FLUC Parameter=Fluctuation (SMPG) (mmol/L)

Ob- s	—	Input ID	STUDY	Class	Level	Values	min
4	1	NN1218-4131	TRTPN		3 2 3 4		5
5	1	NN1218-4131	REGION1		4 ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA		49
6	1	NN1218-4131	BOLAD1		2 BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULI		85

Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Dimensions

Parameter Code=P9PFLUCU Parameter=Fluctuation (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Covariance Parameters	1
2	1	NN1218-4131	Columns in X	10
3	1	NN1218-4131	Columns in Z	0
4	1	NN1218-4131	Subjects	1
5	1	NN1218-4131	Max Obs per Subject	989

Parameter Code=P9P_FLUC Parameter=Fluctuation (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
6	1	NN1218-4131	Covariance Parameters	1
7	1	NN1218-4131	Columns in X	10
8	1	NN1218-4131	Columns in Z	0
9	1	NN1218-4131	Subjects	1
10	1	NN1218-4131	Max Obs per Subject	989

Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Number of Observations

Parameter Code=P9PFLUCU Parameter=Fluctuation (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
1	1	NN1218-4131	Number of Observations Read	989	989	989	989	989
2	1	NN1218-4131	Number of Observations Used	989	989	989	989	989
3	1	NN1218-4131	Number of Observations Not Used	0	989	989	989	989

Parameter Code=P9P_FLUC Parameter=Fluctuation (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
4	1	NN1218-4131	Number of Observations Read	989	989	989	989	989
5	1	NN1218-4131	Number of Observations Used	989	989	989	989	989
6	1	NN1218-4131	Number of Observations Not Used	0	989	989	989	989

Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Covariance Parameter Estimates

Parameter Code=P9PFLUCU Parameter=Fluctuation (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	CovParm	Estimate
1	1	NN1218-4131	Residual	0.1739

Parameter Code=P9P_FLUC Parameter=Fluctuation (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	CovParm	Estimate
20001	1	NN1218-4131	Residual	0.1739

Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Fit Statistics

Parameter Code=P9PFLUCU Parameter=Fluctuation (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	-2 Res Log Likelihood	1110.4
2	1	NN1218-4131	AIC (Smaller is Better)	1112.4
3	1	NN1218-4131	AICC (Smaller is Better)	1112.4
4	1	NN1218-4131	BIC (Smaller is Better)	1117.3

Parameter Code=P9P_FLUC Parameter=Fluctuation (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
5	1	NN1218-4131	-2 Res Log Likelihood	1110.4
6	1	NN1218-4131	AIC (Smaller is Better)	1112.4
7	1	NN1218-4131	AICC (Smaller is Better)	1112.4
8	1	NN1218-4131	BIC (Smaller is Better)	1117.3

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Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis -
on-treatment - full analysis set

The Mixed procedure
Solution for Fixed Effects

Parameter Code=P9PFLUCU Parameter=Fluctuation (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1
1	1	NN1218-4131	TRTPN	2		
2	1	NN1218-4131	TRTPN	3		
3	1	NN1218-4131	TRTPN	4		
4	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)	
5	1	NN1218-4131	REGION1	—	EUROPE	
6	1	NN1218-4131	REGION1	—	JAPAN	
7	1	NN1218-4131	REGION1	—	NORTH AMERICA	
8	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)
9	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY
10	1	NN1218-4131	BASE	—		

Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	1.0797	0.1261	981	8.56	<.0001	0.05	0.8322	1.3271
2	1.0767	0.1267	981	8.50	<.0001	0.05	0.8281	1.3253
3	1.0804	0.1259	981	8.58	<.0001	0.05	0.8332	1.3275
4	-0.07076	0.04871	981	-1.45	0.1466	0.05	-0.1664	0.02483
5	-0.1092	0.03503	981	-3.12	0.0019	0.05	-0.1780	-0.04051
6	0.08130	0.03862	981	2.11	0.0355	0.05	0.005508	0.1571
7	0
8	-0.08045	0.03003	981	-2.68	0.0075	0.05	-0.1394	-0.02152
9	0
10	-0.3176	0.03358	981	-9.46	<.0001	0.05	-0.3835	-0.2517

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Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis -
on-treatment - full analysis set

The Mixed procedure
Solution for Fixed Effects

Parameter Code=P9P_FLUC Parameter=Fluctuation (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
11	1	NN1218-4131	TRTPN	2				
12	1	NN1218-4131	TRTPN	3				
13	1	NN1218-4131	TRTPN	4				
14	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
15	1	NN1218-4131	REGION1	—	EUROPE			
16	1	NN1218-4131	REGION1	—	JAPAN			
17	1	NN1218-4131	REGION1	—	NORTH AMERICA			
18	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
19	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
20	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
11	0.1613	0.04069	981	3.96	<.0001	0.05	0.08145	0.2412
12	0.1583	0.04138	981	3.83	0.0001	0.05	0.07714	0.2395
13	0.1620	0.04095	981	3.96	<.0001	0.05	0.08167	0.2424
14	-0.07076	0.04871	981	-1.45	0.1466	0.05	-0.1664	0.02483
15	-0.1092	0.03503	981	-3.12	0.0019	0.05	-0.1780	-0.04051
16	0.08130	0.03862	981	2.11	0.0355	0.05	0.005508	0.1571
17	0
18	-0.08045	0.03003	981	-2.68	0.0075	0.05	-0.1394	-0.02152
19	0
20	-0.3176	0.03358	981	-9.46	<.0001	0.05	-0.3835	-0.2517

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Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis -
on-treatment - full analysis set

The Mixed procedure
Least Squares Means

Obs	_Imputation_	PARAMCD	PARAM	STUDYID	Effect	TRTPN
1	1	P9PFLUCU	Fluctuation (SMPG) (mg/dL)	NN1218-4131	TRTPN	2
2	1	P9PFLUCU	Fluctuation (SMPG) (mg/dL)	NN1218-4131	TRTPN	3
3	1	P9PFLUCU	Fluctuation (SMPG) (mg/dL)	NN1218-4131	TRTPN	4
4	1	P9P_FLUC	Fluctuation (SMPG) (mmol/L)	NN1218-4131	TRTPN	2
5	1	P9P_FLUC	Fluctuation (SMPG) (mmol/L)	NN1218-4131	TRTPN	3
6	1	P9P_FLUC	Fluctuation (SMPG) (mmol/L)	NN1218-4131	TRTPN	4

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	WORK.IMPUTE	-0.1276	0.02302	981	-5.54	<.0001	0.05	-0.1728	-0.08240
2	WORK.IMPUTE	-0.1305	0.02294	981	-5.69	<.0001	0.05	-0.1756	-0.08552
3	WORK.IMPUTE	-0.1269	0.02301	981	-5.51	<.0001	0.05	-0.1720	-0.08171
4	WORK.IMPUTE	-0.1276	0.02302	981	-5.54	<.0001	0.05	-0.1728	-0.08240
5	WORK.IMPUTE	-0.1305	0.02294	981	-5.69	<.0001	0.05	-0.1756	-0.08552
6	WORK.IMPUTE	-0.1269	0.02301	981	-5.51	<.0001	0.05	-0.1720	-0.08171

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Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Least Squares Means Estimate

Parameter Code=P9PFLUCU Parameter=Fluctuation (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
1	1	NN1218-4131	1	TRTPN	Faster aspart (meal) / NovoRapid (meal)
2	1	NN1218-4131	2	TRTPN	Faster aspart (post) / NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	WORK.IMPUTE	-0.00072	0.03257	981	-0.02	0.9825	0.05	-0.06464	0.06320
2	WORK.IMPUTE	-0.00368	0.03250	981	-0.11	0.9099	0.05	-0.06747	0.06011

Parameter Code=P9P_FLUC Parameter=Fluctuation (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
3	1	NN1218-4131	1	TRTPN	Faster aspart (meal) / NovoRapid (meal)
4	1	NN1218-4131	2	TRTPN	Faster aspart (post) / NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
3	WORK.IMPUTE	-0.00072	0.03257	981	-0.02	0.9825	0.05	-0.06464	0.06320
4	WORK.IMPUTE	-0.00368	0.03250	981	-0.11	0.9099	0.05	-0.06747	0.06011

Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9PFLUCU Parameter=Fluctuation (SMPG) (mg/dL) Study Identifier=NN1218-41

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000029952	0.000530	0.000560	6.99E6	0.056501	0.053480	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.134853	0.023666	-0.18124	-0.08847	6.99E6	-0.160222	-0.113104

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-5.70	<.0001

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Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9P_FLUC Parameter=Fluctuation (SMPG) (mmol/L) Study Identifier=NN1218-4

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000029952	0.000530	0.000560	6.99E6	0.056501	0.053480	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.134853	0.023666	-0.18124	-0.08847	6.99E6	-0.160222	-0.113104

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-5.70	<.0001

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Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9PFLUCU Parameter=Fluctuation (SMPG) (mg/dL) Study Identifier=NN1218-41

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000025166	0.000527	0.000552	9.61E6	0.047798	0.045618	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.133900	0.023488	-0.17994	-0.08786	9.61E6	-0.154874	-0.111720

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-5.70	<.0001

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Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9P_FLUC Parameter=Fluctuation (SMPG) (mmol/L) Study Identifier=NN1218-4

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000025166	0.000527	0.000552	9.61E6	0.047798	0.045618	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.133900	0.023488	-0.17994	-0.08786	9.61E6	-0.154874	-0.111720

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-5.70	<.0001

nn1218/nn1218-4131/ctr_20180214_er
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Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9PFLUCU Parameter=Fluctuation (SMPG) (mg/dL) Study Identifier=NN1218-41

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000028106	0.000530	0.000558	7.87E6	0.053074	0.050400	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.119727	0.023615	-0.16601	-0.07344	7.87E6	-0.140759	-0.098567

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-5.07	<.0001

nn1218/nn1218-4131/ctr_20180214_er
10FEB2018:01:42:12 - a_stat_ratio.sas/a_9pp_fluc_stat_on_fas_app.txt

Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9P_FLUC Parameter=Fluctuation (SMPG) (mmol/L) Study Identifier=NN1218-4

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000028106	0.000530	0.000558	7.87E6	0.053074	0.050400	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.119727	0.023615	-0.16601	-0.07344	7.87E6	-0.140759	-0.098567

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-5.07	<.0001

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Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=P9PFLUCU Label=Faster aspart (meal) / NovoRapid (meal) Parameter=Fluctuation (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000058455	0.001061	0.001120	7.34E6	0.055090	0.052214	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.015126	0.033460	-0.08071	0.050455	7.34E6	-0.048036	0.014649

Parameter Estimates

Parameter	Theta0	t for H0: Parameter=Theta0	Pr > t
Estimate	0	-0.45	0.6512

nn1218/nn1218-4131/ctr_20180214_er
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Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 1613 of 4425	Novo Nordisk
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Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=P9PFLUCU Label=Faster aspart (post) / NovoRapid (meal) Parameter=Fluctuation (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000052749	0.001057	0.001109	8.85E6	0.049923	0.047549	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.014174	0.033308	-0.07946	0.051109	8.85E6	-0.042314	0.014725

Parameter Estimates

Parameter	Theta0	t for H0: Parameter=Theta0	Pr > t
Estimate	0	-0.43	0.6705

nn1218/nn1218-4131/ctr_20180214_er
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Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 1614 of 4425	Novo Nordisk
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Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=P9P_FLUC Label=Faster aspart (meal) / NovoRapid (meal) Parameter=Fluctuation (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000058455	0.001061	0.001120	7.34E6	0.055090	0.052214	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.015126	0.033460	-0.08071	0.050455	7.34E6	-0.048036	0.014649

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-0.45	0.6512

nn1218/nn1218-4131/ctr_20180214_er
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Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 1615 of 4425	Novo Nordisk
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Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=P9P_FLUC Label=Faster aspart (post) / NovoRapid (meal) Parameter=Fluctuation (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000052749	0.001057	0.001109	8.85E6	0.049923	0.047549	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.014174	0.033308	-0.07946	0.051109	8.85E6	-0.042314	0.014725

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-0.43	0.6705

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Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Model Information

Parameter Code=P9PFLUCU Parameter=Fluctuation (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Data Set	WORK.IMPUTE_ABS
2	1	NN1218-4131	Dependent Variable	eotVisitAbs
3	1	NN1218-4131	Covariance Structure	Diagonal
4	1	NN1218-4131	Estimation Method	REML
5	1	NN1218-4131	Residual Variance Method	Profile
6	1	NN1218-4131	Fixed Effects SE Method	Model-Based
7	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=P9P_FLUC Parameter=Fluctuation (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
8	1	NN1218-4131	Data Set	WORK.IMPUTE_ABS
9	1	NN1218-4131	Dependent Variable	eotVisitAbs
10	1	NN1218-4131	Covariance Structure	Diagonal
11	1	NN1218-4131	Estimation Method	REML
12	1	NN1218-4131	Residual Variance Method	Profile
13	1	NN1218-4131	Fixed Effects SE Method	Model-Based
14	1	NN1218-4131	Degrees of Freedom Method	Residual

Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Class Level Information

Parameter Code=P9PFLUCU Parameter=Fluctuation (SMPG) (mg/dL)

Ob- s	—	Input ID	STUDY	Class	Level	Values	min
1	1	NN1218-4131	TRTPN		3 2 3 4		5
2	1	NN1218-4131	REGION1		4 ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA		49
3	1	NN1218-4131	BOLAD1		2 BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULI		85

Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Class Level Information

Parameter Code=P9P FLUC Parameter=Fluctuation (SMPG) (mmol/L)

Ob- s	—	Input on D	STUD Y I D	Class s	Lev els	Val ues	mi n — Le gt h
4	1	NN1218-4131	TRTPN		3 2 3 4		5
5	1	NN1218-4131	REGION1		4 ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA		49
6	1	NN1218-4131	BOLAD1		2 BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULI		85

Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Dimensions

Parameter Code=P9PFLUCU Parameter=Fluctuation (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Covariance Parameters	1
2	1	NN1218-4131	Columns in X	10
3	1	NN1218-4131	Columns in Z	0
4	1	NN1218-4131	Subjects	1
5	1	NN1218-4131	Max Obs per Subject	989

Parameter Code=P9P_FLUC Parameter=Fluctuation (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
6	1	NN1218-4131	Covariance Parameters	1
7	1	NN1218-4131	Columns in X	10
8	1	NN1218-4131	Columns in Z	0
9	1	NN1218-4131	Subjects	1
10	1	NN1218-4131	Max Obs per Subject	989

Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Number of Observations

Parameter Code=P9PFLUCU Parameter=Fluctuation (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
1	1	NN1218-4131	Number of Observations Read	989	989	989	989	989
2	1	NN1218-4131	Number of Observations Used	989	989	989	989	989
3	1	NN1218-4131	Number of Observations Not Used	0	989	989	989	989

Parameter Code=P9P_FLUC Parameter=Fluctuation (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
4	1	NN1218-4131	Number of Observations Read	989	989	989	989	989
5	1	NN1218-4131	Number of Observations Used	989	989	989	989	989
6	1	NN1218-4131	Number of Observations Not Used	0	989	989	989	989

Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Covariance Parameter Estimates

Parameter Code=P9PFLUCU Parameter=Fluctuation (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	CovParm	Estimate
1	1	NN1218-4131	Residual	0.1739

Parameter Code=P9P_FLUC Parameter=Fluctuation (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	CovParm	Estimate
20001	1	NN1218-4131	Residual	0.1739

Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Fit Statistics

Parameter Code=P9PFLUCU Parameter=Fluctuation (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	-2 Res Log Likelihood	1110.4
2	1	NN1218-4131	AIC (Smaller is Better)	1112.4
3	1	NN1218-4131	AICC (Smaller is Better)	1112.4
4	1	NN1218-4131	BIC (Smaller is Better)	1117.3

Parameter Code=P9P_FLUC Parameter=Fluctuation (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
5	1	NN1218-4131	-2 Res Log Likelihood	1110.4
6	1	NN1218-4131	AIC (Smaller is Better)	1112.4
7	1	NN1218-4131	AICC (Smaller is Better)	1112.4
8	1	NN1218-4131	BIC (Smaller is Better)	1117.3

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NN1218-4131

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Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Solution for Fixed Effects

Parameter Code=P9PFLUCU Parameter=Fluctuation (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1
1	1	NN1218-4131	TRTPN	2		
2	1	NN1218-4131	TRTPN	3		
3	1	NN1218-4131	TRTPN	4		
4	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)	
5	1	NN1218-4131	REGION1	—	EUROPE	
6	1	NN1218-4131	REGION1	—	JAPAN	
7	1	NN1218-4131	REGION1	—	NORTH AMERICA	
8	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)
9	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY
10	1	NN1218-4131	BASE	—		

Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	1.0797	0.1261	981	8.56	<.0001	0.05	0.8322	1.3271
2	1.0767	0.1267	981	8.50	<.0001	0.05	0.8281	1.3253
3	1.0804	0.1259	981	8.58	<.0001	0.05	0.8332	1.3275
4	-0.07076	0.04871	981	-1.45	0.1466	0.05	-0.1664	0.02483
5	-0.1092	0.03503	981	-3.12	0.0019	0.05	-0.1780	-0.04051
6	0.08130	0.03862	981	2.11	0.0355	0.05	0.005508	0.1571
7	0
8	-0.08045	0.03003	981	-2.68	0.0075	0.05	-0.1394	-0.02152
9	0
10	0.6824	0.03358	981	20.32	<.0001	0.05	0.6165	0.7483

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Fast-acting insulin aspart
NN1218-4131

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Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis -
on-treatment - full analysis set

The Mixed procedure
Solution for Fixed Effects

Parameter Code=P9P_FLUC Parameter=Fluctuation (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
11	1	NN1218-4131	TRTPN	2				
12	1	NN1218-4131	TRTPN	3				
13	1	NN1218-4131	TRTPN	4				
14	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
15	1	NN1218-4131	REGION1	—	EUROPE			
16	1	NN1218-4131	REGION1	—	JAPAN			
17	1	NN1218-4131	REGION1	—	NORTH AMERICA			
18	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
19	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
20	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
11	0.1613	0.04069	981	3.96	<.0001	0.05	0.08145	0.2412
12	0.1583	0.04138	981	3.83	0.0001	0.05	0.07714	0.2395
13	0.1620	0.04095	981	3.96	<.0001	0.05	0.08167	0.2424
14	-0.07076	0.04871	981	-1.45	0.1466	0.05	-0.1664	0.02483
15	-0.1092	0.03503	981	-3.12	0.0019	0.05	-0.1780	-0.04051
16	0.08130	0.03862	981	2.11	0.0355	0.05	0.005508	0.1571
17	0
18	-0.08045	0.03003	981	-2.68	0.0075	0.05	-0.1394	-0.02152
19	0
20	0.6824	0.03358	981	20.32	<.0001	0.05	0.6165	0.7483

nn1218/nn1218-4131/ctr_20180214_er
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Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis -
on-treatment - full analysis set

The Mixed procedure
Least Squares Means

Obs	_Imputation_	PARAMCD	PARAM	STUDYID	Effect	TRTPN
1	1	P9PFLUCU	Fluctuation (SMPG) (mg/dL)	NN1218-4131	TRTPN	2
20001	1	P9P_FLUC	Fluctuation (SMPG) (mmol/L)	NN1218-4131	TRTPN	2
40001	1	P9PFLUCU	Fluctuation (SMPG) (mg/dL)	NN1218-4131	TRTPN	3
60001	1	P9P_FLUC	Fluctuation (SMPG) (mmol/L)	NN1218-4131	TRTPN	3
80001	1	P9PFLUCU	Fluctuation (SMPG) (mg/dL)	NN1218-4131	TRTPN	4
100001	1	P9P_FLUC	Fluctuation (SMPG) (mmol/L)	NN1218-4131	TRTPN	4

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	WORK.IMPUTE	-0.1276	0.02302	981	-5.54	<.0001	0.05	-0.1728	-0.08240
20001	WORK.IMPUTE	-0.1276	0.02302	981	-5.54	<.0001	0.05	-0.1728	-0.08240
40001	WORK.IMPUTE	-0.1305	0.02294	981	-5.69	<.0001	0.05	-0.1756	-0.08552
60001	WORK.IMPUTE	-0.1305	0.02294	981	-5.69	<.0001	0.05	-0.1756	-0.08552
80001	WORK.IMPUTE	-0.1269	0.02301	981	-5.51	<.0001	0.05	-0.1720	-0.08171
100001	WORK.IMPUTE	-0.1269	0.02301	981	-5.51	<.0001	0.05	-0.1720	-0.08171

nn1218/nn1218-4131/ctr_20180214_er
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Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Least Squares Means Estimate

Parameter Code=P9PFLUCU Parameter=Fluctuation (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
1	1	NN1218-4131	1	TRTPN	Faster aspart (meal) / NovoRapid (meal)
20001	1	NN1218-4131	2	TRTPN	Faster aspart (post) / NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	WORK.IMPUTE	-0.00072	0.03257	981	-0.02	0.9825	0.05	-0.06464	0.06320
20001	WORK.IMPUTE	-0.00368	0.03250	981	-0.11	0.9099	0.05	-0.06747	0.06011

Parameter Code=P9P_FLUC Parameter=Fluctuation (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
40001	1	NN1218-4131	1	TRTPN	Faster aspart (meal) / NovoRapid (meal)
60001	1	NN1218-4131	2	TRTPN	Faster aspart (post) / NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
40001	WORK.IMPUTE	-0.00072	0.03257	981	-0.02	0.9825	0.05	-0.06464	0.06320
60001	WORK.IMPUTE	-0.00368	0.03250	981	-0.11	0.9099	0.05	-0.06747	0.06011

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Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9PFLUCU Parameter=Fluctuation (SMPG) (mg/dL) Study Identifier=NN1218-41

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000029952	0.000530	0.000560	6.99E6	0.056501	0.053480	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	3.436922	0.023666	3.390537	3.483307	6.99E6	3.411552	3.458671

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	145.22	<.0001

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Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9P_FLUC Parameter=Fluctuation (SMPG) (mmol/L) Study Identifier=NN1218-4

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000029952	0.000530	0.000560	6.99E6	0.056501	0.053480	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.545440	0.023666	0.499054	0.591825	6.99E6	0.520070	0.567188

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	23.05	<.0001

nn1218/nn1218-4131/ctr_20180214_er
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Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9PFLUCU Parameter=Fluctuation (SMPG) (mg/dL) Study Identifier=NN1218-41

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000025166	0.000527	0.000552	9.61E6	0.047798	0.045618	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	3.437874	0.023488	3.391839	3.483910	9.61E6	3.416901	3.460055

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	146.37	<.0001

nn1218/nn1218-4131/ctr_20180214_er
10FEB2018:01:42:12 - a_stat_ratio.sas/a_9pp_fluc_stat_on_fas_app.txt

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Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9P_FLUC Parameter=Fluctuation (SMPG) (mmol/L) Study Identifier=NN1218-4

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000025166	0.000527	0.000552	9.61E6	0.047798	0.045618	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.546392	0.023488	0.500357	0.592428	9.61E6	0.525419	0.568572

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	23.26	<.0001

nn1218/nn1218-4131/ctr_20180214_er
10FEB2018:01:42:12 - a_stat_ratio.sas/a_9pp_fluc_stat_on_fas_app.txt

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Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9PFLUCU Parameter=Fluctuation (SMPG) (mg/dL) Study Identifier=NN1218-41

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000028106	0.000530	0.000558	7.87E6	0.053074	0.050400	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	3.452048	0.023615	3.405762	3.498333	7.87E6	3.431015	3.473208

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	146.18	<.0001

nn1218/nn1218-4131/ctr_20180214_er
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Fluctuation in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9P_FLUC Parameter=Fluctuation (SMPG) (mmol/L) Study Identifier=NN1218-4

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000028106	0.000530	0.000558	7.87E6	0.053074	0.050400	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.560566	0.023615	0.514280	0.606851	7.87E6	0.539533	0.581725

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	23.74	<.0001

nn1218/nn1218-4131/ctr_20180214_er
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22: Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=P9PPRANC Planned Treatment for Period 30 (N)=2

Obs	PARAM	Description	Value
1	PPG all meals (SMPG) (mg/dL)	Data Set	WORK.ENDPOINT_PARAM
2	PPG all meals (SMPG) (mg/dL)	Method	Monotone-data_MCMC
3	PPG all meals (SMPG) (mg/dL)	Multiple Imputation Chain	Multiple Chains
4	PPG all meals (SMPG) (mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
5	PPG all meals (SMPG) (mg/dL)	Start	Starting Value
6	PPG all meals (SMPG) (mg/dL)	Prior	Jeffreys
7	PPG all meals (SMPG) (mg/dL)	Number of Imputations	20000
8	PPG all meals (SMPG) (mg/dL)	Number of Burn-in Iterations	200
9	PPG all meals (SMPG) (mg/dL)	Seed for random number generator	1234

Parameter Code=P9PPRANC Planned Treatment for Period 30 (N)=3

Obs	PARAM	Description	Value
10	PPG all meals (SMPG) (mg/dL)	Data Set	WORK.ENDPOINT_PARAM
11	PPG all meals (SMPG) (mg/dL)	Method	Monotone-data_MCMC
12	PPG all meals (SMPG) (mg/dL)	Multiple Imputation Chain	Multiple Chains
13	PPG all meals (SMPG) (mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
14	PPG all meals (SMPG) (mg/dL)	Start	Starting Value
15	PPG all meals (SMPG) (mg/dL)	Prior	Jeffreys
16	PPG all meals (SMPG) (mg/dL)	Number of Imputations	20000
17	PPG all meals (SMPG) (mg/dL)	Number of Burn-in Iterations	200
18	PPG all meals (SMPG) (mg/dL)	Seed for random number generator	1775741187

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=P9PPRANC Planned Treatment for Period 30 (N)=4

Obs	PARAM	Description	Value
19	PPG all meals (SMPG) (mg/dL)	Data Set	WORK.ENDPOINT_PARAM
20	PPG all meals (SMPG) (mg/dL)	Method	Monotone-data_MCMC
21	PPG all meals (SMPG) (mg/dL)	Multiple Imputation Chain	Multiple Chains
22	PPG all meals (SMPG) (mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
23	PPG all meals (SMPG) (mg/dL)	Start	Starting Value
24	PPG all meals (SMPG) (mg/dL)	Prior	Jeffreys
25	PPG all meals (SMPG) (mg/dL)	Number of Imputations	20000
26	PPG all meals (SMPG) (mg/dL)	Number of Burn-in Iterations	200
27	PPG all meals (SMPG) (mg/dL)	Seed for random number generator	244514575

Fast-acting insulin aspart
NN1218-4131

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

The MI Procedure with MCMC
Missing data pattern

Parameter Code=P9PPRANC Planned Treatment for Period 30 (N)=2

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
1	PPG all meals (SMPG) (mg/dL)	1	X	X	X	283	87.35	173.076005	-12.165708	-11.004715
2	PPG all meals (SMPG) (mg/dL)	2	X	X	O	14	4.32	154.773381	11.259714	.
3	PPG all meals (SMPG) (mg/dL)	3	X	.	X	16	4.94	190.406819	.	-29.726271
4	PPG all meals (SMPG) (mg/dL)	4	X	O	O	11	3.40	152.819111	.	.

Parameter Code=P9PPRANC Planned Treatment for Period 30 (N)=3

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
5	PPG all meals (SMPG) (mg/dL)	1	X	X	X	293	90.15	175.101904	0.048261	-1.386925
6	PPG all meals (SMPG) (mg/dL)	2	X	X	O	11	3.38	160.448505	13.192455	.
7	PPG all meals (SMPG) (mg/dL)	3	X	.	X	15	4.62	161.762963	.	19.712993
8	PPG all meals (SMPG) (mg/dL)	4	X	O	O	6	1.85	163.364537	.	.

Parameter Code=P9PPRANC Planned Treatment for Period 30 (N)=4

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
9	PPG all meals (SMPG) (mg/dL)	1	X	X	X	286	87.20	171.762381	-1.722334	-5.471425
10	PPG all meals (SMPG) (mg/dL)	2	X	X	O	13	3.96	166.480017	9.560915	.
11	PPG all meals (SMPG) (mg/dL)	3	X	.	X	17	5.18	163.472105	.	3.205935
12	PPG all meals (SMPG) (mg/dL)	4	X	O	O	12	3.66	174.926093	.	.

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PPRANC Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG all meals (SMPG) (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG all meals (SMPG) (mg/dL)	Method	Monotone
3	1	PPG all meals (SMPG) (mg/dL)	Number of Imputations	1
4	1	PPG all meals (SMPG) (mg/dL)	Seed for random number generator	4321

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

The MI Procedure with Monotone Regression Missing Data Pattern

Parameter Code=P9PPRANC Planned Treatment for Period 30 (N)=2

O b s					P A R A M		G r o u p	R E G I O N 1	B O L A D 1	B A S E	v i s i t 2	v i s i t 3	F r e q	P e r c e n t	B A S E	v i s i t 2	v i s i t 3
1	1	PPG	all	meals	(SMPG)	(mg/dL)	1	X	X	X	X	X	299	92.28	174.003407	-13.067799	-12.006537
2	1	PPG	all	meals	(SMPG)	(mg/dL)	2	X	X	X	X	.	14	4.32	154.773381	11.259714	.
3	1	PPG	all	meals	(SMPG)	(mg/dL)	3	X	X	X	.	.	11	3.40	152.819111	.	.

Fast-acting insulin aspart
NN1218-4131

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PPRANC Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG all meals (SMPG) (mg/dL)	Intercept	
2	1	PPG all meals (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG all meals (SMPG) (mg/dL)	REGION1	EUROPE
4	1	PPG all meals (SMPG) (mg/dL)	REGION1	JAPAN
5	1	PPG all meals (SMPG) (mg/dL)	BOLAD1	
6	1	PPG all meals (SMPG) (mg/dL)	BASE	

Obs	BOLAD1	ObsVal	_1
1		-0.00919	0.022846
2		-0.19016	-0.160853
3		0.00602	-0.122692
4		0.03705	0.020935
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.06405	-0.111999
6		-0.61489	-0.651141

Parameter Code=P9PPRANC Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	PPG all meals (SMPG) (mg/dL)	Intercept			0.00475	-0.025292
8	1	PPG all meals (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)		-0.22246	-0.151057
9	1	PPG all meals (SMPG) (mg/dL)	REGION1	EUROPE		-0.05157	-0.189098

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

The MI Procedure with Monotone Regression Regression Information

Parameter Code=P9PPRANC Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

(continued)

	O	b	s		P	E	R	B	O		I
				A	f	G		L	b		
				R	e	I		A	s		
				A	c	N		D	V		
				M	t	l		l	a		
									l		I
10	1	PPG	all meals	(SMPG)	(mg/dL)	REGION1	JAPAN			0.16636	0.198512
11	1	PPG	all meals	(SMPG)	(mg/dL)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.02277	0.039611	
12	1	PPG	all meals	(SMPG)	(mg/dL)	BASE			-0.36510	-0.316857	
13	1	PPG	all meals	(SMPG)	(mg/dL)	visit2200			0.39394	0.427842	

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PPRANC Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG all meals (SMPG) (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG all meals (SMPG) (mg/dL)	Method	Monotone
3	1	PPG all meals (SMPG) (mg/dL)	Number of Imputations	1
4	1	PPG all meals (SMPG) (mg/dL)	Seed for random number generator	4322

Fast-acting insulin aspart
NN1218-4131

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=P9PPRANC Planned Treatment for Period 30 (N)=3

O b s	I m p u t a t i o n	P A R A M	G r o u p	R E G I O N 1	E B O L A 1	B O L A 1	B O L A 1	B O L A 1	B O L A 1	F r e q	P e r c e n t	B A S E	v i s i t 2 2 0	v i s i t 3 6 0
1	1	PPG all meals (SMPG) (mg/dL)	1	X	X	X	X	X	X	308	94.77	174.452280	1.202993	-0.359331
2	1	PPG all meals (SMPG) (mg/dL)	2	X	X	X	X	X	.	11	3.38	160.448505	13.192455	.
3	1	PPG all meals (SMPG) (mg/dL)	3	X	X	X	.	.	.	6	1.85	163.364537	.	.

Fast-acting insulin aspart
NN1218-4131

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PPRANC Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG all meals (SMPG) (mg/dL)	Intercept	
2	1	PPG all meals (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG all meals (SMPG) (mg/dL)	REGION1	EUROPE
4	1	PPG all meals (SMPG) (mg/dL)	REGION1	JAPAN
5	1	PPG all meals (SMPG) (mg/dL)	BOLAD1	
6	1	PPG all meals (SMPG) (mg/dL)	BASE	

Obs	BOLAD1	ObsVal	_1
1		0.03236	0.134319
2		-0.02022	0.113724
3		-0.19308	-0.190378
4		0.32504	0.229625
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.17902	-0.150222
6		-0.47092	-0.510568

Parameter Code=P9PPRANC Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	PPG all meals (SMPG) (mg/dL)	Intercept			-0.00406	-0.022372
8	1	PPG all meals (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)		-0.19414	-0.229668
9	1	PPG all meals (SMPG) (mg/dL)	REGION1	EUROPE		-0.06775	-0.083947

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

The MI Procedure with Monotone Regression Regression Information

Parameter Code=P9PPRANC Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

(continued)

	O	b	s	-	P A R A M	E f f e c t	R E G I O N 1	B O L A D 1	O b s V a l	I
10	1	PPG	all	meals	(SMPG)	(mg/dL)	REGION1	JAPAN	0.22622	0.191855
11	1	PPG	all	meals	(SMPG)	(mg/dL)	BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.09363	-0.022413
12	1	PPG	all	meals	(SMPG)	(mg/dL)	BASE		-0.32210	-0.330435
13	1	PPG	all	meals	(SMPG)	(mg/dL)	visit2200		0.47902	0.512654

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PPRANC Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG all meals (SMPG) (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG all meals (SMPG) (mg/dL)	Method	Monotone
3	1	PPG all meals (SMPG) (mg/dL)	Number of Imputations	1
4	1	PPG all meals (SMPG) (mg/dL)	Seed for random number generator	4323

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=P9PPRANC Planned Treatment for Period 30 (N)=4

O b s	I m p u t a t i o n	P A R A M	G r o u p	R E G I O N 1	E B O L A 1	B O L A 1	B O L A 1	B O L A 1	B O L A 1	F r e q	P e r c e n t	B A S E	v i s i t 2 2 0	v i s i t 3 6 0
1	1	PPG all meals (SMPG) (mg/dL)	1	X	X	X	X	X	X	303	92.38	171.297250	-0.780200	-4.984577
2	1	PPG all meals (SMPG) (mg/dL)	2	X	X	X	X	X	.	13	3.96	166.480017	9.560915	.
3	1	PPG all meals (SMPG) (mg/dL)	3	X	X	X	.	.	.	12	3.66	174.926093	.	.

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PPRANC Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG all meals (SMPG) (mg/dL)	Intercept	
2	1	PPG all meals (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG all meals (SMPG) (mg/dL)	REGION1	EUROPE
4	1	PPG all meals (SMPG) (mg/dL)	REGION1	JAPAN
5	1	PPG all meals (SMPG) (mg/dL)	BOLAD1	
6	1	PPG all meals (SMPG) (mg/dL)	BASE	

Obs	BOLAD1	ObsVal	_1
1		0.02839	-0.013970
2		-0.03663	0.011424
3		-0.19955	-0.307073
4		0.26894	0.308370
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.14424	-0.149919
6		-0.65714	-0.733964

Parameter Code=P9PPRANC Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	PPG all meals (SMPG) (mg/dL)	Intercept			0.03805	0.042750
8	1	PPG all meals (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)		0.09522	0.023494
9	1	PPG all meals (SMPG) (mg/dL)	REGION1	EUROPE		-0.19114	-0.142599

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- in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PPRANC Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

(continued)

O b s —		P A R A M —		E f f e c t		R E G I O N 1		B O L A D 1		O b s e r v e d		I	
10	1	PPG	all meals (SMPG)	(mg/dL)	REGION1	JAPAN				0.21025	0.281621		
11	1	PPG	all meals (SMPG)	(mg/dL)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)			-0.09860	-0.106462		
12	1	PPG	all meals (SMPG)	(mg/dL)	BASE					-0.42776	-0.352176		
13	1	PPG	all meals (SMPG)	(mg/dL)	visit2200					0.33778	0.286623		

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The MI Procedure with MCMC
Model Information

Parameter Code=P9PPRAN Planned Treatment for Period 30 (N)=2

Obs	PARAM	Description	Value
1	PPG all meals (SMPG) (mmol/L)	Data Set	WORK.ENDPOINT_PARAM
2	PPG all meals (SMPG) (mmol/L)	Method	Monotone-data_MCMC
3	PPG all meals (SMPG) (mmol/L)	Multiple Imputation Chain	Multiple Chains
4	PPG all meals (SMPG) (mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
5	PPG all meals (SMPG) (mmol/L)	Start	Starting Value
6	PPG all meals (SMPG) (mmol/L)	Prior	Jeffreys
7	PPG all meals (SMPG) (mmol/L)	Number of Imputations	20000
8	PPG all meals (SMPG) (mmol/L)	Number of Burn-in Iterations	200
9	PPG all meals (SMPG) (mmol/L)	Seed for random number generator	1234

Parameter Code=P9PPRAN Planned Treatment for Period 30 (N)=3

Obs	PARAM	Description	Value
10	PPG all meals (SMPG) (mmol/L)	Data Set	WORK.ENDPOINT_PARAM
11	PPG all meals (SMPG) (mmol/L)	Method	Monotone-data_MCMC
12	PPG all meals (SMPG) (mmol/L)	Multiple Imputation Chain	Multiple Chains
13	PPG all meals (SMPG) (mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
14	PPG all meals (SMPG) (mmol/L)	Start	Starting Value
15	PPG all meals (SMPG) (mmol/L)	Prior	Jeffreys
16	PPG all meals (SMPG) (mmol/L)	Number of Imputations	20000
17	PPG all meals (SMPG) (mmol/L)	Number of Burn-in Iterations	200
18	PPG all meals (SMPG) (mmol/L)	Seed for random number generator	1775741187

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The MI Procedure with MCMC
Model Information

Parameter Code=P9PPRAN Planned Treatment for Period 30 (N)=4

Obs	PARAM	Description	Value
19	PPG all meals (SMPG) (mmol/L)	Data Set	WORK.ENDPOINT_PARAM
20	PPG all meals (SMPG) (mmol/L)	Method	Monotone-data_MCMC
21	PPG all meals (SMPG) (mmol/L)	Multiple Imputation Chain	Multiple Chains
22	PPG all meals (SMPG) (mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
23	PPG all meals (SMPG) (mmol/L)	Start	Starting Value
24	PPG all meals (SMPG) (mmol/L)	Prior	Jeffreys
25	PPG all meals (SMPG) (mmol/L)	Number of Imputations	20000
26	PPG all meals (SMPG) (mmol/L)	Number of Burn-in Iterations	200
27	PPG all meals (SMPG) (mmol/L)	Seed for random number generator	244514575

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- in-trial - full analysis set

The MI Procedure with MCMC
Missing data pattern

Parameter Code=P9PPRAN Planned Treatment for Period 30 (N)=2

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
1	PPG all meals (SMPG) (mmol/L)	1	X	X	X	283	87.35	9.604662	-0.675123	-0.610695
2	PPG all meals (SMPG) (mmol/L)	2	X	X	O	14	4.32	8.588978	0.624845	.
3	PPG all meals (SMPG) (mmol/L)	3	X	.	X	16	4.94	10.566416	.	-1.649627
4	PPG all meals (SMPG) (mmol/L)	4	X	O	O	11	3.40	8.480528	.	.

Parameter Code=P9PPRAN Planned Treatment for Period 30 (N)=3

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
5	PPG all meals (SMPG) (mmol/L)	1	X	X	X	293	90.15	9.717087	0.002678	-0.076966
6	PPG all meals (SMPG) (mmol/L)	2	X	X	O	11	3.38	8.903913	0.732101	.
7	PPG all meals (SMPG) (mmol/L)	3	X	.	X	15	4.62	8.976857	.	1.093951
8	PPG all meals (SMPG) (mmol/L)	4	X	O	O	6	1.85	9.065735	.	.

Parameter Code=P9PPRAN Planned Treatment for Period 30 (N)=4

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
9	PPG all meals (SMPG) (mmol/L)	1	X	X	X	286	87.20	9.531764	-0.095579	-0.303631
10	PPG all meals (SMPG) (mmol/L)	2	X	X	O	13	3.96	9.238625	0.530572	.
11	PPG all meals (SMPG) (mmol/L)	3	X	.	X	17	5.18	9.071704	.	0.177910
12	PPG all meals (SMPG) (mmol/L)	4	X	O	O	12	3.66	9.707330	.	.

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PPRAN Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG all meals (SMPG) (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG all meals (SMPG) (mmol/L)	Method	Monotone
3	1	PPG all meals (SMPG) (mmol/L)	Number of Imputations	1
4	1	PPG all meals (SMPG) (mmol/L)	Seed for random number generator	4321

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The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=P9PPRAN Planned Treatment for Period 30 (N)=2

O b s	I m p u t a t i o n _	P A R A M	G r o u p	R E G I O N 1	B O L A L 1	B O L A L E	v i s i t 2	v i s i t 3	F r e q	P e r c e n t	B A S E	v i s i t 2	v i s i t 3
1	1	PPG all meals (SMPG) (mmol/L)	1	X	X	X	X	X	299	92.28	9.656127	-0.725183	-0.666290
2	1	PPG all meals (SMPG) (mmol/L)	2	X	X	X	X	.	14	4.32	8.588978	0.624845	.
3	1	PPG all meals (SMPG) (mmol/L)	3	X	X	X	.	.	11	3.40	8.480528	.	.

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PPRAN Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG all meals (SMPG) (mmol/L)	Intercept	
2	1	PPG all meals (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG all meals (SMPG) (mmol/L)	REGION1	EUROPE
4	1	PPG all meals (SMPG) (mmol/L)	REGION1	JAPAN
5	1	PPG all meals (SMPG) (mmol/L)	BOLAD1	
6	1	PPG all meals (SMPG) (mmol/L)	BASE	

Obs	BOLAD1	ObsVal	_1
1		-0.00919	0.022846
2		-0.19016	-0.160853
3		0.00602	-0.122692
4		0.03705	0.020935
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.06405	-0.111999
6		-0.61489	-0.651141

Parameter Code=P9PPRAN Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	PPG all meals (SMPG) (mmol/L)	Intercept			0.00475	-0.025292
8	1	PPG all meals (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)		-0.22246	-0.151057
9	1	PPG all meals (SMPG) (mmol/L)	REGION1	EUROPE		-0.05157	-0.189098

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- in-trial - full analysis set

The MI Procedure with Monotone Regression Regression Information

Parameter Code=P9PPRAN Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

(continued)

	O	b	s	-	P A R A M	E f f e c t	R E G I O N 1	B O L U S D 1	O b s V a l	I
10	1	PPG	all	meals	(SMPG)	(mmol/L)	REGION1	JAPAN	0.16636	0.198512
11	1	PPG	all	meals	(SMPG)	(mmol/L)	BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.02277	0.039611
12	1	PPG	all	meals	(SMPG)	(mmol/L)	BASE		-0.36510	-0.316857
13	1	PPG	all	meals	(SMPG)	(mmol/L)	visit2200		0.39394	0.427842

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PPRAN Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG all meals (SMPG) (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG all meals (SMPG) (mmol/L)	Method	Monotone
3	1	PPG all meals (SMPG) (mmol/L)	Number of Imputations	1
4	1	PPG all meals (SMPG) (mmol/L)	Seed for random number generator	4322

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The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=P9PPRAN Planned Treatment for Period 30 (N)=3

O b s	I m p u t a t i o n	P A R A M	G r o u p	R E G I O N 1	E B L A D 1	B O L A D 1	B L A D 1	B L A D 1	B L A D 1	F r e q	P e r c e n t	B A S E	v i s i t 2 2 0 0	v i s i t 3 6 0 0
1	1	PPG all meals (SMPG) (mmol/L)	1	X	X	X	X	X	X	308	94.77	9.681037	0.066759	-0.019941
2	1	PPG all meals (SMPG) (mmol/L)	2	X	X	X	X	.	.	11	3.38	8.903913	0.732101	.
3	1	PPG all meals (SMPG) (mmol/L)	3	X	X	X	.	.	.	6	1.85	9.065735	.	.

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PPRAN Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG all meals (SMPG) (mmol/L)	Intercept	
2	1	PPG all meals (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG all meals (SMPG) (mmol/L)	REGION1	EUROPE
4	1	PPG all meals (SMPG) (mmol/L)	REGION1	JAPAN
5	1	PPG all meals (SMPG) (mmol/L)	BOLAD1	
6	1	PPG all meals (SMPG) (mmol/L)	BASE	

Obs	BOLAD1	ObsVal	_1
1		0.03236	0.134319
2		-0.02022	0.113724
3		-0.19308	-0.190378
4		0.32504	0.229625
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.17902	-0.150222
6		-0.47092	-0.510568

Parameter Code=P9PPRAN Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	PPG all meals (SMPG) (mmol/L)	Intercept			-0.00406	-0.022372
8	1	PPG all meals (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)		-0.19414	-0.229668
9	1	PPG all meals (SMPG) (mmol/L)	REGION1	EUROPE		-0.06775	-0.083947

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The MI Procedure with Monotone Regression Regression Information

Parameter Code=P9PPRAN Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

(continued)

	O	b	s		P A R A M	E f f e c t	R E G I O N 1	B O L U S D 1	O b s V a l	I
10	1	PPG	all	meals	(SMPG)	(mmol/L)	REGION1	JAPAN	0.22622	0.191855
11	1	PPG	all	meals	(SMPG)	(mmol/L)	BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.09363	-0.022413
12	1	PPG	all	meals	(SMPG)	(mmol/L)	BASE		-0.32210	-0.330435
13	1	PPG	all	meals	(SMPG)	(mmol/L)	visit2200		0.47902	0.512654

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PPRAN Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG all meals (SMPG) (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG all meals (SMPG) (mmol/L)	Method	Monotone
3	1	PPG all meals (SMPG) (mmol/L)	Number of Imputations	1
4	1	PPG all meals (SMPG) (mmol/L)	Seed for random number generator	4323

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

The MI Procedure with Monotone Regression Missing Data Pattern

Parameter Code=P9PPRAN Planned Treatment for Period 30 (N)=4

Obs	I	PPG	all	meals	(SMPG)	(mmol/L)	G	R E G I O N					F	P	B	v	v
								1	2	3	4	5					
1	1	PPG	all	meals	(SMPG)	(mmol/L)	1	X	X	X	X	X	303	92.38	9.505952	-0.043296	-0.276614
2	1	PPG	all	meals	(SMPG)	(mmol/L)	2	X	X	X	X	13	3.96	9.238625	0.530572	.	
3	1	PPG	all	meals	(SMPG)	(mmol/L)	3	X	X	X	.	12	3.66	9.707330	.	.	

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PPRAN Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG all meals (SMPG) (mmol/L)	Intercept	
2	1	PPG all meals (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG all meals (SMPG) (mmol/L)	REGION1	EUROPE
4	1	PPG all meals (SMPG) (mmol/L)	REGION1	JAPAN
5	1	PPG all meals (SMPG) (mmol/L)	BOLAD1	
6	1	PPG all meals (SMPG) (mmol/L)	BASE	

Obs	BOLAD1	ObsVal	_1
1		0.02839	-0.013970
2		-0.03663	0.011424
3		-0.19955	-0.307073
4		0.26894	0.308370
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.14424	-0.149919
6		-0.65714	-0.733964

Parameter Code=P9PPRAN Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	PPG all meals (SMPG) (mmol/L)	Intercept			0.03805	0.042750
8	1	PPG all meals (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)		0.09522	0.023494
9	1	PPG all meals (SMPG) (mmol/L)	REGION1	EUROPE		-0.19114	-0.142599

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The MI Procedure with Monotone Regression Regression Information

Parameter Code=P9PPRAN Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

(continued)

	O	b	s		P A R A M	E f f e c t	R E G I O N 1	B O L U S	O b s V a l	I
10	1	PPG	all	meals	(SMPG)	(mmol/L)	REGION1	JAPAN	0.21025	0.281621
11	1	PPG	all	meals	(SMPG)	(mmol/L)	BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.09860	-0.106462
12	1	PPG	all	meals	(SMPG)	(mmol/L)	BASE		-0.42776	-0.352176
13	1	PPG	all	meals	(SMPG)	(mmol/L)	visit2200		0.33778	0.286623

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=P9PGBC Planned Treatment for Period 30 (N)=2

Obs	PARAM	Description	Value
1	PPG breakfast (SMPG) (mg/dL)	Data Set	WORK.ENDPOINT_PARAM
2	PPG breakfast (SMPG) (mg/dL)	Method	Monotone-data_MCMC
3	PPG breakfast (SMPG) (mg/dL)	Multiple Imputation Chain	Multiple Chains
4	PPG breakfast (SMPG) (mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
5	PPG breakfast (SMPG) (mg/dL)	Start	Starting Value
6	PPG breakfast (SMPG) (mg/dL)	Prior	Jeffreys
7	PPG breakfast (SMPG) (mg/dL)	Number of Imputations	20000
8	PPG breakfast (SMPG) (mg/dL)	Number of Burn-in Iterations	200
9	PPG breakfast (SMPG) (mg/dL)	Seed for random number generator	1234

Parameter Code=P9PGBC Planned Treatment for Period 30 (N)=3

Obs	PARAM	Description	Value
10	PPG breakfast (SMPG) (mg/dL)	Data Set	WORK.ENDPOINT_PARAM
11	PPG breakfast (SMPG) (mg/dL)	Method	Monotone-data_MCMC
12	PPG breakfast (SMPG) (mg/dL)	Multiple Imputation Chain	Multiple Chains
13	PPG breakfast (SMPG) (mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
14	PPG breakfast (SMPG) (mg/dL)	Start	Starting Value
15	PPG breakfast (SMPG) (mg/dL)	Prior	Jeffreys
16	PPG breakfast (SMPG) (mg/dL)	Number of Imputations	20000
17	PPG breakfast (SMPG) (mg/dL)	Number of Burn-in Iterations	200
18	PPG breakfast (SMPG) (mg/dL)	Seed for random number generator	1369257867

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The MI Procedure with MCMC
Model Information

Parameter Code=P9PGBC Planned Treatment for Period 30 (N)=4

Obs	PARAM	Description	Value
19	PPG breakfast (SMPG) (mg/dL)	Data Set	WORK.ENDPOINT_PARAM
20	PPG breakfast (SMPG) (mg/dL)	Method	Monotone-data_MCMC
21	PPG breakfast (SMPG) (mg/dL)	Multiple Imputation Chain	Multiple Chains
22	PPG breakfast (SMPG) (mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
23	PPG breakfast (SMPG) (mg/dL)	Start	Starting Value
24	PPG breakfast (SMPG) (mg/dL)	Prior	Jeffreys
25	PPG breakfast (SMPG) (mg/dL)	Number of Imputations	20000
26	PPG breakfast (SMPG) (mg/dL)	Number of Burn-in Iterations	200
27	PPG breakfast (SMPG) (mg/dL)	Seed for random number generator	175357058

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The MI Procedure with MCMC
Missing data pattern

Parameter Code=P9PGBC Planned Treatment for Period 30 (N)=2

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
1	PPG breakfast (SMPG) (mg/dL)	1	X	X	X	290	88.96	178.619374	-11.873375	-13.603330
2	PPG breakfast (SMPG) (mg/dL)	2	X	X	O	11	3.37	154.285515	2.466667	.
3	PPG breakfast (SMPG) (mg/dL)	3	X	.	X	14	4.29	196.591000	.	-46.186690
4	PPG breakfast (SMPG) (mg/dL)	4	X	O	O	11	3.37	140.179606	.	.

Parameter Code=P9PGBC Planned Treatment for Period 30 (N)=3

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
5	PPG breakfast (SMPG) (mg/dL)	1	X	X	X	300	90.63	178.845528	-2.007032	-1.385110
6	PPG breakfast (SMPG) (mg/dL)	2	X	X	O	13	3.93	174.250513	-1.669538	.
7	PPG breakfast (SMPG) (mg/dL)	3	X	.	X	14	4.23	155.884286	.	19.793262
8	PPG breakfast (SMPG) (mg/dL)	4	X	O	O	4	1.21	196.501833	.	.

Parameter Code=P9PGBC Planned Treatment for Period 30 (N)=4

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
9	PPG breakfast (SMPG) (mg/dL)	1	X	X	X	292	88.75	177.589761	-0.287041	-7.799175
10	PPG breakfast (SMPG) (mg/dL)	2	X	X	O	11	3.34	151.848909	3.915121	.
11	PPG breakfast (SMPG) (mg/dL)	3	X	.	X	14	4.26	136.937262	.	27.484976
12	PPG breakfast (SMPG) (mg/dL)	4	X	O	O	12	3.65	165.952833	.	.

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PGBC Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG breakfast (SMPG) (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG breakfast (SMPG) (mg/dL)	Method	Monotone
3	1	PPG breakfast (SMPG) (mg/dL)	Number of Imputations	1
4	1	PPG breakfast (SMPG) (mg/dL)	Seed for random number generator	4321

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

The MI Procedure with Monotone Regression Missing Data Pattern

Parameter Code=P9PGBC Planned Treatment for Period 30 (N)=2

O	b	s				P A R A M	G r o u p	R E G I O N 1	B O L A D 1	B A S E	v i s i t 2	v i s i t 3	F r e q	P e r c e n t	B A S E	v i s i t 2	v i s i t 3	v i s i t 0	v i s i t 0
1	1	PPG breakfast	(SMPG)	(mg/dL)	1	X	X	X	X	X	304	93.25	179.447014	-11.636056	-15.103879
2	1	PPG breakfast	(SMPG)	(mg/dL)	2	X	X	X	X	.	11	3.37	154.285515	2.466667
3	1	PPG breakfast	(SMPG)	(mg/dL)	3	X	X	X	.	.	11	3.37	140.179606

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGBC Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG breakfast (SMPG) (mg/dL)	Intercept	
2	1	PPG breakfast (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG breakfast (SMPG) (mg/dL)	REGION1	EUROPE
4	1	PPG breakfast (SMPG) (mg/dL)	REGION1	JAPAN
5	1	PPG breakfast (SMPG) (mg/dL)	BOLAD1	
6	1	PPG breakfast (SMPG) (mg/dL)	BASE	

Obs	BOLAD1	ObsVal	_1
1		0.00942	0.041120
2		-0.09003	-0.060746
3		-0.07678	-0.202466
4		0.01777	-0.002813
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.02775	-0.075231
6		-0.63456	-0.672067

Parameter Code=P9PGBC Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	PPG breakfast (SMPG) (mg/dL)	Intercept			0.01656	-0.014422
8	1	PPG breakfast (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)		-0.18773	-0.113818
9	1	PPG breakfast (SMPG) (mg/dL)	REGION1	EUROPE		-0.06765	-0.210208

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGBC Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

(continued)

		Imputed		Observation		Region		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		Observation		Imputed	
		P		E		E		B		O			
		A		f		G		O		b			
		R		e		I		L		s			
		A		c		O		A		V			
		M		t		N		D		a			
						1		1		1			
10	1	PPG breakfast	(SMPG)	(mg/dL)	REGION1	JAPAN				0.24412		0.274893	
11	1	PPG breakfast	(SMPG)	(mg/dL)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)			-0.05987		0.004365	
12	1	PPG breakfast	(SMPG)	(mg/dL)	BASE					-0.43858		-0.386936	
13	1	PPG breakfast	(SMPG)	(mg/dL)	visit2200					0.27308		0.295535	

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
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The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PGBC Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG breakfast (SMPG) (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG breakfast (SMPG) (mg/dL)	Method	Monotone
3	1	PPG breakfast (SMPG) (mg/dL)	Number of Imputations	1
4	1	PPG breakfast (SMPG) (mg/dL)	Seed for random number generator	4322

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=P9PGBC Planned Treatment for Period 30 (N)=3

O b s	I m p u t a t i o n _	P A R A M	G r o u p	R E G I O N 1	E B O L A 1	B O L A 1	B O L A 1	B O L A 1	B O L A 1	F r e q	P e r c e n t	B A S E	v i s i t 2 2 0	v i s i t 3 6 0
1	1	PPG breakfast (SMPG) (mg/dL)	1	X	X	X	X	X	X	314	94.86	177.821778	-1.221450	-0.440851
2	1	PPG breakfast (SMPG) (mg/dL)	2	X	X	X	X	X	.	13	3.93	174.250513	-1.669538	.
3	1	PPG breakfast (SMPG) (mg/dL)	3	X	X	X	.	.	.	4	1.21	196.501833	.	.

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGBC Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG breakfast (SMPG) (mg/dL)	Intercept	
2	1	PPG breakfast (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG breakfast (SMPG) (mg/dL)	REGION1	EUROPE
4	1	PPG breakfast (SMPG) (mg/dL)	REGION1	JAPAN
5	1	PPG breakfast (SMPG) (mg/dL)	BOLAD1	
6	1	PPG breakfast (SMPG) (mg/dL)	BASE	

Obs		BOLAD1	ObsVal	_1
1			0.03330	0.127898
2			0.00723	0.133567
3			-0.17265	-0.171061
4			0.36552	0.276865
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.19356	-0.166959
6			-0.56998	-0.606068

Parameter Code=P9PGBC Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	PPG breakfast (SMPG) (mg/dL)	Intercept			-0.00579	0.068857
8	1	PPG breakfast (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)		-0.11973	-0.184493
9	1	PPG breakfast (SMPG) (mg/dL)	REGION1	EUROPE		-0.03931	-0.060247

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGBC Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

(continued)

		Imputed		Observations		Region		Treatment		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		Statistics	
		P		R		E		B		O			
		A		I		G		L		S			
		R		O		N		D		V			
		A		N		1		1		a			
		M								l		I	
10	1	PPG breakfast	(SMPG) (mg/dL)	REGION1	JAPAN							0.08502	0.113847
11	1	PPG breakfast	(SMPG) (mg/dL)	BOLAD1				BOLUS INSULIN ALGORITHM (SLIDING SCALE)				-0.07647	-0.096952
12	1	PPG breakfast	(SMPG) (mg/dL)	BASE								-0.33378	-0.392720
13	1	PPG breakfast	(SMPG) (mg/dL)	visit2200								0.38385	0.407086

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PGBC Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG breakfast (SMPG) (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG breakfast (SMPG) (mg/dL)	Method	Monotone
3	1	PPG breakfast (SMPG) (mg/dL)	Number of Imputations	1
4	1	PPG breakfast (SMPG) (mg/dL)	Seed for random number generator	4323

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The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=P9PGBC Planned Treatment for Period 30 (N)=4

O b s	I m p u t a t i o n _	P A R A M	G r o u p	R E G I O N 1	E B O L A 1	B O L A 1	B O L A 1	B O L A 1	B O L A 1	F r e q	P e r c e n t	B A S E	v i s i t 2 2 0	v i s i t 3 6 0
1	1	PPG breakfast (SMPG) (mg/dL)	1	X	X	X	X	X	X	306	93.01	175.729843	1.033066	-6.184867
2	1	PPG breakfast (SMPG) (mg/dL)	2	X	X	X	X	X	.	11	3.34	151.848909	3.915121	.
3	1	PPG breakfast (SMPG) (mg/dL)	3	X	X	X	.	.	.	12	3.65	165.952833	.	.

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- in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGBC Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG breakfast (SMPG) (mg/dL)	Intercept	
2	1	PPG breakfast (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG breakfast (SMPG) (mg/dL)	REGION1	EUROPE
4	1	PPG breakfast (SMPG) (mg/dL)	REGION1	JAPAN
5	1	PPG breakfast (SMPG) (mg/dL)	BOLAD1	
6	1	PPG breakfast (SMPG) (mg/dL)	BASE	

Obs	BOLAD1	ObsVal	_1
1		0.03529	-0.007990
2		0.00869	0.057521
3		-0.16736	-0.275801
4		0.24878	0.287470
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.12003	-0.124899
6		-0.63099	-0.702393

Parameter Code=P9PGBC Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	PPG breakfast (SMPG) (mg/dL)	Intercept			0.02676	0.031292
8	1	PPG breakfast (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)		0.01796	-0.050812
9	1	PPG breakfast (SMPG) (mg/dL)	REGION1	EUROPE		-0.13262	-0.087017

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The MI Procedure with Monotone Regression Regression Information

Parameter Code=P9PGBC Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

(continued)

	O	b	s	-	P A R A M	E f f e c t	R E G I O N 1	B O L A D 1	O b s V a l	I
10	1	PPG	breakfast	(SMPG)	(mg/dL)	REGION1	JAPAN		0.20085	0.270530
11	1	PPG	breakfast	(SMPG)	(mg/dL)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.04698	-0.054286
12	1	PPG	breakfast	(SMPG)	(mg/dL)	BASE			-0.44234	-0.374201
13	1	PPG	breakfast	(SMPG)	(mg/dL)	visit2200			0.34993	0.297585

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=P9PB Planned Treatment for Period 30 (N)=2

Obs	PARAM	Description	Value
1	PPG breakfast (SMPG) (mmol/L)	Data Set	WORK.ENDPOINT_PARAM
2	PPG breakfast (SMPG) (mmol/L)	Method	Monotone-data_MCMC
3	PPG breakfast (SMPG) (mmol/L)	Multiple Imputation Chain	Multiple Chains
4	PPG breakfast (SMPG) (mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
5	PPG breakfast (SMPG) (mmol/L)	Start	Starting Value
6	PPG breakfast (SMPG) (mmol/L)	Prior	Jeffreys
7	PPG breakfast (SMPG) (mmol/L)	Number of Imputations	20000
8	PPG breakfast (SMPG) (mmol/L)	Number of Burn-in Iterations	200
9	PPG breakfast (SMPG) (mmol/L)	Seed for random number generator	1234

Parameter Code=P9PB Planned Treatment for Period 30 (N)=3

Obs	PARAM	Description	Value
10	PPG breakfast (SMPG) (mmol/L)	Data Set	WORK.ENDPOINT_PARAM
11	PPG breakfast (SMPG) (mmol/L)	Method	Monotone-data_MCMC
12	PPG breakfast (SMPG) (mmol/L)	Multiple Imputation Chain	Multiple Chains
13	PPG breakfast (SMPG) (mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
14	PPG breakfast (SMPG) (mmol/L)	Start	Starting Value
15	PPG breakfast (SMPG) (mmol/L)	Prior	Jeffreys
16	PPG breakfast (SMPG) (mmol/L)	Number of Imputations	20000
17	PPG breakfast (SMPG) (mmol/L)	Number of Burn-in Iterations	200
18	PPG breakfast (SMPG) (mmol/L)	Seed for random number generator	1369257867

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=P9PB Planned Treatment for Period 30 (N)=4

Obs	PARAM	Description	Value
19	PPG breakfast (SMPG) (mmol/L)	Data Set	WORK.ENDPOINT_PARAM
20	PPG breakfast (SMPG) (mmol/L)	Method	Monotone-data_MCMC
21	PPG breakfast (SMPG) (mmol/L)	Multiple Imputation Chain	Multiple Chains
22	PPG breakfast (SMPG) (mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
23	PPG breakfast (SMPG) (mmol/L)	Start	Starting Value
24	PPG breakfast (SMPG) (mmol/L)	Prior	Jeffreys
25	PPG breakfast (SMPG) (mmol/L)	Number of Imputations	20000
26	PPG breakfast (SMPG) (mmol/L)	Number of Burn-in Iterations	200
27	PPG breakfast (SMPG) (mmol/L)	Seed for random number generator	175357058

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The MI Procedure with MCMC
Missing data pattern

Parameter Code=P9PB Planned Treatment for Period 30 (N)=2

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
1	PPG breakfast (SMPG) (mmol/L)	1	X	X	X	290	88.96	9.912285	-0.658900	-0.754902
2	PPG breakfast (SMPG) (mmol/L)	2	X	X	O	11	3.37	8.561904	0.136885	.
3	PPG breakfast (SMPG) (mmol/L)	3	X	.	X	14	4.29	10.909600	.	-2.563079
4	PPG breakfast (SMPG) (mmol/L)	4	X	O	O	11	3.37	7.779112	.	.

Parameter Code=P9PB Planned Treatment for Period 30 (N)=3

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
5	PPG breakfast (SMPG) (mmol/L)	1	X	X	X	300	90.63	9.924835	-0.111378	-0.076865
6	PPG breakfast (SMPG) (mmol/L)	2	X	X	O	13	3.93	9.669840	-0.092649	.
7	PPG breakfast (SMPG) (mmol/L)	3	X	.	X	14	4.23	8.650626	.	1.098405
8	PPG breakfast (SMPG) (mmol/L)	4	X	O	O	4	1.21	10.904652	.	.

Parameter Code=P9PB Planned Treatment for Period 30 (N)=4

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
9	PPG breakfast (SMPG) (mmol/L)	1	X	X	X	292	88.75	9.855148	-0.015929	-0.432807
10	PPG breakfast (SMPG) (mmol/L)	2	X	X	O	11	3.34	8.426688	0.217265	.
11	PPG breakfast (SMPG) (mmol/L)	3	X	.	X	14	4.26	7.599182	.	1.525248
12	PPG breakfast (SMPG) (mmol/L)	4	X	O	O	12	3.65	9.209369	.	.

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
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The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PB Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG breakfast (SMPG) (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG breakfast (SMPG) (mmol/L)	Method	Monotone
3	1	PPG breakfast (SMPG) (mmol/L)	Number of Imputations	1
4	1	PPG breakfast (SMPG) (mmol/L)	Seed for random number generator	4321

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
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The MI Procedure with Monotone Regression Missing Data Pattern

Parameter Code=P9PB Planned Treatment for Period 30 (N)=2

Obs	1	2	3	PPG breakfast	(SMPG)	(mmol/L)	R E G I O N 1					G r o u p	v i s i t					P e r c e n t	B A S E	v i s i t	v i s i t
							M	M	M	M	M		F r e q	M	M	M	M				
	1	1	1	PPG breakfast	(SMPG)	(mmol/L)	1	X	X	X	X	X	304	93.25	9.958214	-0.645730	-0.838173				
	2	1	1	PPG breakfast	(SMPG)	(mmol/L)	2	X	X	X	X	.	11	3.37	8.561904	0.136885	.				
	3	1	1	PPG breakfast	(SMPG)	(mmol/L)	3	X	X	X	.	.	11	3.37	7.779112	.	.				

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PB Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG breakfast (SMPG) (mmol/L)	Intercept	
2	1	PPG breakfast (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG breakfast (SMPG) (mmol/L)	REGION1	EUROPE
4	1	PPG breakfast (SMPG) (mmol/L)	REGION1	JAPAN
5	1	PPG breakfast (SMPG) (mmol/L)	BOLAD1	
6	1	PPG breakfast (SMPG) (mmol/L)	BASE	

Obs	BOLAD1	ObsVal	_1
1		0.00942	0.041120
2		-0.09003	-0.060746
3		-0.07678	-0.202466
4		0.01777	-0.002813
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.02775	-0.075231
6		-0.63456	-0.672067

Parameter Code=P9PB Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	PPG breakfast (SMPG) (mmol/L)	Intercept			0.01656	-0.014422
8	1	PPG breakfast (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)		-0.18773	-0.113818
9	1	PPG breakfast (SMPG) (mmol/L)	REGION1	EUROPE		-0.06765	-0.210208

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

The MI Procedure with Monotone Regression Regression Information

Parameter Code=P9PB Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

(continued)

	O	b	s		P	E	R	B	O	I
				A	f	E		O	b	
				R	f	G		A	s	
				A	e	I		D	V	
				M	c	N		1	a	
					t	1			l	I
10	1	PPG breakfast	(SMPG)	(mmol/L)	REGION1	JAPAN			0.24412	0.274893
11	1	PPG breakfast	(SMPG)	(mmol/L)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.05987	0.004365
12	1	PPG breakfast	(SMPG)	(mmol/L)	BASE				-0.43858	-0.386936
13	1	PPG breakfast	(SMPG)	(mmol/L)	visit2200				0.27308	0.295535

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PB Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG breakfast (SMPG) (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG breakfast (SMPG) (mmol/L)	Method	Monotone
3	1	PPG breakfast (SMPG) (mmol/L)	Number of Imputations	1
4	1	PPG breakfast (SMPG) (mmol/L)	Seed for random number generator	4322

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=P9PB Planned Treatment for Period 30 (N)=3

O b s	I m p u t a t i o n _	P A R A M	G r o u p	R E G I O N A L E N T I T Y					F r e q	P e r c e n t	B A S E	v i s i t 2 0 0	v i s i t 3 6 0 0
				M E A N S S									
				M	M	M	M	M					
1	1	PPG breakfast (SMPG) (mmol/L)	1	X	X	X	X	X	314	94.86	9.868023	-0.067783	-0.024465
2	1	PPG breakfast (SMPG) (mmol/L)	2	X	X	X	X	.	13	3.93	9.669840	-0.092649	.
3	1	PPG breakfast (SMPG) (mmol/L)	3	X	X	X	.	.	4	1.21	10.904652	.	.

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PB Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG breakfast (SMPG) (mmol/L)	Intercept	
2	1	PPG breakfast (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG breakfast (SMPG) (mmol/L)	REGION1	EUROPE
4	1	PPG breakfast (SMPG) (mmol/L)	REGION1	JAPAN
5	1	PPG breakfast (SMPG) (mmol/L)	BOLAD1	
6	1	PPG breakfast (SMPG) (mmol/L)	BASE	

Obs	BOLAD1	ObsVal	_1
1		0.03330	0.127898
2		0.00723	0.133567
3		-0.17265	-0.171061
4		0.36552	0.276865
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.19356	-0.166959
6		-0.56998	-0.606068

Parameter Code=P9PB Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	PPG breakfast (SMPG) (mmol/L)	Intercept			-0.00579	0.068857
8	1	PPG breakfast (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)		-0.11973	-0.184493
9	1	PPG breakfast (SMPG) (mmol/L)	REGION1	EUROPE		-0.03931	-0.060247

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

The MI Procedure with Monotone Regression Regression Information

Parameter Code=P9PB Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

(continued)

	O	b	s		P A R A M	E f f e c t	R E G I O N 1	B O L A D 1	O b s V a l	I
10	1	PPG	breakfast	(SMPG)	(mmol/L)	REGION1	JAPAN		0.08502	0.113847
11	1	PPG	breakfast	(SMPG)	(mmol/L)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.07647	-0.096952
12	1	PPG	breakfast	(SMPG)	(mmol/L)	BASE			-0.33378	-0.392720
13	1	PPG	breakfast	(SMPG)	(mmol/L)	visit2200			0.38385	0.407086

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PB Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG breakfast (SMPG) (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG breakfast (SMPG) (mmol/L)	Method	Monotone
3	1	PPG breakfast (SMPG) (mmol/L)	Number of Imputations	1
4	1	PPG breakfast (SMPG) (mmol/L)	Seed for random number generator	4323

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- in-trial - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=P9PB Planned Treatment for Period 30 (N)=4

O b s	I m p u t a t i o n _	P A R A M	G r o u p	R E G I O N 1	E B L A D 1	B O L A D 1	B L A D 1	B L A D 1	B L A D 1	F r e q	P e r c e n t	B A S E	v i s i t 2 0 0	v i s i t 3 6 0 0
1	1	PPG breakfast (SMPG) (mmol/L)	1	X	X	X	X	X	X	306	93.01	9.751934	0.057329	-0.343222
2	1	PPG breakfast (SMPG) (mmol/L)	2	X	X	X	X	.	.	11	3.34	8.426688	0.217265	.
3	1	PPG breakfast (SMPG) (mmol/L)	3	X	X	X	.	.	.	12	3.65	9.209369	.	.

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PB Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG breakfast (SMPG) (mmol/L)	Intercept	
2	1	PPG breakfast (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG breakfast (SMPG) (mmol/L)	REGION1	EUROPE
4	1	PPG breakfast (SMPG) (mmol/L)	REGION1	JAPAN
5	1	PPG breakfast (SMPG) (mmol/L)	BOLAD1	
6	1	PPG breakfast (SMPG) (mmol/L)	BASE	

Obs	BOLAD1	ObsVal	_1
1		0.03529	-0.007990
2		0.00869	0.057521
3		-0.16736	-0.275801
4		0.24878	0.287470
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.12003	-0.124899
6		-0.63099	-0.702393

Parameter Code=P9PB Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	PPG breakfast (SMPG) (mmol/L)	Intercept			0.02676	0.031292
8	1	PPG breakfast (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)		0.01796	-0.050812
9	1	PPG breakfast (SMPG) (mmol/L)	REGION1	EUROPE		-0.13262	-0.087017

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
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The MI Procedure with Monotone Regression Regression Information

Parameter Code=P9PB Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

(continued)

	O	B	S		P	E	R	B	O	I
	b	a	t	A	f	E	G	O	b	s
	n	i	e	R	f	N	I	A	s	V
	-			M	c	1		D	a	
10	1	PPG breakfast	(SMPG)	(mmol/L)	REGION1	JAPAN			0.20085	0.270530
11	1	PPG breakfast	(SMPG)	(mmol/L)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.04698	-0.054286
12	1	PPG breakfast	(SMPG)	(mmol/L)	BASE				-0.44234	-0.374201
13	1	PPG breakfast	(SMPG)	(mmol/L)	visit2200				0.34993	0.297585

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The MI Procedure with MCMC
Model Information

Parameter Code=P9PLC Planned Treatment for Period 30 (N)=2

Obs	PARAM	Description	Value
1	PPG lunch (SMPG) (mg/dL)	Data Set	WORK.ENDPOINT_PARAM
2	PPG lunch (SMPG) (mg/dL)	Method	Monotone-data_MCMC
3	PPG lunch (SMPG) (mg/dL)	Multiple Imputation Chain	Multiple Chains
4	PPG lunch (SMPG) (mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
5	PPG lunch (SMPG) (mg/dL)	Start	Starting Value
6	PPG lunch (SMPG) (mg/dL)	Prior	Jeffreys
7	PPG lunch (SMPG) (mg/dL)	Number of Imputations	20000
8	PPG lunch (SMPG) (mg/dL)	Number of Burn-in Iterations	200
9	PPG lunch (SMPG) (mg/dL)	Seed for random number generator	1234

Parameter Code=P9PLC Planned Treatment for Period 30 (N)=3

Obs	PARAM	Description	Value
10	PPG lunch (SMPG) (mg/dL)	Data Set	WORK.ENDPOINT_PARAM
11	PPG lunch (SMPG) (mg/dL)	Method	Monotone-data_MCMC
12	PPG lunch (SMPG) (mg/dL)	Multiple Imputation Chain	Multiple Chains
13	PPG lunch (SMPG) (mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
14	PPG lunch (SMPG) (mg/dL)	Start	Starting Value
15	PPG lunch (SMPG) (mg/dL)	Prior	Jeffreys
16	PPG lunch (SMPG) (mg/dL)	Number of Imputations	20000
17	PPG lunch (SMPG) (mg/dL)	Number of Burn-in Iterations	200
18	PPG lunch (SMPG) (mg/dL)	Seed for random number generator	1964087206

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The MI Procedure with MCMC
Model Information

Parameter Code=P9PLC Planned Treatment for Period 30 (N)=4

Obs	PARAM			Description	Value
19	PPG lunch	(SMPG)	(mg/dL)	Data Set	WORK.ENDPOINT_PARAM
20	PPG lunch	(SMPG)	(mg/dL)	Method	Monotone-data_MCMC
21	PPG lunch	(SMPG)	(mg/dL)	Multiple Imputation Chain	Multiple Chains
22	PPG lunch	(SMPG)	(mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
23	PPG lunch	(SMPG)	(mg/dL)	Start	Starting Value
24	PPG lunch	(SMPG)	(mg/dL)	Prior	Jeffreys
25	PPG lunch	(SMPG)	(mg/dL)	Number of Imputations	20000
26	PPG lunch	(SMPG)	(mg/dL)	Number of Burn-in Iterations	200
27	PPG lunch	(SMPG)	(mg/dL)	Seed for random number generator	686836195

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The MI Procedure with MCMC
Missing data pattern

Parameter Code=P9PLC Planned Treatment for Period 30 (N)=2

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
1	PPG lunch (SMPG) (mg/dL)	1	X	X	X	288	88.07	170.248237	-12.341174	-10.352753
2	PPG lunch (SMPG) (mg/dL)	2	X	X	O	13	3.98	159.276667	2.935897	.
3	PPG lunch (SMPG) (mg/dL)	3	X	.	X	16	4.89	186.284792	.	-21.535458
4	PPG lunch (SMPG) (mg/dL)	4	X	O	O	10	3.06	151.819700	.	.

Parameter Code=P9PLC Planned Treatment for Period 30 (N)=3

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
5	PPG lunch (SMPG) (mg/dL)	1	X	X	X	298	90.85	170.881721	0.587306	-1.064191
6	PPG lunch (SMPG) (mg/dL)	2	X	X	O	13	3.96	139.516103	24.496692	.
7	PPG lunch (SMPG) (mg/dL)	3	X	.	X	13	3.96	146.777179	.	22.783487
8	PPG lunch (SMPG) (mg/dL)	4	X	O	O	4	1.22	150.724667	.	.

Parameter Code=P9PLC Planned Treatment for Period 30 (N)=4

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
9	PPG lunch (SMPG) (mg/dL)	1	X	X	X	293	89.06	172.196182	-3.258523	-7.303625
10	PPG lunch (SMPG) (mg/dL)	2	X	X	O	13	3.95	154.827744	13.977487	.
11	PPG lunch (SMPG) (mg/dL)	3	X	.	X	14	4.26	158.475595	.	1.556452
12	PPG lunch (SMPG) (mg/dL)	4	X	O	O	9	2.74	178.209630	.	.

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09FEB2018:20:27:18 - a_797pp_stat_diff.sas/a_9pp_ppg_stat_in_fas_app.txt

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PLC Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG lunch (SMPG) (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG lunch (SMPG) (mg/dL)	Method	Monotone
3	1	PPG lunch (SMPG) (mg/dL)	Number of Imputations	1
4	1	PPG lunch (SMPG) (mg/dL)	Seed for random number generator	4321

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
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The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=P9PLC Planned Treatment for Period 30 (N)=2

O b s	I m p u t a t i o n	P A R A M	G r o u p	R E G I O N 1	B O L 1	B L A D E	S I S T E M	S I S T E M	F r e q	P e r c e n t	B A S E	v i s i t e s	v i s i t e s
1	1	PPG lunch (SMPG) (mg/dL)	1	X	X	X	X	X	304	92.97	171.092266	-13.154170	-10.941317
2	1	PPG lunch (SMPG) (mg/dL)	2	X	X	X	X	.	13	3.98	159.276667	2.935897	.
3	1	PPG lunch (SMPG) (mg/dL)	3	X	X	X	.	.	10	3.06	151.819700	.	.

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- in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PLC Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG lunch (SMPG) (mg/dL)	Intercept	
2	1	PPG lunch (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG lunch (SMPG) (mg/dL)	REGION1	EUROPE
4	1	PPG lunch (SMPG) (mg/dL)	REGION1	JAPAN
5	1	PPG lunch (SMPG) (mg/dL)	BOLAD1	
6	1	PPG lunch (SMPG) (mg/dL)	BASE	

Obs	BOLAD1	ObsVal	_1
1		-0.02796	0.004185
2		-0.33720	-0.307472
3		0.03155	-0.096692
4		0.22570	0.209793
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.05260	-0.098637
6		-0.60902	-0.636146

Parameter Code=P9PLC Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	PPG lunch (SMPG) (mg/dL)	Intercept			0.01075	-0.014504
8	1	PPG lunch (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)		-0.12340	-0.200407
9	1	PPG lunch (SMPG) (mg/dL)	REGION1	EUROPE		-0.10027	-0.014156

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PLC Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
10	1	PPG lunch (SMPG) (mg/dL)	REGION1	JAPAN		0.20103	0.075680
11	1	PPG lunch (SMPG) (mg/dL)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.00689	0.024308
12	1	PPG lunch (SMPG) (mg/dL)	BASE			-0.57104	-0.472774
13	1	PPG lunch (SMPG) (mg/dL)	visit2200			0.21528	0.298732

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The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PLC Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG lunch (SMPG) (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG lunch (SMPG) (mg/dL)	Method	Monotone
3	1	PPG lunch (SMPG) (mg/dL)	Number of Imputations	1
4	1	PPG lunch (SMPG) (mg/dL)	Seed for random number generator	4322

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- in-trial - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=P9PLC Planned Treatment for Period 30 (N)=3

O b s	I m p u t a t i o n	P A R A M	G r o u p	R E G I O N 1	B O L 1	B L A D E	B L A D E	B L A D E	B L A D E	F r e q	P e r c e n t	B A S E	v i s i t e s	v i s i t e s
1	1	PPG lunch (SMPG) (mg/dL)	1	X	X	X	X	X	X	311	94.82	169.874136	1.827275	-0.067343
2	1	PPG lunch (SMPG) (mg/dL)	2	X	X	X	X	.	.	13	3.96	139.516103	24.496692	.
3	1	PPG lunch (SMPG) (mg/dL)	3	X	X	X	.	.	.	4	1.22	150.724667	.	.

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- in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PLC Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG lunch (SMPG) (mg/dL)	Intercept	
2	1	PPG lunch (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG lunch (SMPG) (mg/dL)	REGION1	EUROPE
4	1	PPG lunch (SMPG) (mg/dL)	REGION1	JAPAN
5	1	PPG lunch (SMPG) (mg/dL)	BOLAD1	
6	1	PPG lunch (SMPG) (mg/dL)	BASE	

Obs		BOLAD1	ObsVal	_1
1			0.02490	0.121962
2			-0.02163	0.107228
3			-0.14892	-0.145997
4			0.24045	0.147893
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.12378	-0.096707
6			-0.55119	-0.585109

Parameter Code=P9PLC Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	PPG lunch (SMPG) (mg/dL)	Intercept			0.00767	0.079339
8	1	PPG lunch (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)		-0.14444	-0.207931
9	1	PPG lunch (SMPG) (mg/dL)	REGION1	EUROPE		-0.03317	-0.054484

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09FEB2018:20:27:18 - a_797pp_stat_diff.sas/a_9pp_ppg_stat_in_fas_app.txt

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PLC Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
10	1	PPG lunch (SMPG) (mg/dL)	REGION1	JAPAN		0.21731	0.246828
11	1	PPG lunch (SMPG) (mg/dL)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.08210	-0.101282
12	1	PPG lunch (SMPG) (mg/dL)	BASE			-0.42348	-0.485249
13	1	PPG lunch (SMPG) (mg/dL)	visit2200			0.33943	0.360699

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PLC Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG lunch (SMPG) (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG lunch (SMPG) (mg/dL)	Method	Monotone
3	1	PPG lunch (SMPG) (mg/dL)	Number of Imputations	1
4	1	PPG lunch (SMPG) (mg/dL)	Seed for random number generator	4323

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- in-trial - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=P9PLC Planned Treatment for Period 30 (N)=4

O b s	I m p u t a t i o n	P A R A M	G r o u p	R E G I O N 1	B O L 1	B L A D E	S I S T E M	S I S T E M	F r e q	P e r c e n t	B A S E	v i s i t e s	v i s i t e s
1	1	PPG lunch (SMPG) (mg/dL)	1	X	X	X	X	X	307	93.31	171.570488	-1.932524	-6.899582
2	1	PPG lunch (SMPG) (mg/dL)	2	X	X	X	X	.	13	3.95	154.827744	13.977487	.
3	1	PPG lunch (SMPG) (mg/dL)	3	X	X	X	.	.	9	2.74	178.209630	.	.

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PLC Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG lunch (SMPG) (mg/dL)	Intercept	
2	1	PPG lunch (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG lunch (SMPG) (mg/dL)	REGION1	EUROPE
4	1	PPG lunch (SMPG) (mg/dL)	REGION1	JAPAN
5	1	PPG lunch (SMPG) (mg/dL)	BOLAD1	
6	1	PPG lunch (SMPG) (mg/dL)	BASE	

Obs	BOLAD1	ObsVal	_1
1		0.03184	-0.008278
2		0.03997	0.085550
3		-0.13817	-0.238860
4		0.12379	0.161216
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.12749	-0.131162
6		-0.69994	-0.773186

Parameter Code=P9PLC Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	PPG lunch (SMPG) (mg/dL)	Intercept			0.05008	0.120935
8	1	PPG lunch (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)		0.12311	0.130662
9	1	PPG lunch (SMPG) (mg/dL)	REGION1	EUROPE		-0.23391	-0.282319

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PLC Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
10	1	PPG lunch (SMPG) (mg/dL)	REGION1	JAPAN		0.25933	0.292965
11	1	PPG lunch (SMPG) (mg/dL)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.10489	-0.153831
12	1	PPG lunch (SMPG) (mg/dL)	BASE			-0.51338	-0.505467
13	1	PPG lunch (SMPG) (mg/dL)	visit2200			0.26107	0.304821

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- in-trial - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=P9PL Planned Treatment for Period 30 (N)=2

Obs	PARAM	Description	Value
1	PPG lunch (SMPG) (mmol/L)	Data Set	WORK.ENDPOINT_PARAM
2	PPG lunch (SMPG) (mmol/L)	Method	Monotone-data_MCMC
3	PPG lunch (SMPG) (mmol/L)	Multiple Imputation Chain	Multiple Chains
4	PPG lunch (SMPG) (mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
5	PPG lunch (SMPG) (mmol/L)	Start	Starting Value
6	PPG lunch (SMPG) (mmol/L)	Prior	Jeffreys
7	PPG lunch (SMPG) (mmol/L)	Number of Imputations	20000
8	PPG lunch (SMPG) (mmol/L)	Number of Burn-in Iterations	200
9	PPG lunch (SMPG) (mmol/L)	Seed for random number generator	1234

Parameter Code=P9PL Planned Treatment for Period 30 (N)=3

Obs	PARAM	Description	Value
10	PPG lunch (SMPG) (mmol/L)	Data Set	WORK.ENDPOINT_PARAM
11	PPG lunch (SMPG) (mmol/L)	Method	Monotone-data_MCMC
12	PPG lunch (SMPG) (mmol/L)	Multiple Imputation Chain	Multiple Chains
13	PPG lunch (SMPG) (mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
14	PPG lunch (SMPG) (mmol/L)	Start	Starting Value
15	PPG lunch (SMPG) (mmol/L)	Prior	Jeffreys
16	PPG lunch (SMPG) (mmol/L)	Number of Imputations	20000
17	PPG lunch (SMPG) (mmol/L)	Number of Burn-in Iterations	200
18	PPG lunch (SMPG) (mmol/L)	Seed for random number generator	1964087206

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=P9PL Planned Treatment for Period 30 (N)=4

Obs	PARAM			Description	Value
19	PPG lunch	(SMPG)	(mmol/L)	Data Set	WORK.ENDPOINT_PARAM
20	PPG lunch	(SMPG)	(mmol/L)	Method	Monotone-data_MCMC
21	PPG lunch	(SMPG)	(mmol/L)	Multiple Imputation Chain	Multiple Chains
22	PPG lunch	(SMPG)	(mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
23	PPG lunch	(SMPG)	(mmol/L)	Start	Starting Value
24	PPG lunch	(SMPG)	(mmol/L)	Prior	Jeffreys
25	PPG lunch	(SMPG)	(mmol/L)	Number of Imputations	20000
26	PPG lunch	(SMPG)	(mmol/L)	Number of Burn-in Iterations	200
27	PPG lunch	(SMPG)	(mmol/L)	Seed for random number generator	686836195

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

The MI Procedure with MCMC
Missing data pattern

Parameter Code=P9PL Planned Treatment for Period 30 (N)=2

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
1	PPG lunch (SMPG) (mmol/L)	1	X	X	X	288	88.07	9.447738	-0.684860	-0.574515
2	PPG lunch (SMPG) (mmol/L)	2	X	X	O	13	3.98	8.838883	0.162924	.
3	PPG lunch (SMPG) (mmol/L)	3	X	.	X	16	4.89	10.337669	.	-1.195086
4	PPG lunch (SMPG) (mmol/L)	4	X	O	O	10	3.06	8.425067	.	.

Parameter Code=P9PL Planned Treatment for Period 30 (N)=3

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
5	PPG lunch (SMPG) (mmol/L)	1	X	X	X	298	90.85	9.482892	0.032592	-0.059056
6	PPG lunch (SMPG) (mmol/L)	2	X	X	O	13	3.96	7.742292	1.359417	.
7	PPG lunch (SMPG) (mmol/L)	3	X	.	X	13	3.96	8.145237	.	1.264344
8	PPG lunch (SMPG) (mmol/L)	4	X	O	O	4	1.22	8.364299	.	.

Parameter Code=P9PL Planned Treatment for Period 30 (N)=4

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
9	PPG lunch (SMPG) (mmol/L)	1	X	X	X	293	89.06	9.555837	-0.180828	-0.405307
10	PPG lunch (SMPG) (mmol/L)	2	X	X	O	13	3.95	8.591995	0.775665	.
11	PPG lunch (SMPG) (mmol/L)	3	X	.	X	14	4.26	8.794428	.	0.086374
12	PPG lunch (SMPG) (mmol/L)	4	X	O	O	9	2.74	9.889547	.	.

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- in-trial - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PL Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG lunch (SMPG) (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG lunch (SMPG) (mmol/L)	Method	Monotone
3	1	PPG lunch (SMPG) (mmol/L)	Number of Imputations	1
4	1	PPG lunch (SMPG) (mmol/L)	Seed for random number generator	4321

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

The MI Procedure with Monotone Regression Missing Data Pattern

Parameter Code=P9PL Planned Treatment for Period 30 (N)=2

O b s		I m p u t a t i o n _					R E G I O N 1		B O L A D 1		B A A S E		v i s i t 2		v i s i t 3		P e r c e n t	B A S E	v i s i t 2	v i s i t 3
			P A R A M	G r o u p	M i s s	M i s s	M i s s	M i s s	M i s s	F r e q										
1	1	PPG lunch (SMPG)	(mmol/L)	1	X	X	X	X	X		304	92.97	9.494576	-0.729976	-0.607176					
2	1	PPG lunch (SMPG)	(mmol/L)	2	X	X	X	X	X	.	13	3.98	8.838883	0.162924	.					
3	1	PPG lunch (SMPG)	(mmol/L)	3	X	X	X	X	.	.	10	3.06	8.425067	.	.					

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PL Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG lunch (SMPG) (mmol/L)	Intercept	
2	1	PPG lunch (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG lunch (SMPG) (mmol/L)	REGION1	EUROPE
4	1	PPG lunch (SMPG) (mmol/L)	REGION1	JAPAN
5	1	PPG lunch (SMPG) (mmol/L)	BOLAD1	
6	1	PPG lunch (SMPG) (mmol/L)	BASE	
Obs		BOLAD1	ObsVal	_1
1			-0.02796	0.004185
2			-0.33720	-0.307472
3			0.03155	-0.096692
4			0.22570	0.209793
5		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.05260	-0.098637
6			-0.60902	-0.636146

Parameter Code=P9PL Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	PPG lunch (SMPG) (mmol/L)	Intercept			0.01075	-0.014504
8	1	PPG lunch (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)		-0.12340	-0.200407
9	1	PPG lunch (SMPG) (mmol/L)	REGION1	EUROPE		-0.10027	-0.014156

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PL Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
10	1	PPG lunch (SMPG) (mmol/L)	REGION1	JAPAN		0.20103	0.075680
11	1	PPG lunch (SMPG) (mmol/L)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.00689	0.024308
12	1	PPG lunch (SMPG) (mmol/L)	BASE			-0.57104	-0.472774
13	1	PPG lunch (SMPG) (mmol/L)	visit2200			0.21528	0.298732

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PL Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG lunch (SMPG) (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG lunch (SMPG) (mmol/L)	Method	Monotone
3	1	PPG lunch (SMPG) (mmol/L)	Number of Imputations	1
4	1	PPG lunch (SMPG) (mmol/L)	Seed for random number generator	4322

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=P9PL Planned Treatment for Period 30 (N)=3

O b s	I m p u t a t i o n _						P A R A M	G r o u p	R E G I O N 1					F r e q	P e r c e n t	B A S E	v i s i t 2 0 0	v i s i t 3 6 0 0
									\bar{M} i s s	\bar{M} i s s	\bar{M} i s s	\bar{M} i s s	\bar{M} i s s					
1	1	PPG	lunch	(SMPG)	(mmol/L)	1	X	X	X	X	X	311	94.82	9.426978	0.101403	-0.003737		
2	1	PPG	lunch	(SMPG)	(mmol/L)	2	X	X	X	X	.	13	3.96	7.742292	1.359417	.		
3	1	PPG	lunch	(SMPG)	(mmol/L)	3	X	X	X	.	.	4	1.22	8.364299	.	.		

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PL Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG lunch (SMPG) (mmol/L)	Intercept	
2	1	PPG lunch (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG lunch (SMPG) (mmol/L)	REGION1	EUROPE
4	1	PPG lunch (SMPG) (mmol/L)	REGION1	JAPAN
5	1	PPG lunch (SMPG) (mmol/L)	BOLAD1	
6	1	PPG lunch (SMPG) (mmol/L)	BASE	

Obs	BOLAD1	ObsVal	_1
1		0.02490	0.121962
2		-0.02163	0.107228
3		-0.14892	-0.145997
4		0.24045	0.147893
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.12378	-0.096707
6		-0.55119	-0.585109

Parameter Code=P9PL Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	PPG lunch (SMPG) (mmol/L)	Intercept			0.00767	0.079339
8	1	PPG lunch (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)		-0.14444	-0.207931
9	1	PPG lunch (SMPG) (mmol/L)	REGION1	EUROPE		-0.03317	-0.054484

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PL Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
10	1	PPG lunch (SMPG) (mmol/L)	REGION1	JAPAN		0.21731	0.246828
11	1	PPG lunch (SMPG) (mmol/L)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.08210	-0.101282
12	1	PPG lunch (SMPG) (mmol/L)	BASE			-0.42348	-0.485249
13	1	PPG lunch (SMPG) (mmol/L)	visit2200			0.33943	0.360699

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
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The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PL Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG lunch (SMPG) (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG lunch (SMPG) (mmol/L)	Method	Monotone
3	1	PPG lunch (SMPG) (mmol/L)	Number of Imputations	1
4	1	PPG lunch (SMPG) (mmol/L)	Seed for random number generator	4323

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- in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PL Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG lunch (SMPG) (mmol/L)	Intercept	
2	1	PPG lunch (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG lunch (SMPG) (mmol/L)	REGION1	EUROPE
4	1	PPG lunch (SMPG) (mmol/L)	REGION1	JAPAN
5	1	PPG lunch (SMPG) (mmol/L)	BOLAD1	
6	1	PPG lunch (SMPG) (mmol/L)	BASE	

Obs	BOLAD1	ObsVal	_1
1		0.03184	-0.008278
2		0.03997	0.085550
3		-0.13817	-0.238860
4		0.12379	0.161216
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.12749	-0.131162
6		-0.69994	-0.773186

Parameter Code=P9PL Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	PPG lunch (SMPG) (mmol/L)	Intercept			0.05008	0.120935
8	1	PPG lunch (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)		0.12311	0.130662
9	1	PPG lunch (SMPG) (mmol/L)	REGION1	EUROPE		-0.23391	-0.282319

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PL Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
10	1	PPG lunch (SMPG) (mmol/L)	REGION1	JAPAN		0.25933	0.292965
11	1	PPG lunch (SMPG) (mmol/L)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.10489	-0.153831
12	1	PPG lunch (SMPG) (mmol/L)	BASE			-0.51338	-0.505467
13	1	PPG lunch (SMPG) (mmol/L)	visit2200			0.26107	0.304821

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The MI Procedure with MCMC
Model Information

Parameter Code=P9PEVC Planned Treatment for Period 30 (N)=2

Obs	PARAM	Description	Value
1	PPG main evening meal (SMPG) (mg/dL)	Data Set	WORK.ENDPOINT_PARAM
2	PPG main evening meal (SMPG) (mg/dL)	Method	Monotone-data MCMC
3	PPG main evening meal (SMPG) (mg/dL)	Multiple Imputation Chain	Multiple Chains
4	PPG main evening meal (SMPG) (mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
5	PPG main evening meal (SMPG) (mg/dL)	Start	Starting Value
6	PPG main evening meal (SMPG) (mg/dL)	Prior	Jeffreys
7	PPG main evening meal (SMPG) (mg/dL)	Number of Imputations	20000
8	PPG main evening meal (SMPG) (mg/dL)	Number of Burn-in Iterations	200
9	PPG main evening meal (SMPG) (mg/dL)	Seed for random number generator	1234

Parameter Code=P9PEVC Planned Treatment for Period 30 (N)=3

Obs	PARAM	Description	Value
10	PPG main evening meal (SMPG) (mg/dL)	Data Set	WORK.ENDPOINT_PARAM
11	PPG main evening meal (SMPG) (mg/dL)	Method	Monotone-data MCMC
12	PPG main evening meal (SMPG) (mg/dL)	Multiple Imputation Chain	Multiple Chains
13	PPG main evening meal (SMPG) (mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
14	PPG main evening meal (SMPG) (mg/dL)	Start	Starting Value
15	PPG main evening meal (SMPG) (mg/dL)	Prior	Jeffreys
16	PPG main evening meal (SMPG) (mg/dL)	Number of Imputations	20000
17	PPG main evening meal (SMPG) (mg/dL)	Number of Burn-in Iterations	200
18	PPG main evening meal (SMPG) (mg/dL)	Seed for random number generator	1652582263

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=P9PEVC Planned Treatment for Period 30 (N)=4

Obs	PARAM	Description	Value
19	PPG main evening meal (SMPG) (mg/dL)	Data Set	WORK.ENDPOINT_PARAM
20	PPG main evening meal (SMPG) (mg/dL)	Method	Monotone-data_MCMC
21	PPG main evening meal (SMPG) (mg/dL)	Multiple Imputation Chain	Multiple Chains
22	PPG main evening meal (SMPG) (mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
23	PPG main evening meal (SMPG) (mg/dL)	Start	Starting Value
24	PPG main evening meal (SMPG) (mg/dL)	Prior	Jeffreys
25	PPG main evening meal (SMPG) (mg/dL)	Number of Imputations	20000
26	PPG main evening meal (SMPG) (mg/dL)	Number of Burn-in Iterations	200
27	PPG main evening meal (SMPG) (mg/dL)	Seed for random number generator	116507659

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

The MI Procedure with MCMC

Missing data pattern

Parameter Code=P9PEVC Planned Treatment for Period 30 (N)=2

[illegible]

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

The MI Procedure with MCMC

Missing data pattern

Parameter Code=P9PEVC Planned Treatment for Period 30 (N)=3

O b s							v i s i t i t y						v i s i t y				
							B A S E	2 2 0 0	3 6 0 0				P e r c e n t	B A S E	2 2 0 0	3 6 0 0	
P A R A M							G r o u p	\bar{M} i s s	\bar{M} i s s	\bar{M} i s s	F r e q						
5	PPG	main	evening	meal	(SMPG)	(mg/dL)	1	X	X	X	298	91.13	175.481819	1.632962		0.002544	
6	PPG	main	evening	meal	(SMPG)	(mg/dL)	2	X	X	O	10	3.06	164.420200	23.233800		.	
7	PPG	main	evening	meal	(SMPG)	(mg/dL)	3	X	.	X	14	4.28	192.684476	.		-18.280738	
8	PPG	main	evening	meal	(SMPG)	(mg/dL)	4	X	O	O	5	1.53	162.957667	.			

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
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The MI Procedure with MCMC

Missing data pattern

Parameter Code=P9PEVC Planned Treatment for Period 30 (N)=4

O b s			P A R A M	G r o u p	v i s i t B A S E \bar{M}			F r e q	P e r c e n t	B A S E	v i s i t 2 0 0		v i s i t 3 6 0 0	
					i s s	i s s	i s s				2 2 0 0	3 6 0 0		
9	PPG	main evening meal	(SMPG)	(mg/dL)	1	X	X	X	294	89.63	167.039449	-1.076643	-2.038533	
10	PPG	main evening meal	(SMPG)	(mg/dL)	2	X	X	O	11	3.35	176.995939	-7.308909	.	
11	PPG	main evening meal	(SMPG)	(mg/dL)	3	X	.	X	14	4.27	174.830762	.	-8.434095	
12	PPG	main evening meal	(SMPG)	(mg/dL)	4	X	O	O	9	2.74	189.076148	.	.	

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PEVC Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG main evening meal (SMPG) (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG main evening meal (SMPG) (mg/dL)	Method	Monotone
3	1	PPG main evening meal (SMPG) (mg/dL)	Number of Imputations	1
4	1	PPG main evening meal (SMPG) (mg/dL)	Seed for random number generator	4321

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

The MI Procedure with Monotone Regression Missing Data Pattern

Parameter Code=P9PEVC Planned Treatment for Period 30 (N)=2

O b s	I m p u t a t i o n _	P A R A M	G r o u p	R E G I O N A L E S					F r e q	P e r c e n t	B A S E	v i s i t 2 0 0	v i s i t 3 6 0 0
				M	M	M	M	M					
1	1	PPG main evening meal (SMPG) (mg/dL)	1	X	X	X	X	X	305	93.56	172.130977	-11.976084	-9.818440
2	1	PPG main evening meal (SMPG) (mg/dL)	2	X	X	X	X	.	11	3.37	137.514485	12.307455	.
3	1	PPG main evening meal (SMPG) (mg/dL)	3	X	X	X	.	.	10	3.07	160.788767	.	.

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PEVC Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG main evening meal (SMPG) (mg/dL)	Intercept	
2	1	PPG main evening meal (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG main evening meal (SMPG) (mg/dL)	REGION1	EUROPE
4	1	PPG main evening meal (SMPG) (mg/dL)	REGION1	JAPAN
5	1	PPG main evening meal (SMPG) (mg/dL)	BOLAD1	
6	1	PPG main evening meal (SMPG) (mg/dL)	BASE	

Obs	BOLAD1	ObsVal	_1
1		0.00909	0.039558
2		0.02742	0.056240
3		-0.02641	-0.147403
4		-0.07712	-0.093917
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.03928	-0.082956
6		-0.65371	-0.684738

Parameter Code=P9PEVC Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	PPG main evening meal (SMPG) (mg/dL)	Intercept			-0.02584	-0.051308
8	1	PPG main evening meal (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)		-0.27569	-0.351455
9	1	PPG main evening meal (SMPG) (mg/dL)	REGION1	EUROPE		0.02871	0.116485

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

The MI Procedure with Monotone Regression Regression Information

Parameter Code=P9PEVC Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

(continued)

	O b s _	P A R A M	E f f e c t	R E G I O N l	B O L U S D l	O b s V a l	I
10	1	PPG main evening meal (SMPG) (mg/dL)	REGION1	JAPAN		0.05664	-0.069475
11	1	PPG main evening meal (SMPG) (mg/dL)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.01517	0.015235
12	1	PPG main evening meal (SMPG) (mg/dL)	BASE			-0.38101	-0.289766
13	1	PPG main evening meal (SMPG) (mg/dL)	visit2200			0.33358	0.419216

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PEVC Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG main evening meal (SMPG) (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG main evening meal (SMPG) (mg/dL)	Method	Monotone
3	1	PPG main evening meal (SMPG) (mg/dL)	Number of Imputations	1
4	1	PPG main evening meal (SMPG) (mg/dL)	Seed for random number generator	4322

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

The MI Procedure with Monotone Regression Missing Data Pattern

Parameter Code=P9PEVC Planned Treatment for Period 30 (N)=3

O b s	I m p u t a t i o n —	P A R A M	G r o u p	R E G I O N A L E S					F r e q	P e r c e n t	B A S E	v i s i t 2 0 0	v i s i t 3 6 0 0
				\bar{M}	\bar{M}	\bar{M}	\bar{M}	\bar{M}					
1	1 PPG main evening meal (SMPG) (mg/dL)		1	X	X	X	X	X	312	95.41	176.253733	0.554357	-0.817860
2	1 PPG main evening meal (SMPG) (mg/dL)		2	X	X	X	X	.	10	3.06	164.420200	23.233800	.
3	1 PPG main evening meal (SMPG) (mg/dL)		3	X	X	X	.	.	5	1.53	162.957667	.	.

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PEVC Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG main evening meal (SMPG) (mg/dL)	Intercept	
2	1	PPG main evening meal (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG main evening meal (SMPG) (mg/dL)	REGION1	EUROPE
4	1	PPG main evening meal (SMPG) (mg/dL)	REGION1	JAPAN
5	1	PPG main evening meal (SMPG) (mg/dL)	BOLAD1	
6	1	PPG main evening meal (SMPG) (mg/dL)	BASE	

Obs	BOLAD1	ObsVal	_1
1		0.03458	0.127330
2		0.06117	0.185387
3		-0.21022	-0.209235
4		0.15983	0.074423
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.08759	-0.062172
6		-0.60459	-0.648910

Parameter Code=P9PEVC Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	PPG main evening meal (SMPG) (mg/dL)	Intercept			0.00517	-0.050701
8	1	PPG main evening meal (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)		-0.11757	-0.206612
9	1	PPG main evening meal (SMPG) (mg/dL)	REGION1	EUROPE		-0.11992	-0.098593

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- in-trial - full analysis set

The MI Procedure with Monotone Regression Regression Information

Parameter Code=P9PEVC Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

(continued)

	O	b	s		P	E	R	B	O	I	
	n	a		A	f	G		L	b		
	s	m		M	c	N		D	V		
	-				t	l		1	a	I	
10	1	PPG	main	evening meal	(SMPG)	(mg/dL)	REGION1	JAPAN		0.26964	0.268900
11	1	PPG	main	evening meal	(SMPG)	(mg/dL)	BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.07461	-0.086907	
12	1	PPG	main	evening meal	(SMPG)	(mg/dL)	BASE		-0.47509	-0.414128	
13	1	PPG	main	evening meal	(SMPG)	(mg/dL)	visit2200		0.31430	0.328462	

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PEVC Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG main evening meal (SMPG) (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG main evening meal (SMPG) (mg/dL)	Method	Monotone
3	1	PPG main evening meal (SMPG) (mg/dL)	Number of Imputations	1
4	1	PPG main evening meal (SMPG) (mg/dL)	Seed for random number generator	4323

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PEVC Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG main evening meal (SMPG) (mg/dL)	Intercept	
2	1	PPG main evening meal (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG main evening meal (SMPG) (mg/dL)	REGION1	EUROPE
4	1	PPG main evening meal (SMPG) (mg/dL)	REGION1	JAPAN
5	1	PPG main evening meal (SMPG) (mg/dL)	BOLAD1	
6	1	PPG main evening meal (SMPG) (mg/dL)	BASE	

Obs	BOLAD1	ObsVal	_1
1		0.01812	-0.024894
2		-0.07131	-0.022082
3		-0.14433	-0.252488
4		0.31184	0.349090
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.13239	-0.136829
6		-0.62079	-0.697369

Parameter Code=P9PEVC Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	PPG main evening meal (SMPG) (mg/dL)	Intercept			-0.0005194	0.073420
8	1	PPG main evening meal (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)		0.00601	0.013703
9	1	PPG main evening meal (SMPG) (mg/dL)	REGION1	EUROPE		-0.08792	-0.137351

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PEVC Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

(continued)

Imputed		Observation		Region		Treatment		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		Statistics	
O	b	P	A	E	R	E	O	B	O	s	t
s	n	M	A	t	N	1	D	1	1	l	I
10	1	PPG main evening meal (SMPG) (mg/dL)	REGION1	JAPAN						-0.00540	0.029130
11	1	PPG main evening meal (SMPG) (mg/dL)	BOLAD1							-0.01973	-0.070563
12	1	PPG main evening meal (SMPG) (mg/dL)	BASE							-0.47372	-0.460325
13	1	PPG main evening meal (SMPG) (mg/dL)	visit2200							0.29674	0.343030

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The MI Procedure with MCMC
Model Information

Parameter Code=P9PEV Planned Treatment for Period 30 (N)=2

Obs	PARAM	Description	Value
1	PPG main evening meal (SMPG) (mmol/L)	Data Set	WORK.ENDPOINT_PARAM
2	PPG main evening meal (SMPG) (mmol/L)	Method	Monotone-data_MCMC
3	PPG main evening meal (SMPG) (mmol/L)	Multiple Imputation Chain	Multiple Chains
4	PPG main evening meal (SMPG) (mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
5	PPG main evening meal (SMPG) (mmol/L)	Start	Starting Value
6	PPG main evening meal (SMPG) (mmol/L)	Prior	Jeffreys
7	PPG main evening meal (SMPG) (mmol/L)	Number of Imputations	20000
8	PPG main evening meal (SMPG) (mmol/L)	Number of Burn-in Iterations	200
9	PPG main evening meal (SMPG) (mmol/L)	Seed for random number generator	1234

Parameter Code=P9PEV Planned Treatment for Period 30 (N)=3

Obs	PARAM	Description	Value
10	PPG main evening meal (SMPG) (mmol/L)	Data Set	WORK.ENDPOINT_PARAM
11	PPG main evening meal (SMPG) (mmol/L)	Method	Monotone-data_MCMC
12	PPG main evening meal (SMPG) (mmol/L)	Multiple Imputation Chain	Multiple Chains
13	PPG main evening meal (SMPG) (mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
14	PPG main evening meal (SMPG) (mmol/L)	Start	Starting Value
15	PPG main evening meal (SMPG) (mmol/L)	Prior	Jeffreys
16	PPG main evening meal (SMPG) (mmol/L)	Number of Imputations	20000
17	PPG main evening meal (SMPG) (mmol/L)	Number of Burn-in Iterations	200
18	PPG main evening meal (SMPG) (mmol/L)	Seed for random number generator	1652582263

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The MI Procedure with MCMC
Model Information

Parameter Code=P9PEV Planned Treatment for Period 30 (N)=4

Obs	PARAM			Description	Value
19	PPG main evening meal	(SMPG)	(mmol/L)	Data Set	WORK.ENDPOINT_PARAM
20	PPG main evening meal	(SMPG)	(mmol/L)	Method	Monotone-data_MCMC
21	PPG main evening meal	(SMPG)	(mmol/L)	Multiple Imputation Chain	Multiple Chains
22	PPG main evening meal	(SMPG)	(mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
23	PPG main evening meal	(SMPG)	(mmol/L)	Start	Starting Value
24	PPG main evening meal	(SMPG)	(mmol/L)	Prior	Jeffreys
25	PPG main evening meal	(SMPG)	(mmol/L)	Number of Imputations	20000
26	PPG main evening meal	(SMPG)	(mmol/L)	Number of Burn-in Iterations	200
27	PPG main evening meal	(SMPG)	(mmol/L)	Seed for random number generator	116507659

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
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The MI Procedure with MCMC

Missing data pattern

Parameter Code=P9PEV Planned Treatment for Period 30 (N)=2

O b s							B A S E			F r e q	P e r c e n t	B A S E	v i s i t 2 2 0 0	v i s i t 3 6 0 0
							v i s i t 2 3 6 0 0							
							v i s i t 2 3 6 0 0							
							v i s i t 2 3 6 0 0							
	P A R A M	G r o u p	M i s s	M i s s	M i s s									
1	PPG main evening meal (SMPG) (mmol/L)	1	X	X	X	287	88.04	9.485058	-0.629185	-0.557248				
2	PPG main evening meal (SMPG) (mmol/L)	2	X	X	O	11	3.37	7.631214	0.682989	.				
3	PPG main evening meal (SMPG) (mmol/L)	3	X	.	X	18	5.52	10.623063	.	-0.347392				
4	PPG main evening meal (SMPG) (mmol/L)	4	X	O	O	10	3.07	8.922795	.	.				

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The MI Procedure with MCMC

Missing data pattern

Parameter Code=P9PEV Planned Treatment for Period 30 (N)=3

O b s							v i s i t t						v i s i t t		
							B A S E				P e r c e n t		v i s i t t		
							M̄				F r e q		A S E		
							s s s						0 0 0		
				P A R A M			G r o u p								
5	PPG	main	evening	meal	(SMPG)	(mmol/L)	1	X	X	X	298	91.13	9.738170	0.090619	0.000141
6	PPG	main	evening	meal	(SMPG)	(mmol/L)	2	X	X	O	10	3.06	9.124317	1.289334	.
7	PPG	main	evening	meal	(SMPG)	(mmol/L)	3	X	.	X	14	4.28	10.692812	.	-1.014469
8	PPG	main	evening	meal	(SMPG)	(mmol/L)	4	X	O	O	5	1.53	9.043156	.	.

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The MI Procedure with MCMC

Missing data pattern

Parameter Code=P9PEV Planned Treatment for Period 30 (N)=4

O b s							v i s i t t						v i s i t				
							B A S E						v i s i t				
							2 2 0 0						3 6 0 0				
	P A R A M						G r o u p			F r e q			P e r c e n t				
						\bar{M} i s s			\bar{M} i s s			\bar{M} i s s			B A S E		
9	PPG	main	evening	meal	(SMPG)	(mmol/L)	1	X	X	X	294	89.63	9.269670	-0.059747	-0.113126		
10	PPG	main	evening	meal	(SMPG)	(mmol/L)	2	X	X	O	11	3.35	9.822194	-0.405600	.		
11	PPG	main	evening	meal	(SMPG)	(mmol/L)	3	X	.	X	14	4.27	9.702040	.	-0.468041		
12	PPG	main	evening	meal	(SMPG)	(mmol/L)	4	X	O	O	9	2.74	10.492572	.	.		

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PEV Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG main evening meal (SMPG) (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG main evening meal (SMPG) (mmol/L)	Method	Monotone
3	1	PPG main evening meal (SMPG) (mmol/L)	Number of Imputations	1
4	1	PPG main evening meal (SMPG) (mmol/L)	Seed for random number generator	4321

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

The MI Procedure with Monotone Regression Missing Data Pattern

Parameter Code=P9PEV Planned Treatment for Period 30 (N)=2

O	b	s	I	m	p	u	t	a	t	i	o	n	P	A	R	M	G	r	o	u	p	R	E	B	G	O	I	L	B	O	A	A	N	D	S	O	O	1	1	E	O	O	F	r	e	q	P	e	r	c	e	n	t	B	A	S	E	v	i	s	i	t	2	2	0	0	v	i	s	i	t	3	6	0	0	v	i	s	i	t
1	1	PPG	main	evening	meal	(SMPG)	(mmol/L)	1	X	X	X	X	X	X	X	305	93.56	9.552218	-0.664600	-0.544864																																																												
2	1	PPG	main	evening	meal	(SMPG)	(mmol/L)	2	X	X	X	X	.	11	3.37	7.631214	0.682989	.																																																														
3	1	PPG	main	evening	meal	(SMPG)	(mmol/L)	3	X	X	X	.	.	10	3.07	8.922795	.	.																																																														

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PEV Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG main evening meal (SMPG) (mmol/L)	Intercept	
2	1	PPG main evening meal (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG main evening meal (SMPG) (mmol/L)	REGION1	EUROPE
4	1	PPG main evening meal (SMPG) (mmol/L)	REGION1	JAPAN
5	1	PPG main evening meal (SMPG) (mmol/L)	BOLAD1	
6	1	PPG main evening meal (SMPG) (mmol/L)	BASE	

Obs	BOLAD1	ObsVal	_1
1		0.00909	0.039558
2		0.02742	0.056240
3		-0.02641	-0.147403
4		-0.07712	-0.093917
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.03928	-0.082956
6		-0.65371	-0.684738

Parameter Code=P9PEV Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	PPG main evening meal (SMPG) (mmol/L)	Intercept			-0.02584	-0.051308
8	1	PPG main evening meal (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)		-0.27569	-0.351455
9	1	PPG main evening meal (SMPG) (mmol/L)	REGION1	EUROPE		0.02871	0.116485

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PEV Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

(continued)

Imputed		Region		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		Observations	
O	P	E	R	B	O		
b	A	f	E	O	b		
n	R	f	I	L	s		
s	A	e	O	A	V		
_	M	c	N	D	a		
		t	1	1	1		
10	1	PPG main evening meal (SMPG) (mmol/L)	REGION1 JAPAN			0.05664	-0.069475
11	1	PPG main evening meal (SMPG) (mmol/L)	BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.01517	0.015235
12	1	PPG main evening meal (SMPG) (mmol/L)	BASE			-0.38101	-0.289766
13	1	PPG main evening meal (SMPG) (mmol/L)	visit2200			0.33358	0.419216

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PEV Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG main evening meal (SMPG) (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG main evening meal (SMPG) (mmol/L)	Method	Monotone
3	1	PPG main evening meal (SMPG) (mmol/L)	Number of Imputations	1
4	1	PPG main evening meal (SMPG) (mmol/L)	Seed for random number generator	4322

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

The MI Procedure with Monotone Regression Missing Data Pattern

Parameter Code=P9PEV Planned Treatment for Period 30 (N)=3

O b s		I m p u t a t i o n		P A R A M		G r o u p		R E G I O N		F r e q		P e r c e n t		v i s i t		v i s i t		
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	
1	1	PPG	main	evening	meal	(SMPG)	(mmol/L)	1	X	X	X	X	X	312	95.41	9.781006	0.030763	-0.045386
2	1	PPG	main	evening	meal	(SMPG)	(mmol/L)	2	X	X	X	X	.	10	3.06	9.124317	1.289334	.
3	1	PPG	main	evening	meal	(SMPG)	(mmol/L)	3	X	X	X	.	.	5	1.53	9.043156	.	.

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PEV Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG main evening meal (SMPG) (mmol/L)	Intercept	
2	1	PPG main evening meal (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG main evening meal (SMPG) (mmol/L)	REGION1	EUROPE
4	1	PPG main evening meal (SMPG) (mmol/L)	REGION1	JAPAN
5	1	PPG main evening meal (SMPG) (mmol/L)	BOLAD1	
6	1	PPG main evening meal (SMPG) (mmol/L)	BASE	

Obs	BOLAD1	ObsVal	_1
1		0.03458	0.127330
2		0.06117	0.185387
3		-0.21022	-0.209235
4		0.15983	0.074423
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.08759	-0.062172
6		-0.60459	-0.648910

Parameter Code=P9PEV Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	PPG main evening meal (SMPG) (mmol/L)	Intercept			0.00517	-0.050701
8	1	PPG main evening meal (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)		-0.11757	-0.206612
9	1	PPG main evening meal (SMPG) (mmol/L)	REGION1	EUROPE		-0.11992	-0.098593

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The MI Procedure with Monotone Regression Regression Information

Parameter Code=P9PEV Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

(continued)

	O b s _	P A R A M	E f f e c t	R E G I O N 1	B O L U S D 1	O b s V a l	I
10	1	PPG main evening meal (SMPG) (mmol/L)	REGION1	JAPAN		0.26964	0.268900
11	1	PPG main evening meal (SMPG) (mmol/L)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.07461	-0.086907
12	1	PPG main evening meal (SMPG) (mmol/L)	BASE			-0.47509	-0.414128
13	1	PPG main evening meal (SMPG) (mmol/L)	visit2200			0.31430	0.328462

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PEV Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG main evening meal (SMPG) (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG main evening meal (SMPG) (mmol/L)	Method	Monotone
3	1	PPG main evening meal (SMPG) (mmol/L)	Number of Imputations	1
4	1	PPG main evening meal (SMPG) (mmol/L)	Seed for random number generator	4323

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

The MI Procedure with Monotone Regression Missing Data Pattern

Parameter Code=P9PEV Planned Treatment for Period 30 (N)=4

		O b s		I m p u t a t i o n		P A R A M		G r o u p		R E G O I L B O N D 1		v v i i s s i i t t 2 3 6 0 0		P e r c e n t		v v i i s s i i t t 2 3 6 0 0		
1	1	PPG	main	evening	meal	(SMPG)	(mmol/L)	1	X	X	X	X	X	308	93.90	9.289323	-0.106886	-0.129259
2	1	PPG	main	evening	meal	(SMPG)	(mmol/L)	2	X	X	X	X	.	11	3.35	9.822194	-0.405600	.
3	1	PPG	main	evening	meal	(SMPG)	(mmol/L)	3	X	X	X	.	.	9	2.74	10.492572	.	.

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PEV Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG main evening meal (SMPG) (mmol/L)	Intercept	
2	1	PPG main evening meal (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG main evening meal (SMPG) (mmol/L)	REGION1	EUROPE
4	1	PPG main evening meal (SMPG) (mmol/L)	REGION1	JAPAN
5	1	PPG main evening meal (SMPG) (mmol/L)	BOLAD1	
6	1	PPG main evening meal (SMPG) (mmol/L)	BASE	

Obs	BOLAD1	ObsVal	_1
1		0.01812	-0.024894
2		-0.07131	-0.022082
3		-0.14433	-0.252488
4		0.31184	0.349090
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.13239	-0.136829
6		-0.62079	-0.697369

Parameter Code=P9PEV Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	PPG main evening meal (SMPG) (mmol/L)	Intercept			-0.0005194	0.073420
8	1	PPG main evening meal (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)		0.00601	0.013703
9	1	PPG main evening meal (SMPG) (mmol/L)	REGION1	EUROPE		-0.08792	-0.137351

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PEV Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

(continued)

Imputed		Region		BOLUS		INSULIN		ALGORITHM		(SLIDING SCALE)		-0.00540		0.029130	
Observed		PFA		EFG		EFG		EFG		EFG		EFG		EFG	
S		M		T		1		1		1		1		1	
10	1	PPG	main	evening	meal	(SMPG)	(mmol/L)	REGION1	JAPAN						
11	1	PPG	main	evening	meal	(SMPG)	(mmol/L)	BOLAD1		BOLUS	INSULIN	ALGORITHM	(SLIDING	SCALE)	
12	1	PPG	main	evening	meal	(SMPG)	(mmol/L)	BASE							
13	1	PPG	main	evening	meal	(SMPG)	(mmol/L)	visit2200							

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
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The Mixed procedure
Model Information

Parameter Code=P9PB Parameter=PPG breakfast (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Data Set	WORK.IMPUTE
2	1	NN1218-4131	Dependent Variable	eotVisit
3	1	NN1218-4131	Covariance Structure	Diagonal
4	1	NN1218-4131	Estimation Method	REML
5	1	NN1218-4131	Residual Variance Method	Profile
6	1	NN1218-4131	Fixed Effects SE Method	Model-Based
7	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=P9PEV Parameter=PPG main evening meal (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
8	1	NN1218-4131	Data Set	WORK.IMPUTE
9	1	NN1218-4131	Dependent Variable	eotVisit
10	1	NN1218-4131	Covariance Structure	Diagonal
11	1	NN1218-4131	Estimation Method	REML
12	1	NN1218-4131	Residual Variance Method	Profile
13	1	NN1218-4131	Fixed Effects SE Method	Model-Based
14	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=P9PEVC Parameter=PPG main evening meal (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
15	1	NN1218-4131	Data Set	WORK.IMPUTE
16	1	NN1218-4131	Dependent Variable	eotVisit
17	1	NN1218-4131	Covariance Structure	Diagonal

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The Mixed procedure
Model Information

Parameter Code=P9PEVC Parameter=PPG main evening meal (SMPG) (mg/dL)

(continued)

Obs	_Imputation_	STUDYID	Descr	Value
18	1	NN1218-4131	Estimation Method	REML
19	1	NN1218-4131	Residual Variance Method	Profile
20	1	NN1218-4131	Fixed Effects SE Method	Model-Based
21	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=P9PGBC Parameter=PPG breakfast (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
22	1	NN1218-4131	Data Set	WORK.IMPUTE
23	1	NN1218-4131	Dependent Variable	eotVisit
24	1	NN1218-4131	Covariance Structure	Diagonal
25	1	NN1218-4131	Estimation Method	REML
26	1	NN1218-4131	Residual Variance Method	Profile
27	1	NN1218-4131	Fixed Effects SE Method	Model-Based
28	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=P9PL Parameter=PPG lunch (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
29	1	NN1218-4131	Data Set	WORK.IMPUTE
30	1	NN1218-4131	Dependent Variable	eotVisit
31	1	NN1218-4131	Covariance Structure	Diagonal
32	1	NN1218-4131	Estimation Method	REML

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The Mixed procedure
Model Information

Parameter Code=P9PL Parameter=PPG lunch (SMPG) (mmol/L)

(continued)

Obs	_Imputation_	STUDYID	Descr	Value
33	1	NN1218-4131	Residual Variance Method	Profile
34	1	NN1218-4131	Fixed Effects SE Method	Model-Based
35	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=P9PLC Parameter=PPG lunch (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
36	1	NN1218-4131	Data Set	WORK.IMPUTE
37	1	NN1218-4131	Dependent Variable	eotVisit
38	1	NN1218-4131	Covariance Structure	Diagonal
39	1	NN1218-4131	Estimation Method	REML
40	1	NN1218-4131	Residual Variance Method	Profile
41	1	NN1218-4131	Fixed Effects SE Method	Model-Based
42	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=P9PPRAN Parameter=PPG all meals (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
43	1	NN1218-4131	Data Set	WORK.IMPUTE
44	1	NN1218-4131	Dependent Variable	eotVisit
45	1	NN1218-4131	Covariance Structure	Diagonal
46	1	NN1218-4131	Estimation Method	REML
47	1	NN1218-4131	Residual Variance Method	Profile

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The Mixed procedure
Model Information

Parameter Code=P9PPRAN Parameter=PPG all meals (SMPG) (mmol/L)

(continued)

Obs	_Imputation_	STUDYID	Descr	Value
48	1	NN1218-4131	Fixed Effects SE Method	Model-Based
49	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=P9PPRANC Parameter=PPG all meals (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
50	1	NN1218-4131	Data Set	WORK.IMPUTE
51	1	NN1218-4131	Dependent Variable	eotVisit
52	1	NN1218-4131	Covariance Structure	Diagonal
53	1	NN1218-4131	Estimation Method	REML
54	1	NN1218-4131	Residual Variance Method	Profile
55	1	NN1218-4131	Fixed Effects SE Method	Model-Based
56	1	NN1218-4131	Degrees of Freedom Method	Residual


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The Mixed procedure
Class Level Information

Parameter Code=P9PEVC Parameter=PPG main evening meal (SMPG) (mg/dL)

Ob- s	—	Input on ID	STUDY ID	Class s	Lev- els	Val- ues	mi- n
7	1	NN1218-4131	TRTPN		3 2 3 4		5
8	1	NN1218-4131	REGION1		4 ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA		49
9	1	NN1218-4131	BOLAD1		2 BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULI		85

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The Mixed procedure
Class Level Information

Parameter Code=P9PGBC Parameter=PPG breakfast (SMPG) (mg/dL)

		Input		Stat		Level		Variable		Minimum	
		Obs		on		Y		I		D	
10	1	NN1218-4131	TRTPN	3	2	3	4				5
11	1	NN1218-4131	REGION1	4	ASIA (EXCLUDING JAPAN)	EUROPE	JAPAN	NORTH AMERICA			49
12	1	NN1218-4131	BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	CARBOHYDRATE COUNTING (FLEXIBLE)	BOLUS INSULI				85

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The Mixed procedure
Class Level Information

Parameter Code=P9PLC Parameter=PPG lunch (SMPG) (mg/dL)

O b s		I n		S t u d y		C l a s s		L e v e l		V a r i a b l e		m i n	
16		1		NN1218-4131		TRTPN		3 2 3 4				5	
17		1		NN1218-4131		REGION1		4 ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA				49	
18		1		NN1218-4131		BOLAD1		2 BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULI				85	

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Class Level Information

Parameter Code=P9PPRAN Parameter=PPG all meals (SMPG) (mmol/L)

O b s		I n		S t u d y		C l a s s		L e v e l		V a r i a b l e		m i n	
19		1		NN1218-4131		TRTPN		3 2 3 4				5	
20		1		NN1218-4131		REGION1		4 ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA				49	
21		1		NN1218-4131		BOLAD1		2 BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULI				85	

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The Mixed procedure
Class Level Information

Parameter Code=P9PPRANC Parameter=PPG all meals (SMPG) (mg/dL)

O b s		I n		S t u d y		C l a s s		L e v e l s		V a r i a b l e s		m i n	
22	1	NN1218-4131	TRTPN	3	2	3	4					5	
23	1	NN1218-4131	REGION1	4	ASIA (EXCLUDING JAPAN)	EUROPE	JAPAN	NORTH AMERICA				49	
24	1	NN1218-4131	BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	CARBOHYDRATE COUNTING (FLEXIBLE)	BOLUS INSULI	85					

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The Mixed procedure
Dimensions

Parameter Code=P9PB Parameter=PPG breakfast (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Covariance Parameters	1
2	1	NN1218-4131	Columns in X	10
3	1	NN1218-4131	Columns in Z	0
4	1	NN1218-4131	Subjects	1
5	1	NN1218-4131	Max Obs per Subject	986

Parameter Code=P9PEV Parameter=PPG main evening meal (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
6	1	NN1218-4131	Covariance Parameters	1
7	1	NN1218-4131	Columns in X	10
8	1	NN1218-4131	Columns in Z	0
9	1	NN1218-4131	Subjects	1
10	1	NN1218-4131	Max Obs per Subject	981

Parameter Code=P9PEVC Parameter=PPG main evening meal (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
11	1	NN1218-4131	Covariance Parameters	1
12	1	NN1218-4131	Columns in X	10
13	1	NN1218-4131	Columns in Z	0
14	1	NN1218-4131	Subjects	1
15	1	NN1218-4131	Max Obs per Subject	981

nn1218/nn1218-4131/ctr_20180214_er
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The Mixed procedure
Dimensions

Parameter Code=P9PGBC Parameter=PPG breakfast (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
16	1	NN1218-4131	Covariance Parameters	1
17	1	NN1218-4131	Columns in X	10
18	1	NN1218-4131	Columns in Z	0
19	1	NN1218-4131	Subjects	1
20	1	NN1218-4131	Max Obs per Subject	986

Parameter Code=P9PL Parameter=PPG lunch (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
21	1	NN1218-4131	Covariance Parameters	1
22	1	NN1218-4131	Columns in X	10
23	1	NN1218-4131	Columns in Z	0
24	1	NN1218-4131	Subjects	1
25	1	NN1218-4131	Max Obs per Subject	984

Parameter Code=P9PLC Parameter=PPG lunch (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
26	1	NN1218-4131	Covariance Parameters	1
27	1	NN1218-4131	Columns in X	10
28	1	NN1218-4131	Columns in Z	0
29	1	NN1218-4131	Subjects	1
30	1	NN1218-4131	Max Obs per Subject	984

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
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The Mixed procedure
Dimensions

Parameter Code=P9PPRAN Parameter=PPG all meals (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
31	1	NN1218-4131	Covariance Parameters	1
32	1	NN1218-4131	Columns in X	10
33	1	NN1218-4131	Columns in Z	0
34	1	NN1218-4131	Subjects	1
35	1	NN1218-4131	Max Obs per Subject	977

Parameter Code=P9PPRANC Parameter=PPG all meals (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
36	1	NN1218-4131	Covariance Parameters	1
37	1	NN1218-4131	Columns in X	10
38	1	NN1218-4131	Columns in Z	0
39	1	NN1218-4131	Subjects	1
40	1	NN1218-4131	Max Obs per Subject	977

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
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The Mixed procedure
Number of Observations

Parameter Code=P9PB Parameter=PPG breakfast (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
1	1	NN1218-4131	Number of Observations Read	986	986	986	986	986
2	1	NN1218-4131	Number of Observations Used	986	986	986	986	986
3	1	NN1218-4131	Number of Observations Not Used	0	986	986	986	986

Parameter Code=P9PEV Parameter=PPG main evening meal (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
4	1	NN1218-4131	Number of Observations Read	981	981	981	981	981
5	1	NN1218-4131	Number of Observations Used	981	981	981	981	981
6	1	NN1218-4131	Number of Observations Not Used	0	981	981	981	981

Parameter Code=P9PEVC Parameter=PPG main evening meal (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
7	1	NN1218-4131	Number of Observations Read	981	981	981	981	981
8	1	NN1218-4131	Number of Observations Used	981	981	981	981	981
9	1	NN1218-4131	Number of Observations Not Used	0	981	981	981	981

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The Mixed procedure
Number of Observations

Parameter Code=P9PGBC Parameter=PPG breakfast (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
10	1	NN1218-4131	Number of Observations Read	986	986	986	986	986
11	1	NN1218-4131	Number of Observations Used	986	986	986	986	986
12	1	NN1218-4131	Number of Observations Not Used	0	986	986	986	986

Parameter Code=P9PL Parameter=PPG lunch (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
13	1	NN1218-4131	Number of Observations Read	984	984	984	984	984
14	1	NN1218-4131	Number of Observations Used	984	984	984	984	984
15	1	NN1218-4131	Number of Observations Not Used	0	984	984	984	984

Parameter Code=P9PLC Parameter=PPG lunch (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
16	1	NN1218-4131	Number of Observations Read	984	984	984	984	984
17	1	NN1218-4131	Number of Observations Used	984	984	984	984	984
18	1	NN1218-4131	Number of Observations Not Used	0	984	984	984	984

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
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The Mixed procedure
Number of Observations

Parameter Code=P9PPRAN Parameter=PPG all meals (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
19	1	NN1218-4131	Number of Observations Read	977	977	977	977	977
20	1	NN1218-4131	Number of Observations Used	977	977	977	977	977
21	1	NN1218-4131	Number of Observations Not Used	0	977	977	977	977

Parameter Code=P9PPRANC Parameter=PPG all meals (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
22	1	NN1218-4131	Number of Observations Read	977	977	977	977	977
23	1	NN1218-4131	Number of Observations Used	977	977	977	977	977
24	1	NN1218-4131	Number of Observations Not Used	0	977	977	977	977

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
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The Mixed procedure
Covariance Parameter Estimates

Parameter Code=P9PB Parameter=PPG breakfast (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	CovParm	Estimate
1	1	NN1218-4131	Residual	6.8567

Parameter Code=P9PEV Parameter=PPG main evening meal (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	CovParm	Estimate
20001	1	NN1218-4131	Residual	7.0241

Parameter Code=P9PEVC Parameter=PPG main evening meal (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	CovParm	Estimate
40001	1	NN1218-4131	Residual	2280.87

Parameter Code=P9PGBC Parameter=PPG breakfast (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	CovParm	Estimate
60001	1	NN1218-4131	Residual	2226.51

Parameter Code=P9PL Parameter=PPG lunch (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	CovParm	Estimate
80001	1	NN1218-4131	Residual	5.8169

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
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The Mixed procedure
Covariance Parameter Estimates

Parameter Code=P9PLC Parameter=PPG lunch (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	CovParm	Estimate
100001	1	NN1218-4131	Residual	1888.87

Parameter Code=P9PPRAN Parameter=PPG all meals (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	CovParm	Estimate
120001	1	NN1218-4131	Residual	3.3310

Parameter Code=P9PPRANC Parameter=PPG all meals (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	CovParm	Estimate
140001	1	NN1218-4131	Residual	1081.66

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
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The Mixed procedure
Fit Statistics

Parameter Code=P9PB Parameter=PPG breakfast (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	-2 Res Log Likelihood	4704.9
2	1	NN1218-4131	AIC (Smaller is Better)	4706.9
3	1	NN1218-4131	AICC (Smaller is Better)	4706.9
4	1	NN1218-4131	BIC (Smaller is Better)	4711.8

Parameter Code=P9PEV Parameter=PPG main evening meal (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
5	1	NN1218-4131	-2 Res Log Likelihood	4704.5
6	1	NN1218-4131	AIC (Smaller is Better)	4706.5
7	1	NN1218-4131	AICC (Smaller is Better)	4706.6
8	1	NN1218-4131	BIC (Smaller is Better)	4711.4

Parameter Code=P9PEVC Parameter=PPG main evening meal (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
9	1	NN1218-4131	-2 Res Log Likelihood	10337.2
10	1	NN1218-4131	AIC (Smaller is Better)	10339.2
11	1	NN1218-4131	AICC (Smaller is Better)	10339.2
12	1	NN1218-4131	BIC (Smaller is Better)	10344.0

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
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The Mixed procedure
Fit Statistics

Parameter Code=P9PGBC Parameter=PPG breakfast (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
13	1	NN1218-4131	-2 Res Log Likelihood	10366.4
14	1	NN1218-4131	AIC (Smaller is Better)	10368.4
15	1	NN1218-4131	AICC (Smaller is Better)	10368.4
16	1	NN1218-4131	BIC (Smaller is Better)	10373.3

Parameter Code=P9PL Parameter=PPG lunch (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
17	1	NN1218-4131	-2 Res Log Likelihood	4534.8
18	1	NN1218-4131	AIC (Smaller is Better)	4536.8
19	1	NN1218-4131	AICC (Smaller is Better)	4536.8
20	1	NN1218-4131	BIC (Smaller is Better)	4541.7

Parameter Code=P9PLC Parameter=PPG lunch (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
21	1	NN1218-4131	-2 Res Log Likelihood	10184.7
22	1	NN1218-4131	AIC (Smaller is Better)	10186.7
23	1	NN1218-4131	AICC (Smaller is Better)	10186.7
24	1	NN1218-4131	BIC (Smaller is Better)	10191.6

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
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The Mixed procedure
Fit Statistics

Parameter Code=P9PPRAN Parameter=PPG all meals (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
25	1	NN1218-4131	-2 Res Log Likelihood	3961.8
26	1	NN1218-4131	AIC (Smaller is Better)	3963.8
27	1	NN1218-4131	AICC (Smaller is Better)	3963.8
28	1	NN1218-4131	BIC (Smaller is Better)	3968.7

Parameter Code=P9PPRANC Parameter=PPG all meals (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
29	1	NN1218-4131	-2 Res Log Likelihood	9571.3
30	1	NN1218-4131	AIC (Smaller is Better)	9573.3
31	1	NN1218-4131	AICC (Smaller is Better)	9573.3
32	1	NN1218-4131	BIC (Smaller is Better)	9578.2

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The Mixed procedure
Solution for Fixed Effects

Parameter Code=P9PB Parameter=PPG breakfast (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1			BOLAD1
1	1	NN1218-4131	TRTPN	2				
2	1	NN1218-4131	TRTPN	3				
3	1	NN1218-4131	TRTPN	4				
4	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
5	1	NN1218-4131	REGION1	—	EUROPE			
6	1	NN1218-4131	REGION1	—	JAPAN			
7	1	NN1218-4131	REGION1	—	NORTH AMERICA			
8	1	NN1218-4131	BOLAD1	—				BOLUS INSULIN ALGORITHM (SLIDING SCALE)
9	1	NN1218-4131	BOLAD1	—				CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY
10	1	NN1218-4131	BASE	—				

Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	6.1588	0.3518	978	17.51	<.0001	0.05	5.4685	6.8491
2	6.8894	0.3524	978	19.55	<.0001	0.05	6.1978	7.5810
3	6.4480	0.3487	978	18.49	<.0001	0.05	5.7637	7.1322
4	-0.2660	0.3061	978	-0.87	0.3851	0.05	-0.8667	0.3347
5	-0.4300	0.2175	978	-1.98	0.0483	0.05	-0.8568	-0.00317
6	0.8679	0.2431	978	3.57	0.0004	0.05	0.3908	1.3450
7	0
8	-0.6700	0.1893	978	-3.54	0.0004	0.05	-1.0415	-0.2986
9	0
10	-0.6655	0.02865	978	-23.22	<.0001	0.05	-0.7217	-0.6092

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The Mixed procedure
Solution for Fixed Effects

Parameter Code=P9PEV Parameter=PPG main evening meal (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1			BOLAD1
11	1	NN1218-4131	TRTPN	2				
12	1	NN1218-4131	TRTPN	3				
13	1	NN1218-4131	TRTPN	4				
14	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
15	1	NN1218-4131	REGION1	—	EUROPE			
16	1	NN1218-4131	REGION1	—	JAPAN			
17	1	NN1218-4131	REGION1	—	NORTH AMERICA			
18	1	NN1218-4131	BOLAD1	—				BOLUS INSULIN ALGORITHM (SLIDING SCALE)
19	1	NN1218-4131	BOLAD1	—				CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY
20	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
11	7.2384	0.3482	973	20.79	<.0001	0.05	6.5550	7.9218
12	7.8386	0.3563	973	22.00	<.0001	0.05	7.1394	8.5378
13	7.3701	0.3460	973	21.30	<.0001	0.05	6.6910	8.0491
14	-0.7660	0.3110	973	-2.46	0.0140	0.05	-1.3763	-0.1556
15	-0.7523	0.2210	973	-3.40	0.0007	0.05	-1.1861	-0.3185
16	0.1925	0.2449	973	0.79	0.4321	0.05	-0.2881	0.6731
17	0
18	-0.4005	0.1916	973	-2.09	0.0369	0.05	-0.7765	-0.02439
19	0
20	-0.7515	0.02877	973	-26.12	<.0001	0.05	-0.8080	-0.6950

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The Mixed procedure
Solution for Fixed Effects

Parameter Code=P9PEVC Parameter=PPG main evening meal (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
21	1	NN1218-4131	TRTPN	2				
22	1	NN1218-4131	TRTPN	3				
23	1	NN1218-4131	TRTPN	4				
24	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
25	1	NN1218-4131	REGION1	—	EUROPE			
26	1	NN1218-4131	REGION1	—	JAPAN			
27	1	NN1218-4131	REGION1	—	NORTH AMERICA			
28	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
29	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
30	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
21	130.44	6.2753	973	20.79	<.0001	0.05	118.12	142.75
22	141.25	6.4203	973	22.00	<.0001	0.05	128.65	153.85
23	132.81	6.2354	973	21.30	<.0001	0.05	120.57	145.04
24	-13.8027	5.6047	973	-2.46	0.0140	0.05	-24.8013	-2.8040
25	-13.5566	3.9831	973	-3.40	0.0007	0.05	-21.3730	-5.7401
26	3.4687	4.4135	973	0.79	0.4321	0.05	-5.1924	12.1298
27	0
28	-7.2161	3.4532	973	-2.09	0.0369	0.05	-13.9927	-0.4395
29	0
30	-0.7515	0.02877	973	-26.12	<.0001	0.05	-0.8080	-0.6950

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Parameter Code=P9PGBC Parameter=PPG breakfast (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
31	1	NN1218-4131	TRTPN	2				
32	1	NN1218-4131	TRTPN	3				
33	1	NN1218-4131	TRTPN	4				
34	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
35	1	NN1218-4131	REGION1	—	EUROPE			
36	1	NN1218-4131	REGION1	—	JAPAN			
37	1	NN1218-4131	REGION1	—	NORTH AMERICA			
38	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
39	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
40	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
31	110.98	6.3388	978	17.51	<.0001	0.05	98.5419	123.42
32	124.15	6.3507	978	19.55	<.0001	0.05	111.68	136.61
33	116.19	6.2828	978	18.49	<.0001	0.05	103.86	128.52
34	-4.7933	5.5164	978	-0.87	0.3851	0.05	-15.6186	6.0320
35	-7.7481	3.9192	978	-1.98	0.0483	0.05	-15.4390	-0.05709
36	15.6394	4.3810	978	3.57	0.0004	0.05	7.0422	24.2366
37	0
38	-12.0742	3.4112	978	-3.54	0.0004	0.05	-18.7682	-5.3802
39	0
40	-0.6655	0.02865	978	-23.22	<.0001	0.05	-0.7217	-0.6092

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- in-trial - full analysis set

The Mixed procedure
Solution for Fixed Effects

Parameter Code=P9PL Parameter=PPG lunch (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1			BOLAD1
41	1	NN1218-4131	TRTPN	2				
42	1	NN1218-4131	TRTPN	3				
43	1	NN1218-4131	TRTPN	4				
44	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
45	1	NN1218-4131	REGION1	—	EUROPE			
46	1	NN1218-4131	REGION1	—	JAPAN			
47	1	NN1218-4131	REGION1	—	NORTH AMERICA			
48	1	NN1218-4131	BOLAD1	—				BOLUS INSULIN ALGORITHM (SLIDING SCALE)
49	1	NN1218-4131	BOLAD1	—				CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY
50	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
41	6.6993	0.3196	976	20.96	<.0001	0.05	6.0722	7.3264
42	7.1960	0.3175	976	22.66	<.0001	0.05	6.5729	7.8190
43	6.8288	0.3210	976	21.28	<.0001	0.05	6.1989	7.4586
44	-0.1215	0.2819	976	-0.43	0.6666	0.05	-0.6746	0.4317
45	-0.4068	0.2005	976	-2.03	0.0427	0.05	-0.8003	-0.01334
46	0.9927	0.2268	976	4.38	<.0001	0.05	0.5476	1.4378
47	0
48	-0.5350	0.1738	976	-3.08	0.0021	0.05	-0.8760	-0.1939
49	0
50	-0.7414	0.02765	976	-26.82	<.0001	0.05	-0.7957	-0.6872

nn1218/nn1218-4131/ctr_20180214_er
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The Mixed procedure
Solution for Fixed Effects

Parameter Code=P9PLC Parameter=PPG lunch (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
51	1	NN1218-4131	TRTPN	2				
52	1	NN1218-4131	TRTPN	3				
53	1	NN1218-4131	TRTPN	4				
54	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
55	1	NN1218-4131	REGION1	—	EUROPE			
56	1	NN1218-4131	REGION1	—	JAPAN			
57	1	NN1218-4131	REGION1	—	NORTH AMERICA			
58	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
59	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
60	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
51	120.72	5.7585	976	20.96	<.0001	0.05	109.42	132.02
52	129.67	5.7216	976	22.66	<.0001	0.05	118.44	140.90
53	123.05	5.7840	976	21.28	<.0001	0.05	111.70	134.40
54	-2.1888	5.0793	976	-0.43	0.6666	0.05	-12.1563	7.7788
55	-7.3313	3.6134	976	-2.03	0.0427	0.05	-14.4222	-0.2405
56	17.8878	4.0871	976	4.38	<.0001	0.05	9.8672	25.9084
57	0
58	-9.6404	3.1316	976	-3.08	0.0021	0.05	-15.7858	-3.4949
59	0
60	-0.7414	0.02765	976	-26.82	<.0001	0.05	-0.7957	-0.6872

nn1218/nn1218-4131/ctr_20180214_er
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The Mixed procedure
Solution for Fixed Effects

Parameter Code=P9PPRAN Parameter=PPG all meals (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
61	1	NN1218-4131	TRTPN	2				
62	1	NN1218-4131	TRTPN	3				
63	1	NN1218-4131	TRTPN	4				
64	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
65	1	NN1218-4131	REGION1	—	EUROPE			
66	1	NN1218-4131	REGION1	—	JAPAN			
67	1	NN1218-4131	REGION1	—	NORTH AMERICA			
68	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
69	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
70	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
61	5.6928	0.2995	969	19.01	<.0001	0.05	5.1051	6.2805
62	6.3053	0.3009	969	20.95	<.0001	0.05	5.7148	6.8959
63	5.9164	0.2973	969	19.90	<.0001	0.05	5.3330	6.4998
64	-0.3316	0.2139	969	-1.55	0.1214	0.05	-0.7514	0.08819
65	-0.4764	0.1524	969	-3.13	0.0018	0.05	-0.7756	-0.1773
66	0.5814	0.1710	969	3.40	0.0007	0.05	0.2458	0.9169
67	0
68	-0.5474	0.1324	969	-4.13	<.0001	0.05	-0.8073	-0.2875
69	0
70	-0.6153	0.02715	969	-22.66	<.0001	0.05	-0.6685	-0.5620

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The Mixed procedure
Solution for Fixed Effects

Parameter Code=P9PPRANC Parameter=PPG all meals (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1			BOLAD1
71	1	NN1218-4131	TRTPN	2				
72	1	NN1218-4131	TRTPN	3				
73	1	NN1218-4131	TRTPN	4				
74	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
75	1	NN1218-4131	REGION1	—	EUROPE			
76	1	NN1218-4131	REGION1	—	JAPAN			
77	1	NN1218-4131	REGION1	—	NORTH AMERICA			
78	1	NN1218-4131	BOLAD1	—				BOLUS INSULIN ALGORITHM (SLIDING SCALE)
79	1	NN1218-4131	BOLAD1	—				CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY
80	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
71	102.58	5.3962	969	19.01	<.0001	0.05	91.9947	113.17
72	113.62	5.4227	969	20.95	<.0001	0.05	102.98	124.26
73	106.61	5.3569	969	19.90	<.0001	0.05	96.1009	117.13
74	-5.9751	3.8546	969	-1.55	0.1214	0.05	-13.5395	1.5892
75	-8.5853	2.7470	969	-3.13	0.0018	0.05	-13.9761	-3.1946
76	10.4760	3.0810	969	3.40	0.0007	0.05	4.4298	16.5222
77	0
78	-9.8645	2.3867	969	-4.13	<.0001	0.05	-14.5482	-5.1809
79	0
80	-0.6153	0.02715	969	-22.66	<.0001	0.05	-0.6685	-0.5620

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
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The Mixed procedure
Least Squares Means

Obs	_Imputation_	PARAMCD	PARAM	STUDYID	Effect	TRTPN
1	1	P9PB	PPG breakfast (SMPG) (mmol/L)	NN1218-4131	TRTPN	2
2	1	P9PB	PPG breakfast (SMPG) (mmol/L)	NN1218-4131	TRTPN	3
3	1	P9PB	PPG breakfast (SMPG) (mmol/L)	NN1218-4131	TRTPN	4
4	1	P9PEV	PPG main evening meal (SMPG) (mmol/L)	NN1218-4131	TRTPN	2
5	1	P9PEV	PPG main evening meal (SMPG) (mmol/L)	NN1218-4131	TRTPN	3
6	1	P9PEV	PPG main evening meal (SMPG) (mmol/L)	NN1218-4131	TRTPN	4
7	1	P9PEVC	PPG main evening meal (SMPG) (mg/dL)	NN1218-4131	TRTPN	2
8	1	P9PEVC	PPG main evening meal (SMPG) (mg/dL)	NN1218-4131	TRTPN	3
9	1	P9PEVC	PPG main evening meal (SMPG) (mg/dL)	NN1218-4131	TRTPN	4
10	1	P9PGBC	PPG breakfast (SMPG) (mg/dL)	NN1218-4131	TRTPN	2
11	1	P9PGBC	PPG breakfast (SMPG) (mg/dL)	NN1218-4131	TRTPN	3
12	1	P9PGBC	PPG breakfast (SMPG) (mg/dL)	NN1218-4131	TRTPN	4
13	1	P9PL	PPG lunch (SMPG) (mmol/L)	NN1218-4131	TRTPN	2
14	1	P9PL	PPG lunch (SMPG) (mmol/L)	NN1218-4131	TRTPN	3

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	WORK.IMPUTE	-0.7165	0.1452	978	-4.93	<.0001	0.05	-1.0015	-0.4315
2	WORK.IMPUTE	0.01410	0.1441	978	0.10	0.9221	0.05	-0.2686	0.2968
3	WORK.IMPUTE	-0.4273	0.1445	978	-2.96	0.0032	0.05	-0.7109	-0.1437
4	WORK.IMPUTE	-0.4542	0.1470	973	-3.09	0.0021	0.05	-0.7427	-0.1657
5	WORK.IMPUTE	0.1460	0.1469	973	0.99	0.3205	0.05	-0.1422	0.4342
6	WORK.IMPUTE	-0.3225	0.1466	973	-2.20	0.0280	0.05	-0.6102	-0.03490
7	WORK.IMPUTE	-8.1847	2.6495	973	-3.09	0.0021	0.05	-13.3840	-2.9853
8	WORK.IMPUTE	2.6305	2.6463	973	0.99	0.3205	0.05	-2.5625	7.8235
9	WORK.IMPUTE	-5.8122	2.6413	973	-2.20	0.0280	0.05	-10.9954	-0.6289
10	WORK.IMPUTE	-12.9118	2.6172	978	-4.93	<.0001	0.05	-18.0477	-7.7759
11	WORK.IMPUTE	0.2540	2.5960	978	0.10	0.9221	0.05	-4.8403	5.3483
12	WORK.IMPUTE	-7.7007	2.6042	978	-2.96	0.0032	0.05	-12.8112	-2.5902
13	WORK.IMPUTE	-0.5091	0.1336	976	-3.81	0.0001	0.05	-0.7712	-0.2469
14	WORK.IMPUTE	-0.01242	0.1333	976	-0.09	0.9258	0.05	-0.2740	0.2492

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
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The Mixed procedure
Least Squares Means

Obs	_Imputation_	PARAMCD	PARAM	STUDYID	Effect	TRTPN
15	1	P9PL	PPG lunch (SMPG) (mmol/L)	NN1218-4131	TRTPN	4
16	1	P9PLC	PPG lunch (SMPG) (mg/dL)	NN1218-4131	TRTPN	2
17	1	P9PLC	PPG lunch (SMPG) (mg/dL)	NN1218-4131	TRTPN	3
18	1	P9PLC	PPG lunch (SMPG) (mg/dL)	NN1218-4131	TRTPN	4
19	1	P9PPRAN	PPG all meals (SMPG) (mmol/L)	NN1218-4131	TRTPN	2
20	1	P9PPRAN	PPG all meals (SMPG) (mmol/L)	NN1218-4131	TRTPN	3
21	1	P9PPRAN	PPG all meals (SMPG) (mmol/L)	NN1218-4131	TRTPN	4
22	1	P9PPRANC	PPG all meals (SMPG) (mg/dL)	NN1218-4131	TRTPN	2
23	1	P9PPRANC	PPG all meals (SMPG) (mg/dL)	NN1218-4131	TRTPN	3
24	1	P9PPRANC	PPG all meals (SMPG) (mg/dL)	NN1218-4131	TRTPN	4

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
15	WORK.IMPUTE	-0.3796	0.1331	976	-2.85	0.0044	0.05	-0.6408	-0.1184
16	WORK.IMPUTE	-9.1737	2.4071	976	-3.81	0.0001	0.05	-13.8975	-4.4499
17	WORK.IMPUTE	-0.2238	2.4025	976	-0.09	0.9258	0.05	-4.9383	4.4908
18	WORK.IMPUTE	-6.8405	2.3982	976	-2.85	0.0044	0.05	-11.5467	-2.1344
19	WORK.IMPUTE	-0.5753	0.1016	969	-5.66	<.0001	0.05	-0.7746	-0.3760
20	WORK.IMPUTE	0.03726	0.1013	969	0.37	0.7132	0.05	-0.1616	0.2361
21	WORK.IMPUTE	-0.3517	0.1009	969	-3.49	0.0005	0.05	-0.5497	-0.1537
22	WORK.IMPUTE	-10.3663	1.8300	969	-5.66	<.0001	0.05	-13.9575	-6.7750
23	WORK.IMPUTE	0.6714	1.8261	969	0.37	0.7132	0.05	-2.9121	4.2550
24	WORK.IMPUTE	-6.3372	1.8179	969	-3.49	0.0005	0.05	-9.9047	-2.7697

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

The Mixed procedure
Least Squares Means Estimate

Parameter Code=P9PB Parameter=PPG breakfast (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
1	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
2	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	WORK.IMPUTE	-0.2892	0.2051	978	-1.41	0.1588	0.05	-0.6916	0.1132
2	WORK.IMPUTE	0.4414	0.2041	978	2.16	0.0308	0.05	0.04089	0.8420

Parameter Code=P9PEV Parameter=PPG main evening meal (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
3	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
4	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
3	WORK.IMPUTE	-0.1317	0.2077	973	-0.63	0.5264	0.05	-0.5393	0.2760
4	WORK.IMPUTE	0.4685	0.2077	973	2.26	0.0243	0.05	0.06096	0.8761

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
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The Mixed procedure
Least Squares Means Estimate

Parameter Code=P9PEVC Parameter=PPG main evening meal (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
5	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
6	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
5	WORK.IMPUTE	-2.3725	3.7436	973	-0.63	0.5264	0.05	-9.7189	4.9739
6	WORK.IMPUTE	8.4427	3.7425	973	2.26	0.0243	0.05	1.0984	15.7869

Parameter Code=P9PGBC Parameter=PPG breakfast (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
7	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
8	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
7	WORK.IMPUTE	-5.2111	3.6950	978	-1.41	0.1588	0.05	-12.4622	2.0400
8	WORK.IMPUTE	7.9547	3.6781	978	2.16	0.0308	0.05	0.7368	15.1727

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
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The Mixed procedure
Least Squares Means Estimate

Parameter Code=P9PL Parameter=PPG lunch (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
9	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
10	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
9	WORK.IMPUTE	-0.1295	0.1887	976	-0.69	0.4927	0.05	-0.4997	0.2408
10	WORK.IMPUTE	0.3672	0.1884	976	1.95	0.0516	0.05	-0.00256	0.7369

Parameter Code=P9PLC Parameter=PPG lunch (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
11	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
12	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
11	WORK.IMPUTE	-2.3331	3.4000	976	-0.69	0.4927	0.05	-9.0054	4.3391
12	WORK.IMPUTE	6.6168	3.3953	976	1.95	0.0516	0.05	-0.04616	13.2797

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
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The Mixed procedure
Least Squares Means Estimate

Parameter Code=P9PPRAN Parameter=PPG all meals (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
13	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
14	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
13	WORK.IMPUTE	-0.2236	0.1433	969	-1.56	0.1189	0.05	-0.5047	0.05756
14	WORK.IMPUTE	0.3889	0.1430	969	2.72	0.0067	0.05	0.1083	0.6696

Parameter Code=P9PPRANC Parameter=PPG all meals (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
15	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
16	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
15	WORK.IMPUTE	-4.0290	2.5816	969	-1.56	0.1189	0.05	-9.0953	1.0372
16	WORK.IMPUTE	7.0087	2.5773	969	2.72	0.0067	0.05	1.9509	12.0664

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9PB Parameter=PPG breakfast (SMPG) (mmol/L) Study Identifier=NN1218-413

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.001592	0.020960	0.022552	4.01E6	0.075941	0.070582	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.712671	0.150172	-1.00700	-0.41834	4.01E6	-0.872842	-0.562492

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-4.75	<.0001

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9PEV Parameter=PPG main evening meal (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.001573	0.021785	0.023358	4.41E6	0.072198	0.067337	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.500414	0.152834	-0.79996	-0.20087	4.41E6	-0.668999	-0.316034

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-3.27	0.0011

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9PEVC Parameter=PPG main evening meal (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.510714	7.074144	7.584883	4.41E6	0.072198	0.067337	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-9.017467	2.754067	-14.4153	-3.61959	4.41E6	-12.055368	-5.694928

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-3.27	0.0011

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9PGBC Parameter=PPG breakfast (SMPG) (mg/dL) Study Identifier=NN1218-41

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.516836	6.806072	7.322934	4.01E6	0.075941	0.070582	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-12.842337	2.706092	-18.1462	-7.53849	4.01E6	-15.728609	-10.136114

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-4.75	<.0001

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9PL Parameter=PPG lunch (SMPG) (mmol/L) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.001227	0.017549	0.018775	4.68E6	0.069907	0.065340	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.530545	0.137024	-0.79911	-0.26198	4.68E6	-0.678382	-0.392067

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-3.87	0.0001

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9PLC Parameter=PPG lunch (SMPG) (mg/dL) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.398340	5.698410	6.096770	4.68E6	0.069907	0.065340	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-9.560429	2.469164	-14.3999	-4.72096	4.68E6	-12.224446	-7.065043

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-3.87	0.0001

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9PPRAN Parameter=PPG all meals (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000823	0.010277	0.011099	3.64E6	0.080051	0.074118	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.579831	0.105353	-0.78632	-0.37334	3.64E6	-0.695546	-0.469935

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-5.50	<.0001

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9PPRANC Parameter=PPG all meals (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.267121	3.337044	3.604178	3.64E6	0.080051	0.074118	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-10.448555	1.898467	-14.1695	-6.72763	3.64E6	-12.533734	-8.468220

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-5.50	<.0001

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9PB Parameter=PPG breakfast (SMPG) (mmol/L) Study Identifier=NN1218-413

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.001143	0.020621	0.021764	7.25E6	0.055432	0.052521	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.015074	0.147528	-0.30422	0.274075	7.25E6	-0.159979	0.128503

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-0.10	0.9186

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9PEV Parameter=PPG main evening meal (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.001007	0.021732	0.022739	1.02E7	0.046330	0.044279	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.125614	0.150795	-0.16994	0.421168	1.02E7	0.002646	0.252874

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	0.83	0.4048

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9PEVC Parameter=PPG main evening meal (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.326935	7.056934	7.383885	1.02E7	0.046330	0.044279	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits	DF	Minimum	Maximum
Estimate	2.263568	2.717331	-3.06230 7.589439	1.02E7	0.047681	4.556792

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	0.83	0.4048

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9PGBC Parameter=PPG breakfast (SMPG) (mg/dL) Study Identifier=NN1218-41

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.371162	6.696180	7.067361	7.25E6	0.055432	0.052521	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.271634	2.658451	-5.48210	4.938835	7.25E6	-2.882825	2.315628

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-0.10	0.9186

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9PL Parameter=PPG lunch (SMPG) (mmol/L) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000878	0.017480	0.018358	8.75E6	0.050216	0.047815	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.043532	0.135493	-0.30909	0.222029	8.75E6	-0.164934	0.077620

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-0.32	0.7480

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9PLC Parameter=PPG lunch (SMPG) (mg/dL) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.285023	5.676271	5.961309	8.75E6	0.050216	0.047815	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.784454	2.441579	-5.56986	4.000954	8.75E6	-2.972112	1.398707

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-0.32	0.7480

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9PPRAN Parameter=PPG all meals (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000480	0.010233	0.010713	9.96E6	0.046901	0.044800	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.013585	0.103501	-0.18927	0.216444	9.96E6	-0.074564	0.108734

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	0.13	0.8956

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9PPRANC Parameter=PPG all meals (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.155833	3.322727	3.478568	9.96E6	0.046901	0.044800	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.244810	1.865092	-3.41070	3.900324	9.96E6	-1.343636	1.959388

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	0.13	0.8956

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Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 1810 of 4425	Novo Nordisk
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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9PB Parameter=PPG breakfast (SMPG) (mmol/L) Study Identifier=NN1218-413

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.001254	0.020753	0.022007	6.16E6	0.060411	0.056970	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.398404	0.148347	-0.68916	-0.10765	6.16E6	-0.562430	-0.249077

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-2.69	0.0072

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9PEV Parameter=PPG main evening meal (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.001249	0.021651	0.022899	6.72E6	0.057683	0.054537	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.292458	0.151326	-0.58905	0.004135	6.72E6	-0.422821	-0.128870

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-1.93	0.0533

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9PEVC Parameter=PPG main evening meal (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.405513	7.030383	7.435917	6.72E6	0.057683	0.054537	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-5.270087	2.726888	-10.6147	0.074515	6.72E6	-7.619239	-2.322236

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-1.93	0.0533

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9PGBC Parameter=PPG breakfast (SMPG) (mg/dL) Study Identifier=NN1218-41

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.407086	6.738929	7.146035	6.16E6	0.060411	0.056970	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-7.179246	2.673207	-12.4186	-1.93986	6.16E6	-10.134983	-4.488365

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-2.69	0.0072

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9PL Parameter=PPG lunch (SMPG) (mmol/L) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.001363	0.017418	0.018781	3.8E6	0.078242	0.072565	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.340339	0.137042	-0.60894	-0.07174	3.8E6	-0.507689	-0.194900

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-2.48	0.0130

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9PLC Parameter=PPG lunch (SMPG) (mg/dL) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.442508	5.655925	6.098455	3.8E6	0.078242	0.072565	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-6.132907	2.469505	-10.9730	-1.29276	3.8E6	-9.148564	-3.512102

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-2.48	0.0130

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9PPRAN Parameter=PPG all meals (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000793	0.010141	0.010934	3.8E6	0.078248	0.072570	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.330939	0.104567	-0.53589	-0.12599	3.8E6	-0.442933	-0.213783

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-3.16	0.0016

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9PPRANC Parameter=PPG all meals (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.257652	3.292942	3.550607	3.8E6	0.078248	0.072570	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-5.963518	1.884305	-9.65669	-2.27035	3.8E6	-7.981657	-3.852367

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-3.16	0.0016

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

Parameter Code=P9PB Label=Faster aspart (meal) - NovoRapid (meal) Parameter=PPG breakfast (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.002861	0.041779	0.044640	4.87E6	0.068473	0.064086	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.314267	0.211281	-0.72837	0.099837	4.87E6	-0.516115	-0.099722

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-1.49	0.1369

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

Parameter Code=P9PB Label=Faster aspart (post) - NovoRapid (meal) Parameter=PPG breakfast (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.002402	0.041398	0.043799	6.65E6	0.058020	0.054839	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.383330	0.209283	-0.02686	0.793518	6.65E6	0.196241	0.579241

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	1.83	0.0670

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

Parameter Code=P9PEV Label=Faster aspart (meal) - NovoRapid (meal) Parameter=PPG main evening meal (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.002901	0.043492	0.046393	5.11E6	0.066700	0.062530	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.207957	0.215391	-0.63012	0.214202	5.11E6	-0.413620	0.007988

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-0.97	0.3343

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

Parameter Code=P9PEV Label=Faster aspart (post) - NovoRapid (meal) Parameter=PPG main evening meal (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.002295	0.043467	0.045762	7.95E6	0.052795	0.050148	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.418072	0.213919	-0.00120	0.837346	7.95E6	0.206237	0.595553

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	1.95	0.0507

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

Parameter Code=P9PEVC Label=Faster aspart (meal) - NovoRapid (meal) Parameter=PPG main evening meal (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.941950	14.122825	15.064822	5.11E6	0.066700	0.062530	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-3.747380	3.881343	-11.3547	3.859914	5.11E6	-7.453425	0.143943

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-0.97	0.3343

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

Parameter Code=P9PEVC Label=Faster aspart (post) - NovoRapid (meal) Parameter=PPG main evening meal (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.745141	14.114522	14.859701	7.95E6	0.052795	0.050148	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits	DF	Minimum	Maximum
Estimate	7.533656	3.854828	-0.02167 15.08898	7.95E6	3.716385	10.731860

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	1.95	0.0507

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

Parameter Code=P9PGBC Label=Faster aspart (meal) - NovoRapid (meal) Parameter=PPG breakfast (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.928895	13.566491	14.495432	4.87E6	0.068473	0.064086	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-5.663090	3.807287	-13.1252	1.799056	4.87E6	-9.300400	-1.796989

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-1.49	0.1369

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

Parameter Code=P9PGBC Label=Faster aspart (post) - NovoRapid (meal) Parameter=PPG breakfast (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.779903	13.442615	14.222557	6.65E6	0.058020	0.054839	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	6.907613	3.771281	-0.48396	14.29919	6.65E6	3.536260	10.437916

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	1.83	0.0670

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

Parameter Code=P9PL Label=Faster aspart (meal) - NovoRapid (meal) Parameter=PPG lunch (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.002624	0.035011	0.037635	4.11E6	0.074939	0.069715	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.190207	0.193997	-0.57043	0.190021	4.11E6	-0.388365	0.020581

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-0.98	0.3269

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

Parameter Code=P9PL Label=Faster aspart (post) - NovoRapid (meal) Parameter=PPG lunch (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.002221	0.034914	0.037135	5.59E6	0.063619	0.059814	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.296806	0.192705	-0.08089	0.674501	5.59E6	0.107618	0.477549

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	1.54	0.1235

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

Parameter Code=P9PLC Label=Faster aspart (meal) - NovoRapid (meal) Parameter=PPG lunch (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.851930	11.368823	12.220796	4.11E6	0.074939	0.069715	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-3.427522	3.495825	-10.2792	3.424172	4.11E6	-6.998343	0.370862

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-0.98	0.3269

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

Parameter Code=P9PLC Label=Faster aspart (post) - NovoRapid (meal) Parameter=PPG lunch (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.721232	11.337246	12.058514	5.59E6	0.063619	0.059814	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits	DF	Minimum	Maximum
Estimate	5.348453	3.472537	-1.45760 12.15450	5.59E6	1.939277	8.605434

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	1.54	0.1235

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

Parameter Code=P9PPRAN Label=Faster aspart (meal) - NovoRapid (meal) Parameter=PPG all meals (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.001661	0.020452	0.022113	3.54E6	0.081212	0.075113	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.248892	0.148703	-0.54034	0.042560	3.54E6	-0.414556	-0.090927

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-1.67	0.0942

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

Parameter Code=P9PPRAN Label=Faster aspart (post) - NovoRapid (meal) Parameter=PPG all meals (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.001250	0.020383	0.021633	5.99E6	0.061319	0.057777	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.344524	0.147081	0.056251	0.632798	5.99E6	0.215160	0.476856

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	2.34	0.0192

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

Parameter Code=P9PPRANC Label=Faster aspart (meal) - NovoRapid (meal) Parameter=PPG all meals (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.539309	6.641057	7.180392	3.54E6	0.081212	0.075113	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-4.485036	2.679625	-9.73701	0.766935	3.54E6	-7.470293	-1.638506

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-1.67	0.0942

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- in-trial - full analysis set

Parameter Code=P9PPRANC Label=Faster aspart (post) - NovoRapid (meal) Parameter=PPG all meals (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.405835	6.618746	7.024601	5.99E6	0.061319	0.057777	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits	DF	Minimum	Maximum
Estimate	6.208329	2.650396	1.013646 11.40301	5.99E6	3.877174	8.592943

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	2.34	0.0192

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
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The Mixed procedure
Model Information

Parameter Code=P9PB Parameter=PPG breakfast (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Data Set	WORK.IMPUTE_ABS
2	1	NN1218-4131	Dependent Variable	eotVisitAbs
3	1	NN1218-4131	Covariance Structure	Diagonal
4	1	NN1218-4131	Estimation Method	REML
5	1	NN1218-4131	Residual Variance Method	Profile
6	1	NN1218-4131	Fixed Effects SE Method	Model-Based
7	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=P9PEV Parameter=PPG main evening meal (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
8	1	NN1218-4131	Data Set	WORK.IMPUTE_ABS
9	1	NN1218-4131	Dependent Variable	eotVisitAbs
10	1	NN1218-4131	Covariance Structure	Diagonal
11	1	NN1218-4131	Estimation Method	REML
12	1	NN1218-4131	Residual Variance Method	Profile
13	1	NN1218-4131	Fixed Effects SE Method	Model-Based
14	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=P9PEVC Parameter=PPG main evening meal (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
15	1	NN1218-4131	Data Set	WORK.IMPUTE_ABS
16	1	NN1218-4131	Dependent Variable	eotVisitAbs
17	1	NN1218-4131	Covariance Structure	Diagonal

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
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The Mixed procedure
Model Information

Parameter Code=P9PEVC Parameter=PPG main evening meal (SMPG) (mg/dL)

(continued)

Obs	_Imputation_	STUDYID	Descr	Value
18	1	NN1218-4131	Estimation Method	REML
19	1	NN1218-4131	Residual Variance Method	Profile
20	1	NN1218-4131	Fixed Effects SE Method	Model-Based
21	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=P9PGBC Parameter=PPG breakfast (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
22	1	NN1218-4131	Data Set	WORK.IMPUTE_ABS
23	1	NN1218-4131	Dependent Variable	eotVisitAbs
24	1	NN1218-4131	Covariance Structure	Diagonal
25	1	NN1218-4131	Estimation Method	REML
26	1	NN1218-4131	Residual Variance Method	Profile
27	1	NN1218-4131	Fixed Effects SE Method	Model-Based
28	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=P9PL Parameter=PPG lunch (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
29	1	NN1218-4131	Data Set	WORK.IMPUTE_ABS
30	1	NN1218-4131	Dependent Variable	eotVisitAbs
31	1	NN1218-4131	Covariance Structure	Diagonal
32	1	NN1218-4131	Estimation Method	REML

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

The Mixed procedure
Model Information

Parameter Code=P9PL Parameter=PPG lunch (SMPG) (mmol/L)

(continued)

Obs	_Imputation_	STUDYID	Descr	Value
33	1	NN1218-4131	Residual Variance Method	Profile
34	1	NN1218-4131	Fixed Effects SE Method	Model-Based
35	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=P9PLC Parameter=PPG lunch (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
36	1	NN1218-4131	Data Set	WORK.IMPUTE_ABS
37	1	NN1218-4131	Dependent Variable	eotVisitAbs
38	1	NN1218-4131	Covariance Structure	Diagonal
39	1	NN1218-4131	Estimation Method	REML
40	1	NN1218-4131	Residual Variance Method	Profile
41	1	NN1218-4131	Fixed Effects SE Method	Model-Based
42	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=P9PPRAN Parameter=PPG all meals (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
43	1	NN1218-4131	Data Set	WORK.IMPUTE_ABS
44	1	NN1218-4131	Dependent Variable	eotVisitAbs
45	1	NN1218-4131	Covariance Structure	Diagonal
46	1	NN1218-4131	Estimation Method	REML
47	1	NN1218-4131	Residual Variance Method	Profile

nn1218/nn1218-4131/ctr_20180214_er
09FEB2018:20:27:18 - a_797pp_stat_diff.sas/a_9pp_ppg_stat_in_fas_app.txt

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

The Mixed procedure
Model Information

Parameter Code=P9PPRAN Parameter=PPG all meals (SMPG) (mmol/L)

(continued)

Obs	_Imputation_	STUDYID	Descr	Value
48	1	NN1218-4131	Fixed Effects SE Method	Model-Based
49	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=P9PPRANC Parameter=PPG all meals (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
50	1	NN1218-4131	Data Set	WORK.IMPUTE_ABS
51	1	NN1218-4131	Dependent Variable	eotVisitAbs
52	1	NN1218-4131	Covariance Structure	Diagonal
53	1	NN1218-4131	Estimation Method	REML
54	1	NN1218-4131	Residual Variance Method	Profile
55	1	NN1218-4131	Fixed Effects SE Method	Model-Based
56	1	NN1218-4131	Degrees of Freedom Method	Residual

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The Mixed procedure
Class Level Information

Parameter Code=P9PB Parameter=PPG breakfast (SMPG) (mmol/L)

O b s _		I m p u t a t i o n s		S T U D Y I D		C l a s s e s		L e v e l s		V a r i a b l e s		m i n	
1	1	NN1218-4131	TRTPN					3	2	3	4		5
2	1	NN1218-4131	REGION1					4	ASIA (EXCLUDING JAPAN)	EUROPE	JAPAN	NORTH AMERICA	49
3	1	NN1218-4131	BOLAD1					2	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	CARBOHYDRATE COUNTING (FLEXIBLE)	BOLUS INSULI	85	

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
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The Mixed procedure
Class Level Information

Parameter Code=P9PEV Parameter=PPG main evening meal (SMPG) (mmol/L)

Object	Input	STUDY ID	Classes	Levels	Values	min
4	1	NN1218-4131	TRTPN	3 2 3 4		5
5	1	NN1218-4131	REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA	49
6	1	NN1218-4131	BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULI	85

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
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The Mixed procedure
Class Level Information

Parameter Code=P9PEVC Parameter=PPG main evening meal (SMPG) (mg/dL)

Ob- s	—	Input on ID	STUDY ID	Class s	Le- vel s	Val- ues	mi- n — Le- vel — g- t h
7	1	NN1218-4131	TRTPN		3 2 3 4		5
8	1	NN1218-4131	REGION1		4 ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA		49
9	1	NN1218-4131	BOLAD1		2 BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULI		85

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The Mixed procedure
Class Level Information

Parameter Code=P9PGBC Parameter=PPG breakfast (SMPG) (mg/dL)

O b s		I m p u t a t i o n		S T U D Y I D		C l a s s		L e v e l s		V a l u e s		m i n I e g t h	
10	1	NN1218-4131	TRTPN					3	2	3	4		5
11	1	NN1218-4131	REGION1					4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA				49
12	1	NN1218-4131	BOLAD1					2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULI				85

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
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The Mixed procedure
Class Level Information

Parameter Code=P9PL Parameter=PPG lunch (SMPG) (mmol/L)

Obs	Input	STUDY ID	Classes	Levels	Values	min
13	1	NN1218-4131	TRTPN	3 2 3 4		5
14	1	NN1218-4131	REGION1	4 ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA		49
15	1	NN1218-4131	BOLAD1	2 BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULI		85

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nn1218/nn1218-4131/ctr_20180214_er
09FEB2018:20:27:18 - a 797pp stat diff.sas/a 9pp ppg stat in_fas app.txt
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The Mixed procedure
Class Level Information

Parameter Code=P9PPRAN Parameter=PPG all meals (SMPG) (mmol/L)

O b s		I m p u t a t i o n s		S t u d y I D		C l a s s e s		L e v e l s		V a r i a b l e s		m i n	
19	1	NN1218-4131	TRTPN					3	2	3	4		5
20	1	NN1218-4131	REGION1					4	ASIA (EXCLUDING JAPAN)	EUROPE	JAPAN	NORTH AMERICA	49
21	1	NN1218-4131	BOLAD1					2	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	CARBOHYDRATE COUNTING (FLEXIBLE)	BOLUS INSULI		85

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The Mixed procedure
Class Level Information

Parameter Code=P9PPRANC Parameter=PPG all meals (SMPG) (mg/dL)

O b s		I n		S t		C l		L e		V a		m i	
_		D		Y		s		v		l		n	
22	1	NN1218-4131	TRTPN										5
23	1	NN1218-4131	REGION1										49
24	1	NN1218-4131	BOLAD1										85

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The Mixed procedure
Dimensions

Parameter Code=P9PB Parameter=PPG breakfast (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Covariance Parameters	1
2	1	NN1218-4131	Columns in X	10
3	1	NN1218-4131	Columns in Z	0
4	1	NN1218-4131	Subjects	1
5	1	NN1218-4131	Max Obs per Subject	986

Parameter Code=P9PEV Parameter=PPG main evening meal (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
6	1	NN1218-4131	Covariance Parameters	1
7	1	NN1218-4131	Columns in X	10
8	1	NN1218-4131	Columns in Z	0
9	1	NN1218-4131	Subjects	1
10	1	NN1218-4131	Max Obs per Subject	981

Parameter Code=P9PEVC Parameter=PPG main evening meal (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
11	1	NN1218-4131	Covariance Parameters	1
12	1	NN1218-4131	Columns in X	10
13	1	NN1218-4131	Columns in Z	0
14	1	NN1218-4131	Subjects	1
15	1	NN1218-4131	Max Obs per Subject	981

nn1218/nn1218-4131/ctr_20180214_er
09FEB2018:20:27:18 - a_797pp_stat_diff.sas/a_9pp_ppg_stat_in_fas_app.txt

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

The Mixed procedure
Dimensions

Parameter Code=P9PGBC Parameter=PPG breakfast (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
16	1	NN1218-4131	Covariance Parameters	1
17	1	NN1218-4131	Columns in X	10
18	1	NN1218-4131	Columns in Z	0
19	1	NN1218-4131	Subjects	1
20	1	NN1218-4131	Max Obs per Subject	986

Parameter Code=P9PL Parameter=PPG lunch (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
21	1	NN1218-4131	Covariance Parameters	1
22	1	NN1218-4131	Columns in X	10
23	1	NN1218-4131	Columns in Z	0
24	1	NN1218-4131	Subjects	1
25	1	NN1218-4131	Max Obs per Subject	984

Parameter Code=P9PLC Parameter=PPG lunch (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
26	1	NN1218-4131	Covariance Parameters	1
27	1	NN1218-4131	Columns in X	10
28	1	NN1218-4131	Columns in Z	0
29	1	NN1218-4131	Subjects	1
30	1	NN1218-4131	Max Obs per Subject	984

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

The Mixed procedure
Dimensions

Parameter Code=P9PPRAN Parameter=PPG all meals (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
31	1	NN1218-4131	Covariance Parameters	1
32	1	NN1218-4131	Columns in X	10
33	1	NN1218-4131	Columns in Z	0
34	1	NN1218-4131	Subjects	1
35	1	NN1218-4131	Max Obs per Subject	977

Parameter Code=P9PPRANC Parameter=PPG all meals (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
36	1	NN1218-4131	Covariance Parameters	1
37	1	NN1218-4131	Columns in X	10
38	1	NN1218-4131	Columns in Z	0
39	1	NN1218-4131	Subjects	1
40	1	NN1218-4131	Max Obs per Subject	977

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

The Mixed procedure
Number of Observations

Parameter Code=P9PB Parameter=PPG breakfast (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
1	1	NN1218-4131	Number of Observations Read	986	986	986	986	986
2	1	NN1218-4131	Number of Observations Used	986	986	986	986	986
3	1	NN1218-4131	Number of Observations Not Used	0	986	986	986	986

Parameter Code=P9PEV Parameter=PPG main evening meal (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
4	1	NN1218-4131	Number of Observations Read	981	981	981	981	981
5	1	NN1218-4131	Number of Observations Used	981	981	981	981	981
6	1	NN1218-4131	Number of Observations Not Used	0	981	981	981	981

Parameter Code=P9PEVC Parameter=PPG main evening meal (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
7	1	NN1218-4131	Number of Observations Read	981	981	981	981	981
8	1	NN1218-4131	Number of Observations Used	981	981	981	981	981
9	1	NN1218-4131	Number of Observations Not Used	0	981	981	981	981

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

The Mixed procedure
Number of Observations

Parameter Code=P9PGBC Parameter=PPG breakfast (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
10	1	NN1218-4131	Number of Observations Read	986	986	986	986	986
11	1	NN1218-4131	Number of Observations Used	986	986	986	986	986
12	1	NN1218-4131	Number of Observations Not Used	0	986	986	986	986

Parameter Code=P9PL Parameter=PPG lunch (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
13	1	NN1218-4131	Number of Observations Read	984	984	984	984	984
14	1	NN1218-4131	Number of Observations Used	984	984	984	984	984
15	1	NN1218-4131	Number of Observations Not Used	0	984	984	984	984

Parameter Code=P9PLC Parameter=PPG lunch (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
16	1	NN1218-4131	Number of Observations Read	984	984	984	984	984
17	1	NN1218-4131	Number of Observations Used	984	984	984	984	984
18	1	NN1218-4131	Number of Observations Not Used	0	984	984	984	984

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
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The Mixed procedure
Number of Observations

Parameter Code=P9PPRAN Parameter=PPG all meals (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
19	1	NN1218-4131	Number of Observations Read	977	977	977	977	977
20	1	NN1218-4131	Number of Observations Used	977	977	977	977	977
21	1	NN1218-4131	Number of Observations Not Used	0	977	977	977	977

Parameter Code=P9PPRANC Parameter=PPG all meals (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
22	1	NN1218-4131	Number of Observations Read	977	977	977	977	977
23	1	NN1218-4131	Number of Observations Used	977	977	977	977	977
24	1	NN1218-4131	Number of Observations Not Used	0	977	977	977	977

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
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The Mixed procedure
Covariance Parameter Estimates

Parameter Code=P9PB Parameter=PPG breakfast (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	CovParm	Estimate
1	1	NN1218-4131	Residual	6.8567

Parameter Code=P9PEV Parameter=PPG main evening meal (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	CovParm	Estimate
20001	1	NN1218-4131	Residual	7.0241

Parameter Code=P9PEVC Parameter=PPG main evening meal (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	CovParm	Estimate
40001	1	NN1218-4131	Residual	2280.87

Parameter Code=P9PGBC Parameter=PPG breakfast (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	CovParm	Estimate
60001	1	NN1218-4131	Residual	2226.51

Parameter Code=P9PL Parameter=PPG lunch (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	CovParm	Estimate
80001	1	NN1218-4131	Residual	5.8169

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
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The Mixed procedure
Covariance Parameter Estimates

Parameter Code=P9PLC Parameter=PPG lunch (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	CovParm	Estimate
100001	1	NN1218-4131	Residual	1888.87

Parameter Code=P9PPRAN Parameter=PPG all meals (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	CovParm	Estimate
120001	1	NN1218-4131	Residual	3.3310

Parameter Code=P9PPRANC Parameter=PPG all meals (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	CovParm	Estimate
140001	1	NN1218-4131	Residual	1081.66

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

The Mixed procedure
Fit Statistics

Parameter Code=P9PB Parameter=PPG breakfast (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	-2 Res Log Likelihood	4704.9
2	1	NN1218-4131	AIC (Smaller is Better)	4706.9
3	1	NN1218-4131	AICC (Smaller is Better)	4706.9
4	1	NN1218-4131	BIC (Smaller is Better)	4711.8

Parameter Code=P9PEV Parameter=PPG main evening meal (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
5	1	NN1218-4131	-2 Res Log Likelihood	4704.5
6	1	NN1218-4131	AIC (Smaller is Better)	4706.5
7	1	NN1218-4131	AICC (Smaller is Better)	4706.6
8	1	NN1218-4131	BIC (Smaller is Better)	4711.4

Parameter Code=P9PEVC Parameter=PPG main evening meal (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
9	1	NN1218-4131	-2 Res Log Likelihood	10337.2
10	1	NN1218-4131	AIC (Smaller is Better)	10339.2
11	1	NN1218-4131	AICC (Smaller is Better)	10339.2
12	1	NN1218-4131	BIC (Smaller is Better)	10344.0

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
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The Mixed procedure
Fit Statistics

Parameter Code=P9PGBC Parameter=PPG breakfast (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
13	1	NN1218-4131	-2 Res Log Likelihood	10366.4
14	1	NN1218-4131	AIC (Smaller is Better)	10368.4
15	1	NN1218-4131	AICC (Smaller is Better)	10368.4
16	1	NN1218-4131	BIC (Smaller is Better)	10373.3

Parameter Code=P9PL Parameter=PPG lunch (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
17	1	NN1218-4131	-2 Res Log Likelihood	4534.8
18	1	NN1218-4131	AIC (Smaller is Better)	4536.8
19	1	NN1218-4131	AICC (Smaller is Better)	4536.8
20	1	NN1218-4131	BIC (Smaller is Better)	4541.7

Parameter Code=P9PLC Parameter=PPG lunch (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
21	1	NN1218-4131	-2 Res Log Likelihood	10184.7
22	1	NN1218-4131	AIC (Smaller is Better)	10186.7
23	1	NN1218-4131	AICC (Smaller is Better)	10186.7
24	1	NN1218-4131	BIC (Smaller is Better)	10191.6

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
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The Mixed procedure
Fit Statistics

Parameter Code=P9PPRAN Parameter=PPG all meals (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
25	1	NN1218-4131	-2 Res Log Likelihood	3961.8
26	1	NN1218-4131	AIC (Smaller is Better)	3963.8
27	1	NN1218-4131	AICC (Smaller is Better)	3963.8
28	1	NN1218-4131	BIC (Smaller is Better)	3968.7

Parameter Code=P9PPRANC Parameter=PPG all meals (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
29	1	NN1218-4131	-2 Res Log Likelihood	9571.3
30	1	NN1218-4131	AIC (Smaller is Better)	9573.3
31	1	NN1218-4131	AICC (Smaller is Better)	9573.3
32	1	NN1218-4131	BIC (Smaller is Better)	9578.2

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The Mixed procedure
Solution for Fixed Effects

Parameter Code=P9PB Parameter=PPG breakfast (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1			BOLAD1
1	1	NN1218-4131	TRTPN	2				
2	1	NN1218-4131	TRTPN	3				
3	1	NN1218-4131	TRTPN	4				
4	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
5	1	NN1218-4131	REGION1	—	EUROPE			
6	1	NN1218-4131	REGION1	—	JAPAN			
7	1	NN1218-4131	REGION1	—	NORTH AMERICA			
8	1	NN1218-4131	BOLAD1	—				BOLUS INSULIN ALGORITHM (SLIDING SCALE)
9	1	NN1218-4131	BOLAD1	—				CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY
10	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	6.1588	0.3518	978	17.51	<.0001	0.05	5.4685	6.8491
2	6.8894	0.3524	978	19.55	<.0001	0.05	6.1978	7.5810
3	6.4480	0.3487	978	18.49	<.0001	0.05	5.7637	7.1322
4	-0.2660	0.3061	978	-0.87	0.3851	0.05	-0.8667	0.3347
5	-0.4300	0.2175	978	-1.98	0.0483	0.05	-0.8568	-0.00317
6	0.8679	0.2431	978	3.57	0.0004	0.05	0.3908	1.3450
7	0
8	-0.6700	0.1893	978	-3.54	0.0004	0.05	-1.0415	-0.2986
9	0
10	0.3345	0.02865	978	11.67	<.0001	0.05	0.2783	0.3908

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The Mixed procedure
Solution for Fixed Effects

Parameter Code=P9PEV Parameter=PPG main evening meal (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
11	1	NN1218-4131	TRTPN	2				
12	1	NN1218-4131	TRTPN	3				
13	1	NN1218-4131	TRTPN	4				
14	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
15	1	NN1218-4131	REGION1	—	EUROPE			
16	1	NN1218-4131	REGION1	—	JAPAN			
17	1	NN1218-4131	REGION1	—	NORTH AMERICA			
18	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
19	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
20	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
11	7.2384	0.3482	973	20.79	<.0001	0.05	6.5550	7.9218
12	7.8386	0.3563	973	22.00	<.0001	0.05	7.1394	8.5378
13	7.3701	0.3460	973	21.30	<.0001	0.05	6.6910	8.0491
14	-0.7660	0.3110	973	-2.46	0.0140	0.05	-1.3763	-0.1556
15	-0.7523	0.2210	973	-3.40	0.0007	0.05	-1.1861	-0.3185
16	0.1925	0.2449	973	0.79	0.4321	0.05	-0.2881	0.6731
17	0
18	-0.4005	0.1916	973	-2.09	0.0369	0.05	-0.7765	-0.02439
19	0
20	0.2485	0.02877	973	8.64	<.0001	0.05	0.1920	0.3050

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Solution for Fixed Effects

Parameter Code=P9PEVC Parameter=PPG main evening meal (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1
21	1	NN1218-4131	TRTPN	2		
22	1	NN1218-4131	TRTPN	3		
23	1	NN1218-4131	TRTPN	4		
24	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)	
25	1	NN1218-4131	REGION1	—	EUROPE	
26	1	NN1218-4131	REGION1	—	JAPAN	
27	1	NN1218-4131	REGION1	—	NORTH AMERICA	
28	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)
29	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY
30	1	NN1218-4131	BASE	—		

Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
21	130.44	6.2753	973	20.79	<.0001	0.05	118.12	142.75
22	141.25	6.4203	973	22.00	<.0001	0.05	128.65	153.85
23	132.81	6.2354	973	21.30	<.0001	0.05	120.57	145.04
24	-13.8027	5.6047	973	-2.46	0.0140	0.05	-24.8013	-2.8040
25	-13.5566	3.9831	973	-3.40	0.0007	0.05	-21.3730	-5.7401
26	3.4687	4.4135	973	0.79	0.4321	0.05	-5.1924	12.1298
27	0
28	-7.2161	3.4532	973	-2.09	0.0369	0.05	-13.9927	-0.4395
29	0
30	0.2485	0.02877	973	8.64	<.0001	0.05	0.1920	0.3050

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Parameter Code=P9PGBC Parameter=PPG breakfast (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
31	1	NN1218-4131	TRTPN	2				
32	1	NN1218-4131	TRTPN	3				
33	1	NN1218-4131	TRTPN	4				
34	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
35	1	NN1218-4131	REGION1	—	EUROPE			
36	1	NN1218-4131	REGION1	—	JAPAN			
37	1	NN1218-4131	REGION1	—	NORTH AMERICA			
38	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
39	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
40	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
31	110.98	6.3388	978	17.51	<.0001	0.05	98.5419	123.42
32	124.15	6.3507	978	19.55	<.0001	0.05	111.68	136.61
33	116.19	6.2828	978	18.49	<.0001	0.05	103.86	128.52
34	-4.7933	5.5164	978	-0.87	0.3851	0.05	-15.6186	6.0320
35	-7.7481	3.9192	978	-1.98	0.0483	0.05	-15.4390	-0.05709
36	15.6394	4.3810	978	3.57	0.0004	0.05	7.0422	24.2366
37	0
38	-12.0742	3.4112	978	-3.54	0.0004	0.05	-18.7682	-5.3802
39	0
40	0.3345	0.02865	978	11.67	<.0001	0.05	0.2783	0.3908

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Solution for Fixed Effects

Parameter Code=P9PL Parameter=PPG lunch (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1				BOLAD1
41	1	NN1218-4131	TRTPN	2					
42	1	NN1218-4131	TRTPN	3					
43	1	NN1218-4131	TRTPN	4					
44	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)				
45	1	NN1218-4131	REGION1	—	EUROPE				
46	1	NN1218-4131	REGION1	—	JAPAN				
47	1	NN1218-4131	REGION1	—	NORTH AMERICA				
48	1	NN1218-4131	BOLAD1	—					BOLUS INSULIN ALGORITHM (SLIDING SCALE)
49	1	NN1218-4131	BOLAD1	—					CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY
50	1	NN1218-4131	BASE	—					
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper	
41	6.6993	0.3196	976	20.96	<.0001	0.05	6.0722	7.3264	
42	7.1960	0.3175	976	22.66	<.0001	0.05	6.5729	7.8190	
43	6.8288	0.3210	976	21.28	<.0001	0.05	6.1989	7.4586	
44	-0.1215	0.2819	976	-0.43	0.6666	0.05	-0.6746	0.4317	
45	-0.4068	0.2005	976	-2.03	0.0427	0.05	-0.8003	-0.01334	
46	0.9927	0.2268	976	4.38	<.0001	0.05	0.5476	1.4378	
47	0	
48	-0.5350	0.1738	976	-3.08	0.0021	0.05	-0.8760	-0.1939	
49	0	
50	0.2586	0.02765	976	9.35	<.0001	0.05	0.2043	0.3128	

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Solution for Fixed Effects

Parameter Code=P9PLC Parameter=PPG lunch (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1			BOLAD1
51	1	NN1218-4131	TRTPN	2				
52	1	NN1218-4131	TRTPN	3				
53	1	NN1218-4131	TRTPN	4				
54	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
55	1	NN1218-4131	REGION1	—	EUROPE			
56	1	NN1218-4131	REGION1	—	JAPAN			
57	1	NN1218-4131	REGION1	—	NORTH AMERICA			
58	1	NN1218-4131	BOLAD1	—				BOLUS INSULIN ALGORITHM (SLIDING SCALE)
59	1	NN1218-4131	BOLAD1	—				CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY
60	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
51	120.72	5.7585	976	20.96	<.0001	0.05	109.42	132.02
52	129.67	5.7216	976	22.66	<.0001	0.05	118.44	140.90
53	123.05	5.7840	976	21.28	<.0001	0.05	111.70	134.40
54	-2.1888	5.0793	976	-0.43	0.6666	0.05	-12.1563	7.7788
55	-7.3313	3.6134	976	-2.03	0.0427	0.05	-14.4222	-0.2405
56	17.8878	4.0871	976	4.38	<.0001	0.05	9.8672	25.9084
57	0
58	-9.6404	3.1316	976	-3.08	0.0021	0.05	-15.7858	-3.4949
59	0
60	0.2586	0.02765	976	9.35	<.0001	0.05	0.2043	0.3128

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Parameter Code=P9PPRAN Parameter=PPG all meals (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1			BOLAD1
61	1	NN1218-4131	TRTPN	2				
62	1	NN1218-4131	TRTPN	3				
63	1	NN1218-4131	TRTPN	4				
64	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
65	1	NN1218-4131	REGION1	—	EUROPE			
66	1	NN1218-4131	REGION1	—	JAPAN			
67	1	NN1218-4131	REGION1	—	NORTH AMERICA			
68	1	NN1218-4131	BOLAD1	—				BOLUS INSULIN ALGORITHM (SLIDING SCALE)
69	1	NN1218-4131	BOLAD1	—				CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY
70	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
61	5.6928	0.2995	969	19.01	<.0001	0.05	5.1051	6.2805
62	6.3053	0.3009	969	20.95	<.0001	0.05	5.7148	6.8959
63	5.9164	0.2973	969	19.90	<.0001	0.05	5.3330	6.4998
64	-0.3316	0.2139	969	-1.55	0.1214	0.05	-0.7514	0.08819
65	-0.4764	0.1524	969	-3.13	0.0018	0.05	-0.7756	-0.1773
66	0.5814	0.1710	969	3.40	0.0007	0.05	0.2458	0.9169
67	0
68	-0.5474	0.1324	969	-4.13	<.0001	0.05	-0.8073	-0.2875
69	0
70	0.3847	0.02715	969	14.17	<.0001	0.05	0.3315	0.4380

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Parameter Code=P9PPRANC Parameter=PPG all meals (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1			BOLAD1
71	1	NN1218-4131	TRTPN	2				
72	1	NN1218-4131	TRTPN	3				
73	1	NN1218-4131	TRTPN	4				
74	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
75	1	NN1218-4131	REGION1	—	EUROPE			
76	1	NN1218-4131	REGION1	—	JAPAN			
77	1	NN1218-4131	REGION1	—	NORTH AMERICA			
78	1	NN1218-4131	BOLAD1	—				BOLUS INSULIN ALGORITHM (SLIDING SCALE)
79	1	NN1218-4131	BOLAD1	—				CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY
80	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
71	102.58	5.3962	969	19.01	<.0001	0.05	91.9947	113.17
72	113.62	5.4227	969	20.95	<.0001	0.05	102.98	124.26
73	106.61	5.3569	969	19.90	<.0001	0.05	96.1009	117.13
74	-5.9751	3.8546	969	-1.55	0.1214	0.05	-13.5395	1.5892
75	-8.5853	2.7470	969	-3.13	0.0018	0.05	-13.9761	-3.1946
76	10.4760	3.0810	969	3.40	0.0007	0.05	4.4298	16.5222
77	0
78	-9.8645	2.3867	969	-4.13	<.0001	0.05	-14.5482	-5.1809
79	0
80	0.3847	0.02715	969	14.17	<.0001	0.05	0.3315	0.4380

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Obs	_Imputation_	PARAMCD	PARAM	STUDYID	Effect	TRTPN
1	1	P9PB	PPG breakfast (SMPG) (mmol/L)	NN1218-4131	TRTPN	2
20001	1	P9PEV	PPG main evening meal (SMPG) (mmol/L)	NN1218-4131	TRTPN	2
40001	1	P9PEVC	PPG main evening meal (SMPG) (mg/dL)	NN1218-4131	TRTPN	2
60001	1	P9PGBC	PPG breakfast (SMPG) (mg/dL)	NN1218-4131	TRTPN	2
80001	1	P9PL	PPG lunch (SMPG) (mmol/L)	NN1218-4131	TRTPN	2
100001	1	P9PLC	PPG lunch (SMPG) (mg/dL)	NN1218-4131	TRTPN	2
120001	1	P9PPRAN	PPG all meals (SMPG) (mmol/L)	NN1218-4131	TRTPN	2
140001	1	P9PPRANC	PPG all meals (SMPG) (mg/dL)	NN1218-4131	TRTPN	2
160001	1	P9PB	PPG breakfast (SMPG) (mmol/L)	NN1218-4131	TRTPN	3
180001	1	P9PEV	PPG main evening meal (SMPG) (mmol/L)	NN1218-4131	TRTPN	3
200001	1	P9PEVC	PPG main evening meal (SMPG) (mg/dL)	NN1218-4131	TRTPN	3
220001	1	P9PGBC	PPG breakfast (SMPG) (mg/dL)	NN1218-4131	TRTPN	3
240001	1	P9PL	PPG lunch (SMPG) (mmol/L)	NN1218-4131	TRTPN	3
260001	1	P9PLC	PPG lunch (SMPG) (mg/dL)	NN1218-4131	TRTPN	3

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	WORK.IMPUTE	-0.7165	0.1452	978	-4.93	<.0001	0.05	-1.0015	-0.4315
20001	WORK.IMPUTE	-0.4542	0.1470	973	-3.09	0.0021	0.05	-0.7427	-0.1657
40001	WORK.IMPUTE	-8.1847	2.6495	973	-3.09	0.0021	0.05	-13.3840	-2.9853
60001	WORK.IMPUTE	-12.9118	2.6172	978	-4.93	<.0001	0.05	-18.0477	-7.7759
80001	WORK.IMPUTE	-0.5091	0.1336	976	-3.81	0.0001	0.05	-0.7712	-0.2469
100001	WORK.IMPUTE	-9.1737	2.4071	976	-3.81	0.0001	0.05	-13.8975	-4.4499
120001	WORK.IMPUTE	-0.5753	0.1016	969	-5.66	<.0001	0.05	-0.7746	-0.3760
140001	WORK.IMPUTE	-10.3663	1.8300	969	-5.66	<.0001	0.05	-13.9575	-6.7750
160001	WORK.IMPUTE	0.01410	0.1441	978	0.10	0.9221	0.05	-0.2686	0.2968
180001	WORK.IMPUTE	0.1460	0.1469	973	0.99	0.3205	0.05	-0.1422	0.4342
200001	WORK.IMPUTE	2.6305	2.6463	973	0.99	0.3205	0.05	-2.5625	7.8235
220001	WORK.IMPUTE	0.2540	2.5960	978	0.10	0.9221	0.05	-4.8403	5.3483
240001	WORK.IMPUTE	-0.01242	0.1333	976	-0.09	0.9258	0.05	-0.2740	0.2492
260001	WORK.IMPUTE	-0.2238	2.4025	976	-0.09	0.9258	0.05	-4.9383	4.4908

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Obs	_Imputation_	PARAMCD	PARAM	STUDYID	Effect	TRTPN
280001	1	P9PPRAN	PPG all meals (SMPG) (mmol/L)	NN1218-4131	TRTPN	3
300001	1	P9PPRANC	PPG all meals (SMPG) (mg/dL)	NN1218-4131	TRTPN	3
320001	1	P9PB	PPG breakfast (SMPG) (mmol/L)	NN1218-4131	TRTPN	4
340001	1	P9PEV	PPG main evening meal (SMPG) (mmol/L)	NN1218-4131	TRTPN	4
360001	1	P9PEVC	PPG main evening meal (SMPG) (mg/dL)	NN1218-4131	TRTPN	4
380001	1	P9PGBC	PPG breakfast (SMPG) (mg/dL)	NN1218-4131	TRTPN	4
400001	1	P9PL	PPG lunch (SMPG) (mmol/L)	NN1218-4131	TRTPN	4
420001	1	P9PLC	PPG lunch (SMPG) (mg/dL)	NN1218-4131	TRTPN	4
440001	1	P9PPRAN	PPG all meals (SMPG) (mmol/L)	NN1218-4131	TRTPN	4
460001	1	P9PPRANC	PPG all meals (SMPG) (mg/dL)	NN1218-4131	TRTPN	4

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
280001	WORK.IMPUTE	0.03726	0.1013	969	0.37	0.7132	0.05	-0.1616	0.2361
300001	WORK.IMPUTE	0.6714	1.8261	969	0.37	0.7132	0.05	-2.9121	4.2550
320001	WORK.IMPUTE	-0.4273	0.1445	978	-2.96	0.0032	0.05	-0.7109	-0.1437
340001	WORK.IMPUTE	-0.3225	0.1466	973	-2.20	0.0280	0.05	-0.6102	-0.03490
360001	WORK.IMPUTE	-5.8122	2.6413	973	-2.20	0.0280	0.05	-10.9954	-0.6289
380001	WORK.IMPUTE	-7.7007	2.6042	978	-2.96	0.0032	0.05	-12.8112	-2.5902
400001	WORK.IMPUTE	-0.3796	0.1331	976	-2.85	0.0044	0.05	-0.6408	-0.1184
420001	WORK.IMPUTE	-6.8405	2.3982	976	-2.85	0.0044	0.05	-11.5467	-2.1344
440001	WORK.IMPUTE	-0.3517	0.1009	969	-3.49	0.0005	0.05	-0.5497	-0.1537
460001	WORK.IMPUTE	-6.3372	1.8179	969	-3.49	0.0005	0.05	-9.9047	-2.7697

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

The Mixed procedure
Least Squares Means Estimate

Parameter Code=P9PB Parameter=PPG breakfast (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label				
1	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)				
20001	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)				

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	WORK.IMPUTE	-0.2892	0.2051	978	-1.41	0.1588	0.05	-0.6916	0.1132
20001	WORK.IMPUTE	0.4414	0.2041	978	2.16	0.0308	0.05	0.04089	0.8420

Parameter Code=P9PEV Parameter=PPG main evening meal (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label				
40001	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)				
60001	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)				

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
40001	WORK.IMPUTE	-0.1317	0.2077	973	-0.63	0.5264	0.05	-0.5393	0.2760
60001	WORK.IMPUTE	0.4685	0.2077	973	2.26	0.0243	0.05	0.06096	0.8761

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

The Mixed procedure
Least Squares Means Estimate

Parameter Code=P9PEVC Parameter=PPG main evening meal (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label				
80001	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)				
100001	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)				

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
80001	WORK.IMPUTE	-2.3725	3.7436	973	-0.63	0.5264	0.05	-9.7189	4.9739
100001	WORK.IMPUTE	8.4427	3.7425	973	2.26	0.0243	0.05	1.0984	15.7869

Parameter Code=P9PGBC Parameter=PPG breakfast (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label				
120001	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)				
140001	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)				

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
120001	WORK.IMPUTE	-5.2111	3.6950	978	-1.41	0.1588	0.05	-12.4622	2.0400
140001	WORK.IMPUTE	7.9547	3.6781	978	2.16	0.0308	0.05	0.7368	15.1727

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

The Mixed procedure
Least Squares Means Estimate

Parameter Code=P9PL Parameter=PPG lunch (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
160001	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
180001	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
160001	WORK.IMPUTE	-0.1295	0.1887	976	-0.69	0.4927	0.05	-0.4997	0.2408
180001	WORK.IMPUTE	0.3672	0.1884	976	1.95	0.0516	0.05	-0.00256	0.7369

Parameter Code=P9PLC Parameter=PPG lunch (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
200001	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
220001	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
200001	WORK.IMPUTE	-2.3331	3.4000	976	-0.69	0.4927	0.05	-9.0054	4.3391
220001	WORK.IMPUTE	6.6168	3.3953	976	1.95	0.0516	0.05	-0.04616	13.2797

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

The Mixed procedure
Least Squares Means Estimate

Parameter Code=P9PPRAN Parameter=PPG all meals (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label				
240001	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)				
260001	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)				

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
240001	WORK.IMPUTE	-0.2236	0.1433	969	-1.56	0.1189	0.05	-0.5047	0.05756
260001	WORK.IMPUTE	0.3889	0.1430	969	2.72	0.0067	0.05	0.1083	0.6696

Parameter Code=P9PPRANC Parameter=PPG all meals (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label				
280001	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)				
300001	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)				

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
280001	WORK.IMPUTE	-4.0290	2.5816	969	-1.56	0.1189	0.05	-9.0953	1.0372
300001	WORK.IMPUTE	7.0087	2.5773	969	2.72	0.0067	0.05	1.9509	12.0664

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 1871 of 4425	Novo Nordisk
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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9PB Parameter=PPG breakfast (SMPG) (mmol/L) Study Identifier=NN1218-413

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.001592	0.020960	0.022552	4.01E6	0.075941	0.070582	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	9.086752	0.150172	8.792421	9.381083	4.01E6	8.926582	9.236931

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	60.51	<.0001

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9PEV Parameter=PPG main evening meal (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.001573	0.021785	0.023358	4.41E6	0.072198	0.067337	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	9.018770	0.152834	8.719221	9.318319	4.41E6	8.850185	9.203150

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	59.01	<.0001

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9PEVC Parameter=PPG main evening meal (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.510714	7.074144	7.584883	4.41E6	0.072198	0.067337	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	162.518231	2.754067	157.1204	167.9161	4.41E6	159.480329	165.840770

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	59.01	<.0001

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9PGBC Parameter=PPG breakfast (SMPG) (mg/dL) Study Identifier=NN1218-41

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.516836	6.806072	7.322934	4.01E6	0.075941	0.070582	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	163.743277	2.706092	158.4394	169.0471	4.01E6	160.857004	166.449499

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	60.51	<.0001

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9PL Parameter=PPG lunch (SMPG) (mmol/L) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.001227	0.017549	0.018775	4.68E6	0.069907	0.065340	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	8.895357	0.137024	8.626796	9.163919	4.68E6	8.747521	9.033836

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	64.92	<.0001

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9PLC Parameter=PPG lunch (SMPG) (mg/dL) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.398340	5.698410	6.096770	4.68E6	0.069907	0.065340	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	160.294342	2.469164	155.4549	165.1338	4.68E6	157.630324	162.789728

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	64.92	<.0001

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9PPRAN Parameter=PPG all meals (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000823	0.010277	0.011099	3.64E6	0.080051	0.074118	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	8.992025	0.105353	8.785536	9.198514	3.64E6	8.876311	9.101922

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	85.35	<.0001

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 1878 of 4425	Novo Nordisk
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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9PPRANC Parameter=PPG all meals (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.267121	3.337044	3.604178	3.64E6	0.080051	0.074118	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	162.036296	1.898467	158.3154	165.7572	3.64E6	159.951117	164.016631

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	85.35	<.0001

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9PB Parameter=PPG breakfast (SMPG) (mmol/L) Study Identifier=NN1218-413

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.001143	0.020621	0.021764	7.25E6	0.055432	0.052521	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits	DF	Minimum	Maximum
Estimate	9.784350	0.147528	9.495200 10.07350	7.25E6	9.639444	9.927927

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	66.32	<.0001

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9PEV Parameter=PPG main evening meal (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.001007	0.021732	0.022739	1.02E7	0.046330	0.044279	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	9.644798	0.150795	9.349245	9.940352	1.02E7	9.521830	9.772058

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	63.96	<.0001

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9PEVC Parameter=PPG main evening meal (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.326935	7.056934	7.383885	1.02E7	0.046330	0.044279	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	173.799266	2.717331	168.4734	179.1251	1.02E7	171.583379	176.092489

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	63.96	<.0001

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9PGBC Parameter=PPG breakfast (SMPG) (mg/dL) Study Identifier=NN1218-41

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.371162	6.696180	7.067361	7.25E6	0.055432	0.052521	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	176.313980	2.658451	171.1035	181.5244	7.25E6	173.702788	178.901242

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	66.32	<.0001

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Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 1883 of 4425	Novo Nordisk
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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9PL Parameter=PPG lunch (SMPG) (mmol/L) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000878	0.017480	0.018358	8.75E6	0.050216	0.047815	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	9.382370	0.135493	9.116810	9.647931	8.75E6	9.260969	9.503523

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	69.25	<.0001

nn1218/nn1218-4131/ctr_20180214_er
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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9PLC Parameter=PPG lunch (SMPG) (mg/dL) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.285023	5.676271	5.961309	8.75E6	0.050216	0.047815	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	169.070316	2.441579	164.2849	173.8557	8.75E6	166.882658	171.253477

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	69.25	<.0001

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Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 1885 of 4425	Novo Nordisk
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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9PPRAN Parameter=PPG all meals (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000480	0.010233	0.010713	9.96E6	0.046901	0.044800	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	9.585442	0.103501	9.382583	9.788300	9.96E6	9.497293	9.680590

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	92.61	<.0001

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9PPRANC Parameter=PPG all meals (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.155833	3.322727	3.478568	9.96E6	0.046901	0.044800	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	172.729661	1.865092	169.0741	176.3852	9.96E6	171.141215	174.444239

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	92.61	<.0001

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9PB Parameter=PPG breakfast (SMPG) (mmol/L) Study Identifier=NN1218-413

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.001254	0.020753	0.022007	6.16E6	0.060411	0.056970	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	9.401019	0.148347	9.110265	9.691773	6.16E6	9.236994	9.550347

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	63.37	<.0001

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9PEV Parameter=PPG main evening meal (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.001249	0.021651	0.022899	6.72E6	0.057683	0.054537	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	9.226726	0.151326	8.930134	9.523319	6.72E6	9.096363	9.390314

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	60.97	<.0001

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9PEVC Parameter=PPG main evening meal (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.405513	7.030383	7.435917	6.72E6	0.057683	0.054537	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	166.265610	2.726888	160.9210	171.6102	6.72E6	163.916458	169.213461

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	60.97	<.0001

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9PGBC Parameter=PPG breakfast (SMPG) (mg/dL) Study Identifier=NN1218-41

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.407086	6.738929	7.146035	6.16E6	0.060411	0.056970	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	169.406367	2.673207	164.1670	174.6458	6.16E6	166.450630	172.097249

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	63.37	<.0001

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9PL Parameter=PPG lunch (SMPG) (mmol/L) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.001363	0.017418	0.018781	3.8E6	0.078242	0.072565	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	9.085564	0.137042	8.816966	9.354162	3.8E6	8.918213	9.231003

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	66.30	<.0001

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9PLC Parameter=PPG lunch (SMPG) (mg/dL) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.442508	5.655925	6.098455	3.8E6	0.078242	0.072565	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	163.721863	2.469505	158.8817	168.5620	3.8E6	160.706206	166.342668

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	66.30	<.0001

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9PPRAN Parameter=PPG all meals (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000793	0.010141	0.010934	3.8E6	0.078248	0.072570	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	9.240917	0.104567	9.035969	9.445866	3.8E6	9.128923	9.358073

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	88.37	<.0001

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- in-trial - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9PPRANC Parameter=PPG all meals (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.257652	3.292942	3.550607	3.8E6	0.078248	0.072570	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	166.521332	1.884305	162.8282	170.2145	3.8E6	164.503194	168.632484

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	88.37	<.0001

23: Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=P9PPRANC Planned Treatment for Period 30 (N)=2

Obs	PARAM	Description	Value
1	PPG all meals (SMPG) (mg/dL)	Data Set	WORK.ENDPOINT_PARAM
2	PPG all meals (SMPG) (mg/dL)	Method	Monotone-data_MCMC
3	PPG all meals (SMPG) (mg/dL)	Multiple Imputation Chain	Multiple Chains
4	PPG all meals (SMPG) (mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
5	PPG all meals (SMPG) (mg/dL)	Start	Starting Value
6	PPG all meals (SMPG) (mg/dL)	Prior	Jeffreys
7	PPG all meals (SMPG) (mg/dL)	Number of Imputations	20000
8	PPG all meals (SMPG) (mg/dL)	Number of Burn-in Iterations	200
9	PPG all meals (SMPG) (mg/dL)	Seed for random number generator	1234

Parameter Code=P9PPRANC Planned Treatment for Period 30 (N)=3

Obs	PARAM	Description	Value
10	PPG all meals (SMPG) (mg/dL)	Data Set	WORK.ENDPOINT_PARAM
11	PPG all meals (SMPG) (mg/dL)	Method	Monotone-data_MCMC
12	PPG all meals (SMPG) (mg/dL)	Multiple Imputation Chain	Multiple Chains
13	PPG all meals (SMPG) (mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
14	PPG all meals (SMPG) (mg/dL)	Start	Starting Value
15	PPG all meals (SMPG) (mg/dL)	Prior	Jeffreys
16	PPG all meals (SMPG) (mg/dL)	Number of Imputations	20000
17	PPG all meals (SMPG) (mg/dL)	Number of Burn-in Iterations	200
18	PPG all meals (SMPG) (mg/dL)	Seed for random number generator	678716107

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=P9PPRANC Planned Treatment for Period 30 (N)=4

Obs	PARAM	Description	Value
19	PPG all meals (SMPG) (mg/dL)	Data Set	WORK.ENDPOINT_PARAM
20	PPG all meals (SMPG) (mg/dL)	Method	Monotone-data_MCMC
21	PPG all meals (SMPG) (mg/dL)	Multiple Imputation Chain	Multiple Chains
22	PPG all meals (SMPG) (mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
23	PPG all meals (SMPG) (mg/dL)	Start	Starting Value
24	PPG all meals (SMPG) (mg/dL)	Prior	Jeffreys
25	PPG all meals (SMPG) (mg/dL)	Number of Imputations	20000
26	PPG all meals (SMPG) (mg/dL)	Number of Burn-in Iterations	200
27	PPG all meals (SMPG) (mg/dL)	Seed for random number generator	91941876

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

The MI Procedure with MCMC
Missing data pattern

Parameter Code=P9PPRANC Planned Treatment for Period 30 (N)=2

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
1	PPG all meals (SMPG) (mg/dL)	1	X	X	X	283	87.35	173.076005	-12.165708	-11.047510
2	PPG all meals (SMPG) (mg/dL)	2	X	X	O	14	4.32	154.773381	11.259714	.
3	PPG all meals (SMPG) (mg/dL)	3	X	.	X	15	4.63	195.130237	.	-34.589504
4	PPG all meals (SMPG) (mg/dL)	4	X	O	O	12	3.70	150.047148	.	.

Parameter Code=P9PPRANC Planned Treatment for Period 30 (N)=3

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
5	PPG all meals (SMPG) (mg/dL)	1	X	X	X	292	89.85	175.183303	0.033396	-1.419452
6	PPG all meals (SMPG) (mg/dL)	2	X	X	O	11	3.38	160.448505	13.192455	.
7	PPG all meals (SMPG) (mg/dL)	3	X	.	X	15	4.62	161.762963	.	19.712993
8	PPG all meals (SMPG) (mg/dL)	4	X	O	O	7	2.15	161.645794	.	.

Parameter Code=P9PPRANC Planned Treatment for Period 30 (N)=4

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
9	PPG all meals (SMPG) (mg/dL)	1	X	X	X	285	86.89	171.876362	-1.707520	-5.623372
10	PPG all meals (SMPG) (mg/dL)	2	X	X	O	13	3.96	166.480017	9.560915	.
11	PPG all meals (SMPG) (mg/dL)	3	X	.	X	15	4.57	169.812830	.	-2.725867
12	PPG all meals (SMPG) (mg/dL)	4	X	O	O	15	4.57	164.681615	.	.

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PPRANC Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG all meals (SMPG) (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG all meals (SMPG) (mg/dL)	Method	Monotone
3	1	PPG all meals (SMPG) (mg/dL)	Number of Imputations	1
4	1	PPG all meals (SMPG) (mg/dL)	Seed for random number generator	4321

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression Missing Data Pattern

Parameter Code=P9PPRANC Planned Treatment for Period 30 (N)=2

Obs	I	m	p	u	t	a	t	i	o	n	P	A	R	A	M	G	r	o	u	p	R	E	G	I	O	N	1	B	O	L	A	A	S	E	0	0	F	r	e	q	P	e	r	c	e	n	t	B	A	S	E	-13.365598	-12.232510																																														
																																																						1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46
1	1	PPG	all	meals	(SMPG)	(mg/dL)	1	X	X	X	X	X	X	X	X	298	91.98	174.186118	-13.365598	-12.232510																																																																															
2	1	PPG	all	meals	(SMPG)	(mg/dL)	2	X	X	X	X	X	.	.	.	14	4.32	154.773381	11.259714	.																																																																															
3	1	PPG	all	meals	(SMPG)	(mg/dL)	3	X	X	X	12	3.70	150.047148	.	.																																																																															

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PPRANC Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG all meals (SMPG) (mg/dL)	Intercept	
2	1	PPG all meals (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG all meals (SMPG) (mg/dL)	REGION1	EUROPE
4	1	PPG all meals (SMPG) (mg/dL)	REGION1	JAPAN
5	1	PPG all meals (SMPG) (mg/dL)	BOLAD1	
6	1	PPG all meals (SMPG) (mg/dL)	BASE	

Obs		BOLAD1	ObsVal	_1
1			-0.00497	0.026892
2			-0.18600	-0.156976
3			0.02007	-0.108003
4			0.04481	0.028395
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.06516	-0.113368
6			-0.62492	-0.661967

Parameter Code=P9PPRANC Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	PPG all meals (SMPG) (mg/dL)	Intercept			0.00617	0.059117
8	1	PPG all meals (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)		-0.22282	-0.374664
9	1	PPG all meals (SMPG) (mg/dL)	REGION1	EUROPE		-0.05427	-0.030792

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression Regression Information

Parameter Code=P9PPRANC Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

(continued)

	O	b	s	-	P A R A M	E f f e c t	R E G I O N 1	B O L A D 1	O b s V a l	I
10	1	PPG	all	meals	(SMPG)	(mg/dL)	REGION1	JAPAN	0.16007	0.338763
11	1	PPG	all	meals	(SMPG)	(mg/dL)	BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.02153	0.011875
12	1	PPG	all	meals	(SMPG)	(mg/dL)	BASE		-0.35798	-0.384759
13	1	PPG	all	meals	(SMPG)	(mg/dL)	visit2200		0.39603	0.423057

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PPRANC Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG all meals (SMPG) (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG all meals (SMPG) (mg/dL)	Method	Monotone
3	1	PPG all meals (SMPG) (mg/dL)	Number of Imputations	1
4	1	PPG all meals (SMPG) (mg/dL)	Seed for random number generator	4322

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=P9PPRANC Planned Treatment for Period 30 (N)=3

O b s	I m p u t a t i o n _	P A R A M	G r o u p	R E G I O N 1	E B O L A 1	B O L A 1	B O L A 1	B O L A 1	B O L A 1	F r e q	P e r c e n t	B A S E	v i s i t 2 2 0	v i s i t 3 6 0 0
1	1	PPG all meals (SMPG) (mg/dL)	1	X	X	X	X	X	X	307	94.46	174.527586	0.708337	-0.386922
2	1	PPG all meals (SMPG) (mg/dL)	2	X	X	X	X	X	.	11	3.38	160.448505	13.192455	.
3	1	PPG all meals (SMPG) (mg/dL)	3	X	X	X	.	.	.	7	2.15	161.645794	.	.

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- on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PPRANC Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG all meals (SMPG) (mg/dL)	Intercept	
2	1	PPG all meals (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG all meals (SMPG) (mg/dL)	REGION1	EUROPE
4	1	PPG all meals (SMPG) (mg/dL)	REGION1	JAPAN
5	1	PPG all meals (SMPG) (mg/dL)	BOLAD1	
6	1	PPG all meals (SMPG) (mg/dL)	BASE	

Obs		BOLAD1	ObsVal	_1
1			0.03726	0.140334
2			0.00761	0.142633
3			-0.17936	-0.176678
4			0.29663	0.200363
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.18298	-0.153833
6			-0.45382	-0.493964

Parameter Code=P9PPRANC Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	PPG all meals (SMPG) (mg/dL)	Intercept			-0.00461	-0.013231
8	1	PPG all meals (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)		-0.20949	-0.257018
9	1	PPG all meals (SMPG) (mg/dL)	REGION1	EUROPE		-0.07736	-0.117478

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression Regression Information

Parameter Code=P9PPRANC Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

(continued)

	O	b	s	-	P A R A M	E f f e c t	R E G I O N 1	B O L A D 1	O b s V a l	I
10	1	PPG	all	meals	(SMPG)	(mg/dL)	REGION1	JAPAN	0.24686	0.356345
11	1	PPG	all	meals	(SMPG)	(mg/dL)	BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.09299	-0.118548
12	1	PPG	all	meals	(SMPG)	(mg/dL)	BASE		-0.33616	-0.330864
13	1	PPG	all	meals	(SMPG)	(mg/dL)	visit2200		0.46662	0.405933

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PPRANC Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG all meals (SMPG) (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG all meals (SMPG) (mg/dL)	Method	Monotone
3	1	PPG all meals (SMPG) (mg/dL)	Number of Imputations	1
4	1	PPG all meals (SMPG) (mg/dL)	Seed for random number generator	4323

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=P9PPRANC Planned Treatment for Period 30 (N)=4

O b s	I m p u t a t i o n _	P A R A M	G r o u p	R E G I O N 1	E B O L A 1	B O L A 1	B O L A 1	B O L A 1	B O L A 1	F r e q	P e r c e n t	B A S E	v i s i t 2 2 0	v i s i t 3 6 0 0
1	1	PPG all meals (SMPG) (mg/dL)	1	X	X	X	X	X	X	300	91.46	171.773186	-1.451859	-5.478497
2	1	PPG all meals (SMPG) (mg/dL)	2	X	X	X	X	X	.	13	3.96	166.480017	9.560915	.
3	1	PPG all meals (SMPG) (mg/dL)	3	X	X	X	.	.	.	15	4.57	164.681615	.	.

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- on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PPRANC Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG all meals (SMPG) (mg/dL)	Intercept	
2	1	PPG all meals (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG all meals (SMPG) (mg/dL)	REGION1	EUROPE
4	1	PPG all meals (SMPG) (mg/dL)	REGION1	JAPAN
5	1	PPG all meals (SMPG) (mg/dL)	BOLAD1	
6	1	PPG all meals (SMPG) (mg/dL)	BASE	

Obs	BOLAD1	ObsVal	_1
1		0.03575	-0.006835
2		-0.04021	0.008803
3		-0.17365	-0.281280
4		0.28308	0.322300
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.14887	-0.154772
6		-0.65878	-0.736448

Parameter Code=P9PPRANC Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	PPG all meals (SMPG) (mg/dL)	Intercept			0.04302	0.089309
8	1	PPG all meals (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)		0.10102	0.126073
9	1	PPG all meals (SMPG) (mg/dL)	REGION1	EUROPE		-0.18823	-0.112016

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- on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PPRANC Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

(continued)

		I m p u t a t i o n s		P A R A M		E f f e c t		R E G I O N 1		B O L A D 1		O b s e r v e d		I	
10	1	PPG	all	meals	(SMPG)	(mg/dL)	REGION1	JAPAN				0.18059	-0.003572		
11	1	PPG	all	meals	(SMPG)	(mg/dL)	BOLAD1		BOLUS	INSULIN	ALGORITHM (SLIDING SCALE)	-0.09059	-0.094539		
12	1	PPG	all	meals	(SMPG)	(mg/dL)	BASE					-0.38867	-0.487191		
13	1	PPG	all	meals	(SMPG)	(mg/dL)	visit2200					0.39062	0.284189		

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=P9PPRAN Planned Treatment for Period 30 (N)=2

Obs	PARAM	Description	Value
1	PPG all meals (SMPG) (mmol/L)	Data Set	WORK.ENDPOINT_PARAM
2	PPG all meals (SMPG) (mmol/L)	Method	Monotone-data_MCMC
3	PPG all meals (SMPG) (mmol/L)	Multiple Imputation Chain	Multiple Chains
4	PPG all meals (SMPG) (mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
5	PPG all meals (SMPG) (mmol/L)	Start	Starting Value
6	PPG all meals (SMPG) (mmol/L)	Prior	Jeffreys
7	PPG all meals (SMPG) (mmol/L)	Number of Imputations	20000
8	PPG all meals (SMPG) (mmol/L)	Number of Burn-in Iterations	200
9	PPG all meals (SMPG) (mmol/L)	Seed for random number generator	1234

Parameter Code=P9PPRAN Planned Treatment for Period 30 (N)=3

Obs	PARAM	Description	Value
10	PPG all meals (SMPG) (mmol/L)	Data Set	WORK.ENDPOINT_PARAM
11	PPG all meals (SMPG) (mmol/L)	Method	Monotone-data_MCMC
12	PPG all meals (SMPG) (mmol/L)	Multiple Imputation Chain	Multiple Chains
13	PPG all meals (SMPG) (mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
14	PPG all meals (SMPG) (mmol/L)	Start	Starting Value
15	PPG all meals (SMPG) (mmol/L)	Prior	Jeffreys
16	PPG all meals (SMPG) (mmol/L)	Number of Imputations	20000
17	PPG all meals (SMPG) (mmol/L)	Number of Burn-in Iterations	200
18	PPG all meals (SMPG) (mmol/L)	Seed for random number generator	678716107

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=P9PPRAN Planned Treatment for Period 30 (N)=4

Obs	PARAM	Description	Value
19	PPG all meals (SMPG) (mmol/L)	Data Set	WORK.ENDPOINT_PARAM
20	PPG all meals (SMPG) (mmol/L)	Method	Monotone-data_MCMC
21	PPG all meals (SMPG) (mmol/L)	Multiple Imputation Chain	Multiple Chains
22	PPG all meals (SMPG) (mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
23	PPG all meals (SMPG) (mmol/L)	Start	Starting Value
24	PPG all meals (SMPG) (mmol/L)	Prior	Jeffreys
25	PPG all meals (SMPG) (mmol/L)	Number of Imputations	20000
26	PPG all meals (SMPG) (mmol/L)	Number of Burn-in Iterations	200
27	PPG all meals (SMPG) (mmol/L)	Seed for random number generator	91941876

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- on-treatment - full analysis set

The MI Procedure with MCMC
Missing data pattern

Parameter Code=P9PPRAN Planned Treatment for Period 30 (N)=2

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
1	PPG all meals (SMPG) (mmol/L)	1	X	X	X	283	87.35	9.604662	-0.675123	-0.613069
2	PPG all meals (SMPG) (mmol/L)	2	X	X	O	14	4.32	8.588978	0.624845	.
3	PPG all meals (SMPG) (mmol/L)	3	X	.	X	15	4.63	10.828537	.	-1.919506
4	PPG all meals (SMPG) (mmol/L)	4	X	O	O	12	3.70	8.326701	.	.

Parameter Code=P9PPRAN Planned Treatment for Period 30 (N)=3

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
5	PPG all meals (SMPG) (mmol/L)	1	X	X	X	292	89.85	9.721604	0.001853	-0.078771
6	PPG all meals (SMPG) (mmol/L)	2	X	X	O	11	3.38	8.903913	0.732101	.
7	PPG all meals (SMPG) (mmol/L)	3	X	.	X	15	4.62	8.976857	.	1.093951
8	PPG all meals (SMPG) (mmol/L)	4	X	O	O	7	2.15	8.970355	.	.

Parameter Code=P9PPRAN Planned Treatment for Period 30 (N)=4

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
9	PPG all meals (SMPG) (mmol/L)	1	X	X	X	285	86.89	9.538089	-0.094757	-0.312063
10	PPG all meals (SMPG) (mmol/L)	2	X	X	O	13	3.96	9.238625	0.530572	.
11	PPG all meals (SMPG) (mmol/L)	3	X	.	X	15	4.57	9.423575	.	-0.151269
12	PPG all meals (SMPG) (mmol/L)	4	X	O	O	15	4.57	9.138824	.	.

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- on-treatment - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PPRAN Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG all meals (SMPG) (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG all meals (SMPG) (mmol/L)	Method	Monotone
3	1	PPG all meals (SMPG) (mmol/L)	Number of Imputations	1
4	1	PPG all meals (SMPG) (mmol/L)	Seed for random number generator	4321

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=P9PPRAN Planned Treatment for Period 30 (N)=2

O b s	I m p u t a t i o n _	P A R A M	G r o u p	R E G I O N 1	E B O L A D 1	B O L A D 1	B O L A D 1	B O L A D 1	B O L A D 1	F r e q	P e r c e n t	B A S E	v i s i t 2 2 0 0	v i s i t 3 6 0 0
1	1	PPG all meals (SMPG) (mmol/L)	1	X	X	X	X	X	X	298	91.98	9.666266	-0.741709	-0.678830
2	1	PPG all meals (SMPG) (mmol/L)	2	X	X	X	X	X	.	14	4.32	8.588978	0.624845	.
3	1	PPG all meals (SMPG) (mmol/L)	3	X	X	X	.	.	.	12	3.70	8.326701	.	.

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PPRAN Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG all meals (SMPG) (mmol/L)	Intercept	
2	1	PPG all meals (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG all meals (SMPG) (mmol/L)	REGION1	EUROPE
4	1	PPG all meals (SMPG) (mmol/L)	REGION1	JAPAN
5	1	PPG all meals (SMPG) (mmol/L)	BOLAD1	
6	1	PPG all meals (SMPG) (mmol/L)	BASE	

Obs	BOLAD1	ObsVal	_1
1		-0.00497	0.026892
2		-0.18600	-0.156976
3		0.02007	-0.108003
4		0.04481	0.028395
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.06516	-0.113368
6		-0.62492	-0.661967

Parameter Code=P9PPRAN Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	PPG all meals (SMPG) (mmol/L)	Intercept			0.00617	0.059117
8	1	PPG all meals (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)		-0.22282	-0.374664
9	1	PPG all meals (SMPG) (mmol/L)	REGION1	EUROPE		-0.05427	-0.030792

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression Regression Information

Parameter Code=P9PPRAN Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

(continued)

	O	b	s	P A R A M	E f f e c t	R E G I O N l	B O L U S D l	O b s V a l	I
10	1	PPG	all	meals	(SMPG)	(mmol/L)	REGION1 JAPAN	0.16007	0.338763
11	1	PPG	all	meals	(SMPG)	(mmol/L)	BOLAD1 BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.02153	0.011875
12	1	PPG	all	meals	(SMPG)	(mmol/L)	BASE	-0.35798	-0.384759
13	1	PPG	all	meals	(SMPG)	(mmol/L)	visit2200	0.39603	0.423057

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PPRAN Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG all meals (SMPG) (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG all meals (SMPG) (mmol/L)	Method	Monotone
3	1	PPG all meals (SMPG) (mmol/L)	Number of Imputations	1
4	1	PPG all meals (SMPG) (mmol/L)	Seed for random number generator	4322

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression Missing Data Pattern

Parameter Code=P9PPRAN Planned Treatment for Period 30 (N)=3

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- on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PPRAN Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG all meals (SMPG) (mmol/L)	Intercept	
2	1	PPG all meals (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG all meals (SMPG) (mmol/L)	REGION1	EUROPE
4	1	PPG all meals (SMPG) (mmol/L)	REGION1	JAPAN
5	1	PPG all meals (SMPG) (mmol/L)	BOLAD1	
6	1	PPG all meals (SMPG) (mmol/L)	BASE	

Obs	BOLAD1	ObsVal	_1
1		0.03726	0.140334
2		0.00761	0.142633
3		-0.17936	-0.176678
4		0.29663	0.200363
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.18298	-0.153833
6		-0.45382	-0.493964

Parameter Code=P9PPRAN Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	PPG all meals (SMPG) (mmol/L)	Intercept			-0.00461	-0.013231
8	1	PPG all meals (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)		-0.20949	-0.257018
9	1	PPG all meals (SMPG) (mmol/L)	REGION1	EUROPE		-0.07736	-0.117478

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The MI Procedure with Monotone Regression Regression Information

Parameter Code=P9PPRAN Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

(continued)

O	b	s			P A R A M	E f f e c t	R E G I O N 1	B O L U S D 1	O b s V a l	I
10	1	PPG	all	meals	(SMPG)	(mmol/L)	REGION1	JAPAN	0.24686	0.356345
11	1	PPG	all	meals	(SMPG)	(mmol/L)	BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.09299	-0.118548
12	1	PPG	all	meals	(SMPG)	(mmol/L)	BASE		-0.33616	-0.330864
13	1	PPG	all	meals	(SMPG)	(mmol/L)	visit2200		0.46662	0.405933

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PPRAN Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG all meals (SMPG) (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG all meals (SMPG) (mmol/L)	Method	Monotone
3	1	PPG all meals (SMPG) (mmol/L)	Number of Imputations	1
4	1	PPG all meals (SMPG) (mmol/L)	Seed for random number generator	4323

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- on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PPRAN Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG all meals (SMPG) (mmol/L)	Intercept	
2	1	PPG all meals (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG all meals (SMPG) (mmol/L)	REGION1	EUROPE
4	1	PPG all meals (SMPG) (mmol/L)	REGION1	JAPAN
5	1	PPG all meals (SMPG) (mmol/L)	BOLAD1	
6	1	PPG all meals (SMPG) (mmol/L)	BASE	

Obs	BOLAD1	ObsVal	_1
1		0.03575	-0.006835
2		-0.04021	0.008803
3		-0.17365	-0.281280
4		0.28308	0.322300
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.14887	-0.154772
6		-0.65878	-0.736448

Parameter Code=P9PPRAN Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	PPG all meals (SMPG) (mmol/L)	Intercept			0.04302	0.089309
8	1	PPG all meals (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)		0.10102	0.126073
9	1	PPG all meals (SMPG) (mmol/L)	REGION1	EUROPE		-0.18823	-0.112016

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The MI Procedure with Monotone Regression Regression Information

Parameter Code=P9PPRAN Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

(continued)

	O	b	s	—	P A R A M	E f f e c t	R E G I O N 1	B O L A D 1	O b s V a l	I
10	1	PPG	all	meals	(SMPG)	(mmol/L)	REGION1	JAPAN	0.18059	-0.003572
11	1	PPG	all	meals	(SMPG)	(mmol/L)	BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.09059	-0.094539
12	1	PPG	all	meals	(SMPG)	(mmol/L)	BASE		-0.38867	-0.487191
13	1	PPG	all	meals	(SMPG)	(mmol/L)	visit2200		0.39062	0.284189

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=P9PGBC Planned Treatment for Period 30 (N)=2

Obs	PARAM	Description	Value
1	PPG breakfast (SMPG) (mg/dL)	Data Set	WORK.ENDPOINT_PARAM
2	PPG breakfast (SMPG) (mg/dL)	Method	Monotone-data_MCMC
3	PPG breakfast (SMPG) (mg/dL)	Multiple Imputation Chain	Multiple Chains
4	PPG breakfast (SMPG) (mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
5	PPG breakfast (SMPG) (mg/dL)	Start	Starting Value
6	PPG breakfast (SMPG) (mg/dL)	Prior	Jeffreys
7	PPG breakfast (SMPG) (mg/dL)	Number of Imputations	20000
8	PPG breakfast (SMPG) (mg/dL)	Number of Burn-in Iterations	200
9	PPG breakfast (SMPG) (mg/dL)	Seed for random number generator	1234

Parameter Code=P9PGBC Planned Treatment for Period 30 (N)=3

Obs	PARAM	Description	Value
10	PPG breakfast (SMPG) (mg/dL)	Data Set	WORK.ENDPOINT_PARAM
11	PPG breakfast (SMPG) (mg/dL)	Method	Monotone-data_MCMC
12	PPG breakfast (SMPG) (mg/dL)	Multiple Imputation Chain	Multiple Chains
13	PPG breakfast (SMPG) (mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
14	PPG breakfast (SMPG) (mg/dL)	Start	Starting Value
15	PPG breakfast (SMPG) (mg/dL)	Prior	Jeffreys
16	PPG breakfast (SMPG) (mg/dL)	Number of Imputations	20000
17	PPG breakfast (SMPG) (mg/dL)	Number of Burn-in Iterations	200
18	PPG breakfast (SMPG) (mg/dL)	Seed for random number generator	2011936378

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=P9PGBC Planned Treatment for Period 30 (N)=4

Obs	PARAM	Description	Value
19	PPG breakfast (SMPG) (mg/dL)	Data Set	WORK.ENDPOINT_PARAM
20	PPG breakfast (SMPG) (mg/dL)	Method	Monotone-data_MCMC
21	PPG breakfast (SMPG) (mg/dL)	Multiple Imputation Chain	Multiple Chains
22	PPG breakfast (SMPG) (mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
23	PPG breakfast (SMPG) (mg/dL)	Start	Starting Value
24	PPG breakfast (SMPG) (mg/dL)	Prior	Jeffreys
25	PPG breakfast (SMPG) (mg/dL)	Number of Imputations	20000
26	PPG breakfast (SMPG) (mg/dL)	Number of Burn-in Iterations	200
27	PPG breakfast (SMPG) (mg/dL)	Seed for random number generator	1131914702

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- on-treatment - full analysis set

The MI Procedure with MCMC
Missing data pattern

Parameter Code=P9PGBC Planned Treatment for Period 30 (N)=2

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
1	PPG breakfast (SMPG) (mg/dL)	1	X	X	X	290	88.96	178.619374	-11.873375	-13.584939
2	PPG breakfast (SMPG) (mg/dL)	2	X	X	O	11	3.37	154.285515	2.466667	.
3	PPG breakfast (SMPG) (mg/dL)	3	X	.	X	13	3.99	204.046718	.	-54.380538
4	PPG breakfast (SMPG) (mg/dL)	4	X	O	O	12	3.68	136.803528	.	.

Parameter Code=P9PGBC Planned Treatment for Period 30 (N)=3

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
5	PPG breakfast (SMPG) (mg/dL)	1	X	X	X	299	90.33	178.841667	-1.898360	-1.368561
6	PPG breakfast (SMPG) (mg/dL)	2	X	X	O	13	3.93	174.250513	-1.669538	.
7	PPG breakfast (SMPG) (mg/dL)	3	X	.	X	14	4.23	155.884286	.	19.793262
8	PPG breakfast (SMPG) (mg/dL)	4	X	O	O	5	1.51	193.201467	.	.

Parameter Code=P9PGBC Planned Treatment for Period 30 (N)=4

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
9	PPG breakfast (SMPG) (mg/dL)	1	X	X	X	291	88.45	177.936576	-0.498795	-8.212001
10	PPG breakfast (SMPG) (mg/dL)	2	X	X	O	11	3.34	151.848909	3.915121	.
11	PPG breakfast (SMPG) (mg/dL)	3	X	.	X	12	3.65	141.885139	.	21.579694
12	PPG breakfast (SMPG) (mg/dL)	4	X	O	O	15	4.56	152.173378	.	.

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PGBC Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG breakfast (SMPG) (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG breakfast (SMPG) (mg/dL)	Method	Monotone
3	1	PPG breakfast (SMPG) (mg/dL)	Number of Imputations	1
4	1	PPG breakfast (SMPG) (mg/dL)	Seed for random number generator	4321

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- on-treatment - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=P9PGBC Planned Treatment for Period 30 (N)=2

O b s	I m p u t a t i o n _	P A R A M	G r o u p	R E G I O N 1	E B O L A 1	B O L A 1	B O L A 1	B O L A 1	B O L A 1	F r e q	P e r c e n t	B A S E	v i s i t 2 2 0	v i s i t 3 6 0
1	1	PPG breakfast (SMPG) (mg/dL)	1	X	X	X	X	X	X	303	92.94	179.710316	-12.969169	-15.335245
2	1	PPG breakfast (SMPG) (mg/dL)	2	X	X	X	X	X	.	11	3.37	154.285515	2.466667	.
3	1	PPG breakfast (SMPG) (mg/dL)	3	X	X	X	.	.	.	12	3.68	136.803528	.	.

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGBC Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG breakfast (SMPG) (mg/dL)	Intercept	
2	1	PPG breakfast (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG breakfast (SMPG) (mg/dL)	REGION1	EUROPE
4	1	PPG breakfast (SMPG) (mg/dL)	REGION1	JAPAN
5	1	PPG breakfast (SMPG) (mg/dL)	BOLAD1	
6	1	PPG breakfast (SMPG) (mg/dL)	BASE	

Obs	BOLAD1	ObsVal	_1
1		0.01418	0.045573
2		-0.08695	-0.058089
3		-0.09031	-0.214825
4		0.00764	-0.013229
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.02966	-0.077232
6		-0.64809	-0.686395

Parameter Code=P9PGBC Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	PPG breakfast (SMPG) (mg/dL)	Intercept			0.01834	0.072670
8	1	PPG breakfast (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)		-0.18769	-0.343924
9	1	PPG breakfast (SMPG) (mg/dL)	REGION1	EUROPE		-0.06165	-0.036074

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression Regression Information

Parameter Code=P9PGBC Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

(continued)

	O	b	s	-	P A R A M	E f f e c t	R E G I O N 1	B O L A D 1	O b s V a l	I
10	1	PPG breakfast	(SMPG)	(mg/dL)	REGION1	JAPAN			0.24814	0.428546
11	1	PPG breakfast	(SMPG)	(mg/dL)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.05785	-0.023182
12	1	PPG breakfast	(SMPG)	(mg/dL)	BASE				-0.42487	-0.443024
13	1	PPG breakfast	(SMPG)	(mg/dL)	visit2200				0.28737	0.318126

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PGBC Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG breakfast (SMPG) (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG breakfast (SMPG) (mg/dL)	Method	Monotone
3	1	PPG breakfast (SMPG) (mg/dL)	Number of Imputations	1
4	1	PPG breakfast (SMPG) (mg/dL)	Seed for random number generator	4322

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression Missing Data Pattern

Parameter Code=P9PGBC Planned Treatment for Period 30 (N)=3

Obs	I m p u t a t i o n _	P A R A M	G r o u p	R E G I O N 1 B O L A D S 1 B A S E M M M M M					F r e q	P e r c e n t	B A S E	v i s i t 2 0 0	v i s i t 3 6 0 0	
				X	X	X	X	X						
1	1	PPG breakfast (SMPG)	(mg/dL)	1	X	X	X	X	X	313	94.56	177.814819	-0.869089	-0.422026
2	1	PPG breakfast (SMPG)	(mg/dL)	2	X	X	X	X	.	13	3.93	174.250513	-1.669538	.
3	1	PPG breakfast (SMPG)	(mg/dL)	3	X	X	X	.	.	5	1.51	193.201467	.	.

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- on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGBC Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG breakfast (SMPG) (mg/dL)	Intercept	
2	1	PPG breakfast (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG breakfast (SMPG) (mg/dL)	REGION1	EUROPE
4	1	PPG breakfast (SMPG) (mg/dL)	REGION1	JAPAN
5	1	PPG breakfast (SMPG) (mg/dL)	BOLAD1	
6	1	PPG breakfast (SMPG) (mg/dL)	BASE	

Obs		BOLAD1	ObsVal	_1
1			0.02767	0.121711
2			-0.03003	0.095222
3			-0.18567	-0.184113
4			0.39170	0.303749
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.17998	-0.153503
6			-0.57625	-0.612096

Parameter Code=P9PGBC Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	PPG breakfast (SMPG) (mg/dL)	Intercept			-0.00374	-0.066605
8	1	PPG breakfast (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)		-0.10474	-0.202050
9	1	PPG breakfast (SMPG) (mg/dL)	REGION1	EUROPE		-0.03221	-0.010476

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression Regression Information

Parameter Code=P9PGBC Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

(continued)

	O	b	s	-	P A R A M	E f f e c t	R E G I O N 1	B O L A D 1	O b s V a l	I
10	1	PPG breakfast	(SMPG)	(mg/dL)	REGION1	JAPAN			0.07132	0.068700
11	1	PPG breakfast	(SMPG)	(mg/dL)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.07950	-0.092570
12	1	PPG breakfast	(SMPG)	(mg/dL)	BASE				-0.32413	-0.259055
13	1	PPG breakfast	(SMPG)	(mg/dL)	visit2200				0.39470	0.403745

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PGBC Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG breakfast (SMPG) (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG breakfast (SMPG) (mg/dL)	Method	Monotone
3	1	PPG breakfast (SMPG) (mg/dL)	Number of Imputations	1
4	1	PPG breakfast (SMPG) (mg/dL)	Seed for random number generator	4323

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- on-treatment - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=P9PGBC Planned Treatment for Period 30 (N)=4

O b s	I m p u t a t i o n s	P A R A M	G r o u p	R E G I O N 1	E B O L A 1	B O L A 1	B O L A 1	B O L A 1	B O L A 1	F r e q	P e r c e n t	B A S E	v i s i t 2 0 0	v i s i t 3 6 0 0
1	1	PPG breakfast (SMPG) (mg/dL)	1	X	X	X	X	X	X	303	92.10	176.508796	0.176324	-7.032132
2	1	PPG breakfast (SMPG) (mg/dL)	2	X	X	X	X	X	.	11	3.34	151.848909	3.915121	.
3	1	PPG breakfast (SMPG) (mg/dL)	3	X	X	X	.	.	.	15	4.56	152.173378	.	.

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- on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGBC Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG breakfast (SMPG) (mg/dL)	Intercept	
2	1	PPG breakfast (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG breakfast (SMPG) (mg/dL)	REGION1	EUROPE
4	1	PPG breakfast (SMPG) (mg/dL)	REGION1	JAPAN
5	1	PPG breakfast (SMPG) (mg/dL)	BOLAD1	
6	1	PPG breakfast (SMPG) (mg/dL)	BASE	

Obs	BOLAD1	ObsVal	_1
1		0.03811	-0.005920
2		-0.03184	0.018616
3		-0.17205	-0.281892
4		0.25441	0.293200
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.10686	-0.112046
6		-0.61920	-0.692304

Parameter Code=P9PGBC Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	PPG breakfast (SMPG) (mg/dL)	Intercept			0.03703	0.082429
8	1	PPG breakfast (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)		0.03953	0.064243
9	1	PPG breakfast (SMPG) (mg/dL)	REGION1	EUROPE		-0.12649	-0.053323

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- on-treatment - full analysis set

The MI Procedure with Monotone Regression Regression Information

Parameter Code=P9PGBC Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

(continued)

	O	b	s	-	P A R A M	E f f e c t	R E G I O N 1	B O L A D 1	O b s V a l	I
10	1	PPG	breakfast	(SMPG)	(mg/dL)	REGION1	JAPAN		0.18925	0.012428
11	1	PPG	breakfast	(SMPG)	(mg/dL)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.05519	-0.062537
12	1	PPG	breakfast	(SMPG)	(mg/dL)	BASE			-0.43907	-0.543876
13	1	PPG	breakfast	(SMPG)	(mg/dL)	visit2200			0.35982	0.256064

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=P9PB Planned Treatment for Period 30 (N)=2

Obs	PARAM	Description	Value
1	PPG breakfast (SMPG) (mmol/L)	Data Set	WORK.ENDPOINT_PARAM
2	PPG breakfast (SMPG) (mmol/L)	Method	Monotone-data_MCMC
3	PPG breakfast (SMPG) (mmol/L)	Multiple Imputation Chain	Multiple Chains
4	PPG breakfast (SMPG) (mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
5	PPG breakfast (SMPG) (mmol/L)	Start	Starting Value
6	PPG breakfast (SMPG) (mmol/L)	Prior	Jeffreys
7	PPG breakfast (SMPG) (mmol/L)	Number of Imputations	20000
8	PPG breakfast (SMPG) (mmol/L)	Number of Burn-in Iterations	200
9	PPG breakfast (SMPG) (mmol/L)	Seed for random number generator	1234

Parameter Code=P9PB Planned Treatment for Period 30 (N)=3

Obs	PARAM	Description	Value
10	PPG breakfast (SMPG) (mmol/L)	Data Set	WORK.ENDPOINT_PARAM
11	PPG breakfast (SMPG) (mmol/L)	Method	Monotone-data_MCMC
12	PPG breakfast (SMPG) (mmol/L)	Multiple Imputation Chain	Multiple Chains
13	PPG breakfast (SMPG) (mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
14	PPG breakfast (SMPG) (mmol/L)	Start	Starting Value
15	PPG breakfast (SMPG) (mmol/L)	Prior	Jeffreys
16	PPG breakfast (SMPG) (mmol/L)	Number of Imputations	20000
17	PPG breakfast (SMPG) (mmol/L)	Number of Burn-in Iterations	200
18	PPG breakfast (SMPG) (mmol/L)	Seed for random number generator	2011936378

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=P9PB Planned Treatment for Period 30 (N)=4

Obs	PARAM	Description	Value
19	PPG breakfast (SMPG) (mmol/L)	Data Set	WORK.ENDPOINT_PARAM
20	PPG breakfast (SMPG) (mmol/L)	Method	Monotone-data_MCMC
21	PPG breakfast (SMPG) (mmol/L)	Multiple Imputation Chain	Multiple Chains
22	PPG breakfast (SMPG) (mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
23	PPG breakfast (SMPG) (mmol/L)	Start	Starting Value
24	PPG breakfast (SMPG) (mmol/L)	Prior	Jeffreys
25	PPG breakfast (SMPG) (mmol/L)	Number of Imputations	20000
26	PPG breakfast (SMPG) (mmol/L)	Number of Burn-in Iterations	200
27	PPG breakfast (SMPG) (mmol/L)	Seed for random number generator	1131914702

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- on-treatment - full analysis set

The MI Procedure with MCMC
Missing data pattern

Parameter Code=P9PB Planned Treatment for Period 30 (N)=2

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
1	PPG breakfast (SMPG) (mmol/L)	1	X	X	X	290	88.96	9.912285	-0.658900	-0.753881
2	PPG breakfast (SMPG) (mmol/L)	2	X	X	O	11	3.37	8.561904	0.136885	.
3	PPG breakfast (SMPG) (mmol/L)	3	X	.	X	13	3.99	11.323347	.	-3.017788
4	PPG breakfast (SMPG) (mmol/L)	4	X	O	O	12	3.68	7.591761	.	.

Parameter Code=P9PB Planned Treatment for Period 30 (N)=3

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
5	PPG breakfast (SMPG) (mmol/L)	1	X	X	X	299	90.33	9.924621	-0.105347	-0.075947
6	PPG breakfast (SMPG) (mmol/L)	2	X	X	O	13	3.93	9.669840	-0.092649	.
7	PPG breakfast (SMPG) (mmol/L)	3	X	.	X	14	4.23	8.650626	.	1.098405
8	PPG breakfast (SMPG) (mmol/L)	4	X	O	O	5	1.51	10.721502	.	.

Parameter Code=P9PB Planned Treatment for Period 30 (N)=4

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
9	PPG breakfast (SMPG) (mmol/L)	1	X	X	X	291	88.45	9.874394	-0.027680	-0.455716
10	PPG breakfast (SMPG) (mmol/L)	2	X	X	O	11	3.34	8.426688	0.217265	.
11	PPG breakfast (SMPG) (mmol/L)	3	X	.	X	12	3.65	7.873759	.	1.197541
12	PPG breakfast (SMPG) (mmol/L)	4	X	O	O	15	4.56	8.444694	.	.

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PB Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG breakfast (SMPG) (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG breakfast (SMPG) (mmol/L)	Method	Monotone
3	1	PPG breakfast (SMPG) (mmol/L)	Number of Imputations	1
4	1	PPG breakfast (SMPG) (mmol/L)	Seed for random number generator	4321

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression Missing Data Pattern

Parameter Code=P9PB Planned Treatment for Period 30 (N)=2

	O b s		I m p u t a t i o n _	P A R A M	G r o u p	R E G I O N 1	B O L A D 1	B A S E	v i s i t 2	v i s i t 3	F r e q	P e r c e n t	B A S E	v i s i t 2	v i s i t 3	
	1	1	PPG breakfast	(SMPG)	(mmol/L)	1	X	X	X	X	X	303	92.94	9.972826	-0.719710	-0.851013
	2	1	PPG breakfast	(SMPG)	(mmol/L)	2	X	X	X	X	.	11	3.37	8.561904	0.136885	.
	3	1	PPG breakfast	(SMPG)	(mmol/L)	3	X	X	X	.	.	12	3.68	7.591761	.	.

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PB Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG breakfast (SMPG) (mmol/L)	Intercept	
2	1	PPG breakfast (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG breakfast (SMPG) (mmol/L)	REGION1	EUROPE
4	1	PPG breakfast (SMPG) (mmol/L)	REGION1	JAPAN
5	1	PPG breakfast (SMPG) (mmol/L)	BOLAD1	
6	1	PPG breakfast (SMPG) (mmol/L)	BASE	

Obs	BOLAD1	ObsVal	_1
1		0.01418	0.045573
2		-0.08695	-0.058089
3		-0.09031	-0.214825
4		0.00764	-0.013229
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.02966	-0.077232
6		-0.64809	-0.686395

Parameter Code=P9PB Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	PPG breakfast (SMPG) (mmol/L)	Intercept			0.01834	0.072670
8	1	PPG breakfast (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)		-0.18769	-0.343924
9	1	PPG breakfast (SMPG) (mmol/L)	REGION1	EUROPE		-0.06165	-0.036074

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression Regression Information

Parameter Code=P9PB Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

(continued)

	O	b	s	-	P A R A M	E f f e c t	R E G I O N 1	B O L A D 1	O b s V a l	I
10	1	PPG	breakfast	(SMPG)	(mmol/L)	REGION1	JAPAN		0.24814	0.428546
11	1	PPG	breakfast	(SMPG)	(mmol/L)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.05785	-0.023182
12	1	PPG	breakfast	(SMPG)	(mmol/L)	BASE			-0.42487	-0.443024
13	1	PPG	breakfast	(SMPG)	(mmol/L)	visit2200			0.28737	0.318126

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PB Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG breakfast (SMPG) (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG breakfast (SMPG) (mmol/L)	Method	Monotone
3	1	PPG breakfast (SMPG) (mmol/L)	Number of Imputations	1
4	1	PPG breakfast (SMPG) (mmol/L)	Seed for random number generator	4322

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

The MI Procedure with Monotone Regression Missing Data Pattern

Parameter Code=P9PB Planned Treatment for Period 30 (N)=3

	O b s		I m p u t a t i o n _	P A R A M	G r o u p	R E G I O N 1	B O L D 1	B A S E 1	v i s i t 2	v i s i t 3	F r e q	P e r c e n t	B A S E	v i s i t 2	v i s i t 3	
	1	1	PPG breakfast	(SMPG)	(mmol/L)	1	X	X	X	X	X	313	94.56	9.867637	-0.048229	-0.023420
	2	1	PPG breakfast	(SMPG)	(mmol/L)	2	X	X	X	X	.	13	3.93	9.669840	-0.092649	.
	3	1	PPG breakfast	(SMPG)	(mmol/L)	3	X	X	X	.	.	5	1.51	10.721502	.	.

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PB Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG breakfast (SMPG) (mmol/L)	Intercept	
2	1	PPG breakfast (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG breakfast (SMPG) (mmol/L)	REGION1	EUROPE
4	1	PPG breakfast (SMPG) (mmol/L)	REGION1	JAPAN
5	1	PPG breakfast (SMPG) (mmol/L)	BOLAD1	
6	1	PPG breakfast (SMPG) (mmol/L)	BASE	

Obs	BOLAD1	ObsVal	_1
1		0.02767	0.121711
2		-0.03003	0.095222
3		-0.18567	-0.184113
4		0.39170	0.303749
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.17998	-0.153503
6		-0.57625	-0.612096

Parameter Code=P9PB Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	PPG breakfast (SMPG) (mmol/L)	Intercept			-0.00374	-0.066605
8	1	PPG breakfast (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)		-0.10474	-0.202050
9	1	PPG breakfast (SMPG) (mmol/L)	REGION1	EUROPE		-0.03221	-0.010476

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10FEB2018:18:26:18 - a_797pp_stat_diff.sas/a_9pp_ppg_stat_on_fas_app.txt

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression Regression Information

Parameter Code=P9PB Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

(continued)

	O	b	s_		P A R A M	E f f e c t	R E G I O N 1	B O L A D 1		O b s V a l	I
10	1	PPG breakfast	(SMPG)	(mmol/L)	REGION1	JAPAN				0.07132	0.068700
11	1	PPG breakfast	(SMPG)	(mmol/L)	BOLAD1			BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.07950	-0.092570
12	1	PPG breakfast	(SMPG)	(mmol/L)	BASE					-0.32413	-0.259055
13	1	PPG breakfast	(SMPG)	(mmol/L)	visit2200					0.39470	0.403745

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PB Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG breakfast (SMPG) (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG breakfast (SMPG) (mmol/L)	Method	Monotone
3	1	PPG breakfast (SMPG) (mmol/L)	Number of Imputations	1
4	1	PPG breakfast (SMPG) (mmol/L)	Seed for random number generator	4323

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=P9PB Planned Treatment for Period 30 (N)=4

O b s	I m p u t a t i o n _	P A R A M	G r o u p	R E G I O N 1	E B L A D 1	B O L A D 1	B L A D 1	B L A D 1	B L A D 1	F r e q	P e r c e n t	B A S E	v i s i t 2 0 0	v i s i t 3 6 0 0
1	1	PPG breakfast (SMPG) (mmol/L)	1	X	X	X	X	X	X	303	92.10	9.795161	0.009785	-0.390240
2	1	PPG breakfast (SMPG) (mmol/L)	2	X	X	X	X	.	.	11	3.34	8.426688	0.217265	.
3	1	PPG breakfast (SMPG) (mmol/L)	3	X	X	X	.	.	.	15	4.56	8.444694	.	.

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PB Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG breakfast (SMPG) (mmol/L)	Intercept	
2	1	PPG breakfast (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG breakfast (SMPG) (mmol/L)	REGION1	EUROPE
4	1	PPG breakfast (SMPG) (mmol/L)	REGION1	JAPAN
5	1	PPG breakfast (SMPG) (mmol/L)	BOLAD1	
6	1	PPG breakfast (SMPG) (mmol/L)	BASE	

Obs	BOLAD1	ObsVal	_1
1		0.03811	-0.005920
2		-0.03184	0.018616
3		-0.17205	-0.281892
4		0.25441	0.293200
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.10686	-0.112046
6		-0.61920	-0.692304

Parameter Code=P9PB Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	PPG breakfast (SMPG) (mmol/L)	Intercept			0.03703	0.082429
8	1	PPG breakfast (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)		0.03953	0.064243
9	1	PPG breakfast (SMPG) (mmol/L)	REGION1	EUROPE		-0.12649	-0.053323

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

The MI Procedure with Monotone Regression Regression Information

Parameter Code=P9PB Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

(continued)

	O	b	s		P	E	R	B	O	I
				A	f	E		O	b	
				R	f	G		A	s	
				A	e	I		D	V	
				M	c	N		1	a	
					t	1			l	I
10	1	PPG breakfast	(SMPG)	(mmol/L)	REGION1	JAPAN			0.18925	0.012428
11	1	PPG breakfast	(SMPG)	(mmol/L)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.05519	-0.062537
12	1	PPG breakfast	(SMPG)	(mmol/L)	BASE				-0.43907	-0.543876
13	1	PPG breakfast	(SMPG)	(mmol/L)	visit2200				0.35982	0.256064

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=P9PLC Planned Treatment for Period 30 (N)=2

Obs	PARAM			Description	Value
1	PPG lunch	(SMPG)	(mg/dL)	Data Set	WORK.ENDPOINT_PARAM
2	PPG lunch	(SMPG)	(mg/dL)	Method	Monotone-data_MCMC
3	PPG lunch	(SMPG)	(mg/dL)	Multiple Imputation Chain	Multiple Chains
4	PPG lunch	(SMPG)	(mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
5	PPG lunch	(SMPG)	(mg/dL)	Start	Starting Value
6	PPG lunch	(SMPG)	(mg/dL)	Prior	Jeffreys
7	PPG lunch	(SMPG)	(mg/dL)	Number of Imputations	20000
8	PPG lunch	(SMPG)	(mg/dL)	Number of Burn-in Iterations	200
9	PPG lunch	(SMPG)	(mg/dL)	Seed for random number generator	1234

Parameter Code=P9PLC Planned Treatment for Period 30 (N)=3

Obs	PARAM			Description	Value
10	PPG lunch	(SMPG)	(mg/dL)	Data Set	WORK.ENDPOINT_PARAM
11	PPG lunch	(SMPG)	(mg/dL)	Method	Monotone-data_MCMC
12	PPG lunch	(SMPG)	(mg/dL)	Multiple Imputation Chain	Multiple Chains
13	PPG lunch	(SMPG)	(mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
14	PPG lunch	(SMPG)	(mg/dL)	Start	Starting Value
15	PPG lunch	(SMPG)	(mg/dL)	Prior	Jeffreys
16	PPG lunch	(SMPG)	(mg/dL)	Number of Imputations	20000
17	PPG lunch	(SMPG)	(mg/dL)	Number of Burn-in Iterations	200
18	PPG lunch	(SMPG)	(mg/dL)	Seed for random number generator	1688005726

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=P9PLC Planned Treatment for Period 30 (N)=4

Obs	PARAM			Description	Value
19	PPG lunch	(SMPG)	(mg/dL)	Data Set	WORK.ENDPOINT_PARAM
20	PPG lunch	(SMPG)	(mg/dL)	Method	Monotone-data_MCMC
21	PPG lunch	(SMPG)	(mg/dL)	Multiple Imputation Chain	Multiple Chains
22	PPG lunch	(SMPG)	(mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
23	PPG lunch	(SMPG)	(mg/dL)	Start	Starting Value
24	PPG lunch	(SMPG)	(mg/dL)	Prior	Jeffreys
25	PPG lunch	(SMPG)	(mg/dL)	Number of Imputations	20000
26	PPG lunch	(SMPG)	(mg/dL)	Number of Burn-in Iterations	200
27	PPG lunch	(SMPG)	(mg/dL)	Seed for random number generator	194656119

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

The MI Procedure with MCMC
Missing data pattern

Parameter Code=P9PLC Planned Treatment for Period 30 (N)=2

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
1	PPG lunch (SMPG) (mg/dL)	1	X	X	X	288	88.07	170.248237	-12.341174	-10.500902
2	PPG lunch (SMPG) (mg/dL)	2	X	X	O	13	3.98	159.276667	2.935897	.
3	PPG lunch (SMPG) (mg/dL)	3	X	.	X	15	4.59	187.681556	.	-19.482267
4	PPG lunch (SMPG) (mg/dL)	4	X	O	O	11	3.36	153.048212	.	.

Parameter Code=P9PLC Planned Treatment for Period 30 (N)=3

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
5	PPG lunch (SMPG) (mg/dL)	1	X	X	X	297	90.55	170.830818	0.648768	-1.003801
6	PPG lunch (SMPG) (mg/dL)	2	X	X	O	13	3.96	139.516103	24.496692	.
7	PPG lunch (SMPG) (mg/dL)	3	X	.	X	13	3.96	146.777179	.	22.783487
8	PPG lunch (SMPG) (mg/dL)	4	X	O	O	5	1.52	157.779733	.	.

Parameter Code=P9PLC Planned Treatment for Period 30 (N)=4

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
9	PPG lunch (SMPG) (mg/dL)	1	X	X	X	292	88.75	172.115804	-3.131555	-7.370874
10	PPG lunch (SMPG) (mg/dL)	2	X	X	O	13	3.95	154.827744	13.977487	.
11	PPG lunch (SMPG) (mg/dL)	3	X	.	X	12	3.65	166.054861	.	-8.378583
12	PPG lunch (SMPG) (mg/dL)	4	X	O	O	12	3.65	168.796111	.	.

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PLC Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG lunch (SMPG) (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG lunch (SMPG) (mg/dL)	Method	Monotone
3	1	PPG lunch (SMPG) (mg/dL)	Number of Imputations	1
4	1	PPG lunch (SMPG) (mg/dL)	Seed for random number generator	4321

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- on-treatment - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=P9PLC Planned Treatment for Period 30 (N)=2

O b s	I m p u t a t i o n	P A R A M	G r o u p	R E G I O N l	B O L A L l	B L A D E	B L A D E	B L A D E	B L A D E	F r e q	P e r c e n t	B A S E	v i s i t e s	v i s i t e s
1	1	PPG lunch (SMPG) (mg/dL)	1	X	X	X	X	X	X	303	92.66	171.111273	-13.359814	-10.945524
2	1	PPG lunch (SMPG) (mg/dL)	2	X	X	X	X	.	.	13	3.98	159.276667	2.935897	.
3	1	PPG lunch (SMPG) (mg/dL)	3	X	X	X	.	.	.	11	3.36	153.048212	.	.

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- on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PLC Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG lunch (SMPG) (mg/dL)	Intercept	
2	1	PPG lunch (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG lunch (SMPG) (mg/dL)	REGION1	EUROPE
4	1	PPG lunch (SMPG) (mg/dL)	REGION1	JAPAN
5	1	PPG lunch (SMPG) (mg/dL)	BOLAD1	
6	1	PPG lunch (SMPG) (mg/dL)	BASE	

Obs	BOLAD1	ObsVal	_1
1		-0.02470	0.007330
2		-0.32926	-0.299743
3		0.05452	-0.073203
4		0.23413	0.217834
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.06342	-0.109668
6		-0.61299	-0.640015

Parameter Code=P9PLC Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	PPG lunch (SMPG) (mg/dL)	Intercept			0.01108	-0.018120
8	1	PPG lunch (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)		-0.12140	-0.051146
9	1	PPG lunch (SMPG) (mg/dL)	REGION1	EUROPE		-0.10609	-0.240442

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PLC Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
10	1	PPG lunch (SMPG) (mg/dL)	REGION1	JAPAN		0.18816	0.219872
11	1	PPG lunch (SMPG) (mg/dL)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.00879	0.052410
12	1	PPG lunch (SMPG) (mg/dL)	BASE			-0.56859	-0.522088
13	1	PPG lunch (SMPG) (mg/dL)	visit2200			0.21589	0.247338

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PLC Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG lunch (SMPG) (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG lunch (SMPG) (mg/dL)	Method	Monotone
3	1	PPG lunch (SMPG) (mg/dL)	Number of Imputations	1
4	1	PPG lunch (SMPG) (mg/dL)	Seed for random number generator	4322

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=P9PLC Planned Treatment for Period 30 (N)=3

O b s	I m p u t a t i o n	P A R A M	G r o u p	R E G I O N 1	B O L 1	B L A D E	B L A D E	B L A D E	B L A D E	F r e q	P e r c e n t	B A S E	v i s i t e s	v i s i t e s
1	1	PPG lunch (SMPG) (mg/dL)	1	X	X	X	X	X	X	310	94.51	169.822117	1.067425	-0.006270
2	1	PPG lunch (SMPG) (mg/dL)	2	X	X	X	X	.	.	13	3.96	139.516103	24.496692	.
3	1	PPG lunch (SMPG) (mg/dL)	3	X	X	X	.	.	.	5	1.52	157.779733	.	.

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PLC Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG lunch (SMPG) (mg/dL)	Intercept	
2	1	PPG lunch (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG lunch (SMPG) (mg/dL)	REGION1	EUROPE
4	1	PPG lunch (SMPG) (mg/dL)	REGION1	JAPAN
5	1	PPG lunch (SMPG) (mg/dL)	BOLAD1	
6	1	PPG lunch (SMPG) (mg/dL)	BASE	

Obs	BOLAD1	ObsVal	_1
1		0.01966	0.117286
2		-0.04886	0.080400
3		-0.12761	-0.124706
4		0.25357	0.160667
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.12722	-0.099948
6		-0.54248	-0.576563

Parameter Code=P9PLC Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	PPG lunch (SMPG) (mg/dL)	Intercept			0.00963	-0.051142
8	1	PPG lunch (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)		-0.13649	-0.230003
9	1	PPG lunch (SMPG) (mg/dL)	REGION1	EUROPE		-0.04318	-0.022204

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PLC Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
10	1	PPG lunch (SMPG) (mg/dL)	REGION1	JAPAN		0.21806	0.216488
11	1	PPG lunch (SMPG) (mg/dL)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.08098	-0.094425
12	1	PPG lunch (SMPG) (mg/dL)	BASE			-0.43189	-0.369423
13	1	PPG lunch (SMPG) (mg/dL)	visit2200			0.32884	0.338927

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PLC Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG lunch (SMPG) (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG lunch (SMPG) (mg/dL)	Method	Monotone
3	1	PPG lunch (SMPG) (mg/dL)	Number of Imputations	1
4	1	PPG lunch (SMPG) (mg/dL)	Seed for random number generator	4323

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=P9PLC Planned Treatment for Period 30 (N)=4

O b s	I m p u t a t i o n	P A R A M	G r o u p	R E G I O N 1	B O L 1	B L A D E	B L A D E	B L A D E	B L A D E	F r e q	P e r c e n t	B A S E	v i s i t e s	v i s i t e s
1	1	PPG lunch (SMPG) (mg/dL)	1	X	X	X	X	X	X	304	92.40	171.876556	-2.765879	-7.410652
2	1	PPG lunch (SMPG) (mg/dL)	2	X	X	X	X	X	.	13	3.95	154.827744	13.977487	.
3	1	PPG lunch (SMPG) (mg/dL)	3	X	X	X	.	.	.	12	3.65	168.796111	.	.

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PLC Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG lunch (SMPG) (mg/dL)	Intercept	
2	1	PPG lunch (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG lunch (SMPG) (mg/dL)	REGION1	EUROPE
4	1	PPG lunch (SMPG) (mg/dL)	REGION1	JAPAN
5	1	PPG lunch (SMPG) (mg/dL)	BOLAD1	
6	1	PPG lunch (SMPG) (mg/dL)	BASE	

Obs	BOLAD1	ObsVal	_1
1		0.03890	-0.001328
2		0.05306	0.099515
3		-0.15267	-0.253212
4		0.12535	0.162479
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.13487	-0.138778
6		-0.70024	-0.774027

Parameter Code=P9PLC Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	PPG lunch (SMPG) (mg/dL)	Intercept			0.05434	0.058974
8	1	PPG lunch (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)		0.12687	0.056414
9	1	PPG lunch (SMPG) (mg/dL)	REGION1	EUROPE		-0.22802	-0.181617

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PLC Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
10	1	PPG lunch (SMPG) (mg/dL)	REGION1	JAPAN		0.25086	0.322587
11	1	PPG lunch (SMPG) (mg/dL)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.10850	-0.115546
12	1	PPG lunch (SMPG) (mg/dL)	BASE			-0.51783	-0.440147
13	1	PPG lunch (SMPG) (mg/dL)	visit2200			0.25138	0.213754

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- on-treatment - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=P9PL Planned Treatment for Period 30 (N)=2

Obs	PARAM	Description	Value
1	PPG lunch (SMPG) (mmol/L)	Data Set	WORK.ENDPOINT_PARAM
2	PPG lunch (SMPG) (mmol/L)	Method	Monotone-data_MCMC
3	PPG lunch (SMPG) (mmol/L)	Multiple Imputation Chain	Multiple Chains
4	PPG lunch (SMPG) (mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
5	PPG lunch (SMPG) (mmol/L)	Start	Starting Value
6	PPG lunch (SMPG) (mmol/L)	Prior	Jeffreys
7	PPG lunch (SMPG) (mmol/L)	Number of Imputations	20000
8	PPG lunch (SMPG) (mmol/L)	Number of Burn-in Iterations	200
9	PPG lunch (SMPG) (mmol/L)	Seed for random number generator	1234

Parameter Code=P9PL Planned Treatment for Period 30 (N)=3

Obs	PARAM	Description	Value
10	PPG lunch (SMPG) (mmol/L)	Data Set	WORK.ENDPOINT_PARAM
11	PPG lunch (SMPG) (mmol/L)	Method	Monotone-data_MCMC
12	PPG lunch (SMPG) (mmol/L)	Multiple Imputation Chain	Multiple Chains
13	PPG lunch (SMPG) (mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
14	PPG lunch (SMPG) (mmol/L)	Start	Starting Value
15	PPG lunch (SMPG) (mmol/L)	Prior	Jeffreys
16	PPG lunch (SMPG) (mmol/L)	Number of Imputations	20000
17	PPG lunch (SMPG) (mmol/L)	Number of Burn-in Iterations	200
18	PPG lunch (SMPG) (mmol/L)	Seed for random number generator	1688005726

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=P9PL Planned Treatment for Period 30 (N)=4

Obs	PARAM			Description	Value
19	PPG lunch	(SMPG)	(mmol/L)	Data Set	WORK.ENDPOINT_PARAM
20	PPG lunch	(SMPG)	(mmol/L)	Method	Monotone-data_MCMC
21	PPG lunch	(SMPG)	(mmol/L)	Multiple Imputation Chain	Multiple Chains
22	PPG lunch	(SMPG)	(mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
23	PPG lunch	(SMPG)	(mmol/L)	Start	Starting Value
24	PPG lunch	(SMPG)	(mmol/L)	Prior	Jeffreys
25	PPG lunch	(SMPG)	(mmol/L)	Number of Imputations	20000
26	PPG lunch	(SMPG)	(mmol/L)	Number of Burn-in Iterations	200
27	PPG lunch	(SMPG)	(mmol/L)	Seed for random number generator	194656119

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- on-treatment - full analysis set

The MI Procedure with MCMC
Missing data pattern

Parameter Code=P9PL Planned Treatment for Period 30 (N)=2

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
1	PPG lunch (SMPG) (mmol/L)	1	X	X	X	288	88.07	9.447738	-0.684860	-0.582736
2	PPG lunch (SMPG) (mmol/L)	2	X	X	O	13	3.98	8.838883	0.162924	.
3	PPG lunch (SMPG) (mmol/L)	3	X	.	X	15	4.59	10.415181	.	-1.081147
4	PPG lunch (SMPG) (mmol/L)	4	X	O	O	11	3.36	8.493242	.	.

Parameter Code=P9PL Planned Treatment for Period 30 (N)=3

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
5	PPG lunch (SMPG) (mmol/L)	1	X	X	X	297	90.55	9.480068	0.036003	-0.055705
6	PPG lunch (SMPG) (mmol/L)	2	X	X	O	13	3.96	7.742292	1.359417	.
7	PPG lunch (SMPG) (mmol/L)	3	X	.	X	13	3.96	8.145237	.	1.264344
8	PPG lunch (SMPG) (mmol/L)	4	X	O	O	5	1.52	8.755812	.	.

Parameter Code=P9PL Planned Treatment for Period 30 (N)=4

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
9	PPG lunch (SMPG) (mmol/L)	1	X	X	X	292	88.75	9.551376	-0.173782	-0.409039
10	PPG lunch (SMPG) (mmol/L)	2	X	X	O	13	3.95	8.591995	0.775665	.
11	PPG lunch (SMPG) (mmol/L)	3	X	.	X	12	3.65	9.215031	.	-0.464960
12	PPG lunch (SMPG) (mmol/L)	4	X	O	O	12	3.65	9.367154	.	.

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PL Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG lunch (SMPG) (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG lunch (SMPG) (mmol/L)	Method	Monotone
3	1	PPG lunch (SMPG) (mmol/L)	Number of Imputations	1
4	1	PPG lunch (SMPG) (mmol/L)	Seed for random number generator	4321

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

The MI Procedure with Monotone Regression Missing Data Pattern

Parameter Code=P9PL Planned Treatment for Period 30 (N)=2

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PL Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG lunch (SMPG) (mmol/L)	Intercept	
2	1	PPG lunch (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG lunch (SMPG) (mmol/L)	REGION1	EUROPE
4	1	PPG lunch (SMPG) (mmol/L)	REGION1	JAPAN
5	1	PPG lunch (SMPG) (mmol/L)	BOLAD1	
6	1	PPG lunch (SMPG) (mmol/L)	BASE	

Obs	BOLAD1	ObsVal	_1
1		-0.02470	0.007330
2		-0.32926	-0.299743
3		0.05452	-0.073203
4		0.23413	0.217834
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.06342	-0.109668
6		-0.61299	-0.640015

Parameter Code=P9PL Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	PPG lunch (SMPG) (mmol/L)	Intercept			0.01108	-0.018120
8	1	PPG lunch (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)		-0.12140	-0.051146
9	1	PPG lunch (SMPG) (mmol/L)	REGION1	EUROPE		-0.10609	-0.240442

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PL Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

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Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
10	1	PPG lunch (SMPG) (mmol/L)	REGION1	JAPAN		0.18816	0.219872
11	1	PPG lunch (SMPG) (mmol/L)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.00879	0.052410
12	1	PPG lunch (SMPG) (mmol/L)	BASE			-0.56859	-0.522088
13	1	PPG lunch (SMPG) (mmol/L)	visit2200			0.21589	0.247338

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PL Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG lunch (SMPG) (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG lunch (SMPG) (mmol/L)	Method	Monotone
3	1	PPG lunch (SMPG) (mmol/L)	Number of Imputations	1
4	1	PPG lunch (SMPG) (mmol/L)	Seed for random number generator	4322

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression Missing Data Pattern

Parameter Code=P9PL Planned Treatment for Period 30 (N)=3

O b s		I m p u t a t i o n _	P A R A M	G r o u p	R E G I O N 1	B O L A D 1	B A A E	v i s i t 2	v i s i t 3	F r e q	P e r c e n t	B A S E	v i s i t 2	v i s i t 3		
1	1	PPG	lunch	(SMPG)	(mmol/L)	1	X	X	X	X	X	310	94.51	9.424091	0.059236	-0.000348
2	1	PPG	lunch	(SMPG)	(mmol/L)	2	X	X	X	X	.	13	3.96	7.742292	1.359417	.
3	1	PPG	lunch	(SMPG)	(mmol/L)	3	X	X	X	.	.	5	1.52	8.755812	.	.

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PL Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG lunch (SMPG) (mmol/L)	Intercept	
2	1	PPG lunch (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG lunch (SMPG) (mmol/L)	REGION1	EUROPE
4	1	PPG lunch (SMPG) (mmol/L)	REGION1	JAPAN
5	1	PPG lunch (SMPG) (mmol/L)	BOLAD1	
6	1	PPG lunch (SMPG) (mmol/L)	BASE	
Obs		BOLAD1	ObsVal	_1
1			0.01966	0.117286
2			-0.04886	0.080400
3			-0.12761	-0.124706
4			0.25357	0.160667
5		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.12722	-0.099948
6			-0.54248	-0.576563

Parameter Code=P9PL Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	PPG lunch (SMPG) (mmol/L)	Intercept			0.00963	-0.051142
8	1	PPG lunch (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)		-0.13649	-0.230003
9	1	PPG lunch (SMPG) (mmol/L)	REGION1	EUROPE		-0.04318	-0.022204

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PL Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
10	1	PPG lunch (SMPG) (mmol/L)	REGION1	JAPAN		0.21806	0.216488
11	1	PPG lunch (SMPG) (mmol/L)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.08098	-0.094425
12	1	PPG lunch (SMPG) (mmol/L)	BASE			-0.43189	-0.369423
13	1	PPG lunch (SMPG) (mmol/L)	visit2200			0.32884	0.338927

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PL Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG lunch (SMPG) (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG lunch (SMPG) (mmol/L)	Method	Monotone
3	1	PPG lunch (SMPG) (mmol/L)	Number of Imputations	1
4	1	PPG lunch (SMPG) (mmol/L)	Seed for random number generator	4323

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression Missing Data Pattern

Parameter Code=P9PL Planned Treatment for Period 30 (N)=4

O b s							R E G I O N 1					F r e q	P e r c e n t	B A S E	v i s i t 2	v i s i t 3
							G r o u p	\bar{M} i s s	\bar{M} i s s	\bar{M} i s s	\bar{M} i s s					
				P A R A M											v i s i t 2	v i s i t 3
1	1	PPG	lunch	(SMPG)	(mmol/L)	1	X	X	X	X	X	304	92.40	9.538100	-0.153489	-0.411246
2	1	PPG	lunch	(SMPG)	(mmol/L)	2	X	X	X	X	X	13	3.95	8.591995	0.775665	.
3	1	PPG	lunch	(SMPG)	(mmol/L)	3	X	X	X	.	.	12	3.65	9.367154	.	.

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PL Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG lunch (SMPG) (mmol/L)	Intercept	
2	1	PPG lunch (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG lunch (SMPG) (mmol/L)	REGION1	EUROPE
4	1	PPG lunch (SMPG) (mmol/L)	REGION1	JAPAN
5	1	PPG lunch (SMPG) (mmol/L)	BOLAD1	
6	1	PPG lunch (SMPG) (mmol/L)	BASE	
Obs		BOLAD1	ObsVal	_1
1			0.03890	-0.001328
2			0.05306	0.099515
3			-0.15267	-0.253212
4			0.12535	0.162479
5		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.13487	-0.138778
6			-0.70024	-0.774027

Parameter Code=P9PL Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	PPG lunch (SMPG) (mmol/L)	Intercept			0.05434	0.058974
8	1	PPG lunch (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)		0.12687	0.056414
9	1	PPG lunch (SMPG) (mmol/L)	REGION1	EUROPE		-0.22802	-0.181617

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PL Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
10	1	PPG lunch (SMPG) (mmol/L)	REGION1	JAPAN		0.25086	0.322587
11	1	PPG lunch (SMPG) (mmol/L)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.10850	-0.115546
12	1	PPG lunch (SMPG) (mmol/L)	BASE			-0.51783	-0.440147
13	1	PPG lunch (SMPG) (mmol/L)	visit2200			0.25138	0.213754

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- on-treatment - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=P9PEVC Planned Treatment for Period 30 (N)=2

Obs	PARAM	Description	Value
1	PPG main evening meal (SMPG) (mg/dL)	Data Set	WORK.ENDPOINT_PARAM
2	PPG main evening meal (SMPG) (mg/dL)	Method	Monotone-data_MCMC
3	PPG main evening meal (SMPG) (mg/dL)	Multiple Imputation Chain	Multiple Chains
4	PPG main evening meal (SMPG) (mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
5	PPG main evening meal (SMPG) (mg/dL)	Start	Starting Value
6	PPG main evening meal (SMPG) (mg/dL)	Prior	Jeffreys
7	PPG main evening meal (SMPG) (mg/dL)	Number of Imputations	20000
8	PPG main evening meal (SMPG) (mg/dL)	Number of Burn-in Iterations	200
9	PPG main evening meal (SMPG) (mg/dL)	Seed for random number generator	1234

Parameter Code=P9PEVC Planned Treatment for Period 30 (N)=3

Obs	PARAM	Description	Value
10	PPG main evening meal (SMPG) (mg/dL)	Data Set	WORK.ENDPOINT_PARAM
11	PPG main evening meal (SMPG) (mg/dL)	Method	Monotone-data_MCMC
12	PPG main evening meal (SMPG) (mg/dL)	Multiple Imputation Chain	Multiple Chains
13	PPG main evening meal (SMPG) (mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
14	PPG main evening meal (SMPG) (mg/dL)	Start	Starting Value
15	PPG main evening meal (SMPG) (mg/dL)	Prior	Jeffreys
16	PPG main evening meal (SMPG) (mg/dL)	Number of Imputations	20000
17	PPG main evening meal (SMPG) (mg/dL)	Number of Burn-in Iterations	200
18	PPG main evening meal (SMPG) (mg/dL)	Seed for random number generator	1064396424

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- on-treatment - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=P9PEVC Planned Treatment for Period 30 (N)=4

Obs	PARAM	Description	Value
19	PPG main evening meal (SMPG) (mg/dL)	Data Set	WORK.ENDPOINT_PARAM
20	PPG main evening meal (SMPG) (mg/dL)	Method	Monotone-data_MCMC
21	PPG main evening meal (SMPG) (mg/dL)	Multiple Imputation Chain	Multiple Chains
22	PPG main evening meal (SMPG) (mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
23	PPG main evening meal (SMPG) (mg/dL)	Start	Starting Value
24	PPG main evening meal (SMPG) (mg/dL)	Prior	Jeffreys
25	PPG main evening meal (SMPG) (mg/dL)	Number of Imputations	20000
26	PPG main evening meal (SMPG) (mg/dL)	Number of Burn-in Iterations	200
27	PPG main evening meal (SMPG) (mg/dL)	Seed for random number generator	1711700893

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

The MI Procedure with MCMC

Missing data pattern

Parameter Code=P9PEVC Planned Treatment for Period 30 (N)=2

O		P	G	B	A	S	E	F	P	B	v	v
b		A	r	M	M	i	2	r	e	A	i	i
s		M	p	s	s	s	0	e	n	S	s	s
1	PPG main evening meal (SMPG) (mg/dL)		1	X	X	X	287	88.04	170.920736	-11.337919	-10.038134	
2	PPG main evening meal (SMPG) (mg/dL)		2	X	X	O	11	3.37	137.514485	12.307455	.	
3	PPG main evening meal (SMPG) (mg/dL)		3	X	.	X	17	5.21	197.178235	.	-13.785098	
4	PPG main evening meal (SMPG) (mg/dL)		4	X	O	O	11	3.37	154.686758	.		

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC

Missing data pattern

Parameter Code=P9PEVC Planned Treatment for Period 30 (N)=3

O b s	P A R A M						G r o u p	v i s i t B A S E M M i i s s s			F r e q	P e r c e n t	B A S E	v i s i t 2 0 0	v i s i t 3 6 0
	1	2	3	4	5	6		1	2	3					
5	PPG	main	evening	meal	(SMPG)	(mg/dL)	1	X	X	X	297	90.83	175.776370	1.418483	-0.164676
6	PPG	main	evening	meal	(SMPG)	(mg/dL)	2	X	X	O	10	3.06	164.420200	23.233800	.
7	PPG	main	evening	meal	(SMPG)	(mg/dL)	3	X	.	X	14	4.28	192.684476	.	-18.280738
8	PPG	main	evening	meal	(SMPG)	(mg/dL)	4	X	O	O	6	1.83	150.464722	.	.

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC

Missing data pattern

Parameter Code=P9PEVC Planned Treatment for Period 30 (N)=4

O		P	G	V	V		F	P	B	V	V
b		A	r	i	i		r	e	A	s	s
s		M	o	s	s		q	n	S	i	i
			p	t	t			t	E	t	t
				2	2					2	3
				6	6					0	0
				0	0					0	0
				\bar{M}	\bar{M}					2	3
				i	i					2	6
				s	s					0	0
				s	s					0	0
9	PPG main evening meal (SMPG) (mg/dL)		1	X	X	X	292	89.02	167.452390	-1.045775	-2.319048
10	PPG main evening meal (SMPG) (mg/dL)		2	X	X	O	12	3.66	167.912944	0.522389	.
11	PPG main evening meal (SMPG) (mg/dL)		3	X	.	X	13	3.96	173.894667	.	-5.159795
12	PPG main evening meal (SMPG) (mg/dL)		4	X	O	O	11	3.35	184.925939	.	.

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PEVC Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG main evening meal (SMPG) (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG main evening meal (SMPG) (mg/dL)	Method	Monotone
3	1	PPG main evening meal (SMPG) (mg/dL)	Number of Imputations	1
4	1	PPG main evening meal (SMPG) (mg/dL)	Seed for random number generator	4321

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- on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PEVC Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG main evening meal (SMPG) (mg/dL)	Intercept	
2	1	PPG main evening meal (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG main evening meal (SMPG) (mg/dL)	REGION1	EUROPE
4	1	PPG main evening meal (SMPG) (mg/dL)	REGION1	JAPAN
5	1	PPG main evening meal (SMPG) (mg/dL)	BOLAD1	
6	1	PPG main evening meal (SMPG) (mg/dL)	BASE	

Obs	BOLAD1	ObsVal	_1
1		0.01327	0.043903
2		0.04076	0.069663
3		-0.03227	-0.153951
4		-0.08595	-0.103258
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.03253	-0.076911
6		-0.65254	-0.684709

Parameter Code=P9PEVC Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	PPG main evening meal (SMPG) (mg/dL)	Intercept			-0.02546	-0.054472
8	1	PPG main evening meal (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)		-0.28444	-0.215564
9	1	PPG main evening meal (SMPG) (mg/dL)	REGION1	EUROPE		0.03699	-0.097507

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PEVC Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG main evening meal (SMPG) (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG main evening meal (SMPG) (mg/dL)	Method	Monotone
3	1	PPG main evening meal (SMPG) (mg/dL)	Number of Imputations	1
4	1	PPG main evening meal (SMPG) (mg/dL)	Seed for random number generator	4322

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression Missing Data Pattern

Parameter Code=P9PEVC Planned Treatment for Period 30 (N)=3

Obs		Input		PAR		Gross		Residual		Predicted		Variance		Variance				
1	1	PPG	main	evening	meal	(SMPG)	(mg/dL)	1	X	X	X	X	X	311	95.11	176.537507	0.897515	-0.980190
2	1	PPG	main	evening	meal	(SMPG)	(mg/dL)	2	X	X	X	X	.	10	3.06	164.420200	23.233800	.
3	1	PPG	main	evening	meal	(SMPG)	(mg/dL)	3	X	X	X	.	.	6	1.83	150.464722	.	.

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PEVC Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG main evening meal (SMPG) (mg/dL)	Intercept	
2	1	PPG main evening meal (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG main evening meal (SMPG) (mg/dL)	REGION1	EUROPE
4	1	PPG main evening meal (SMPG) (mg/dL)	REGION1	JAPAN
5	1	PPG main evening meal (SMPG) (mg/dL)	BOLAD1	
6	1	PPG main evening meal (SMPG) (mg/dL)	BASE	

Obs	BOLAD1	ObsVal	_1
1		0.03557	0.129919
2		0.07207	0.198060
3		-0.20738	-0.206486
4		0.16887	0.082233
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.05973	-0.033840
6		-0.59079	-0.636161

Parameter Code=P9PEVC Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	PPG main evening meal (SMPG) (mg/dL)	Intercept			0.00880	-0.008882
8	1	PPG main evening meal (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)		-0.12271	-0.157552
9	1	PPG main evening meal (SMPG) (mg/dL)	REGION1	EUROPE		-0.12410	-0.139062

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The MI Procedure with Monotone Regression Regression Information

Parameter Code=P9PEVC Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

(continued)

	O b s _	P A R A M	E f f e c t	R E G I O N 1	B O L U S D 1	O b s V a l	I
10	1	PPG main evening meal (SMPG) (mg/dL)	REGION1	JAPAN		0.27268	0.240275
11	1	PPG main evening meal (SMPG) (mg/dL)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.08298	-0.015833
12	1	PPG main evening meal (SMPG) (mg/dL)	BASE			-0.48636	-0.502098
13	1	PPG main evening meal (SMPG) (mg/dL)	visit2200			0.30668	0.325662

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PEVC Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG main evening meal (SMPG) (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG main evening meal (SMPG) (mg/dL)	Method	Monotone
3	1	PPG main evening meal (SMPG) (mg/dL)	Number of Imputations	1
4	1	PPG main evening meal (SMPG) (mg/dL)	Seed for random number generator	4323

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression Missing Data Pattern

Parameter Code=P9PEVC Planned Treatment for Period 30 (N)=4

	O	b	s	I m p u t a t i o n —	P A R A M	G r o u p	R E G I O N 1	B B O L A D 1	S S T B A S E E	v v i i s s s s t t 2 3 6 6 0 0 0 0	F r e q	P e r c e n t	B A S E	v i s i t 2 2 0 0	v i s i t 3 6 0 0	
1	1	PPG	main	evening meal (SMPG)	(mg/dL)	1	X	X	X	X	X	305	92.99	167.726979	-0.606316	-2.440129
2	1	PPG	main	evening meal (SMPG)	(mg/dL)	2	X	X	X	X	.	12	3.66	167.912944	0.522389	.
3	1	PPG	main	evening meal (SMPG)	(mq/dL)	3	X	X	X	.	.	11	3.35	184.925939	.	.

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The MI Procedure with Monotone Regression
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Parameter Code=P9PEVC Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG main evening meal (SMPG) (mg/dL)	Intercept	
2	1	PPG main evening meal (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG main evening meal (SMPG) (mg/dL)	REGION1	EUROPE
4	1	PPG main evening meal (SMPG) (mg/dL)	REGION1	JAPAN
5	1	PPG main evening meal (SMPG) (mg/dL)	BOLAD1	
6	1	PPG main evening meal (SMPG) (mg/dL)	BASE	

Obs	BOLAD1	ObsVal	_1
1		0.00958	-0.032814
2		-0.09311	-0.044027
3		-0.13446	-0.240822
4		0.29007	0.326518
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.09900	-0.103608
6		-0.63993	-0.715397

Parameter Code=P9PEVC Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	PPG main evening meal (SMPG) (mg/dL)	Intercept			0.00512	-0.022945
8	1	PPG main evening meal (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)		0.00742	-0.000625
9	1	PPG main evening meal (SMPG) (mg/dL)	REGION1	EUROPE		-0.09163	-0.141023

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The MI Procedure with Monotone Regression Regression Information

Parameter Code=P9PEVC Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

(continued)

	O	P	E	R	B	O		
b	A	f	E	O	L	b		
s	R	e	G	I	A	s		
-	A	c	N	O	D	V		
	M	t	l	l	l	a	I	
10	1	PPG	main evening meal (SMPG)	(mg/dL)	REGION1	JAPAN	-0.00160	0.052818
11	1	PPG	main evening meal (SMPG)	(mg/dL)	BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.02432	0.023638
12	1	PPG	main evening meal (SMPG)	(mg/dL)	BASE		-0.45965	-0.464485
13	1	PPG	main evening meal (SMPG)	(mg/dL)	visit2200		0.30695	0.362451

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The MI Procedure with MCMC
Model Information

Parameter Code=P9PEV Planned Treatment for Period 30 (N)=2

Obs	PARAM	Description	Value
1	PPG main evening meal (SMPG) (mmol/L)	Data Set	WORK.ENDPOINT_PARAM
2	PPG main evening meal (SMPG) (mmol/L)	Method	Monotone-data_MCMC
3	PPG main evening meal (SMPG) (mmol/L)	Multiple Imputation Chain	Multiple Chains
4	PPG main evening meal (SMPG) (mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
5	PPG main evening meal (SMPG) (mmol/L)	Start	Starting Value
6	PPG main evening meal (SMPG) (mmol/L)	Prior	Jeffreys
7	PPG main evening meal (SMPG) (mmol/L)	Number of Imputations	20000
8	PPG main evening meal (SMPG) (mmol/L)	Number of Burn-in Iterations	200
9	PPG main evening meal (SMPG) (mmol/L)	Seed for random number generator	1234

Parameter Code=P9PEV Planned Treatment for Period 30 (N)=3

Obs	PARAM	Description	Value
10	PPG main evening meal (SMPG) (mmol/L)	Data Set	WORK.ENDPOINT_PARAM
11	PPG main evening meal (SMPG) (mmol/L)	Method	Monotone-data_MCMC
12	PPG main evening meal (SMPG) (mmol/L)	Multiple Imputation Chain	Multiple Chains
13	PPG main evening meal (SMPG) (mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
14	PPG main evening meal (SMPG) (mmol/L)	Start	Starting Value
15	PPG main evening meal (SMPG) (mmol/L)	Prior	Jeffreys
16	PPG main evening meal (SMPG) (mmol/L)	Number of Imputations	20000
17	PPG main evening meal (SMPG) (mmol/L)	Number of Burn-in Iterations	200
18	PPG main evening meal (SMPG) (mmol/L)	Seed for random number generator	1064396424

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The MI Procedure with MCMC
Model Information

Parameter Code=P9PEV Planned Treatment for Period 30 (N)=4

Obs	PARAM			Description	Value
19	PPG	main evening meal	(SMPG) (mmol/L)	Data Set	WORK.ENDPOINT_PARAM
20	PPG	main evening meal	(SMPG) (mmol/L)	Method	Monotone-data_MCMC
21	PPG	main evening meal	(SMPG) (mmol/L)	Multiple Imputation Chain	Multiple Chains
22	PPG	main evening meal	(SMPG) (mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
23	PPG	main evening meal	(SMPG) (mmol/L)	Start	Starting Value
24	PPG	main evening meal	(SMPG) (mmol/L)	Prior	Jeffreys
25	PPG	main evening meal	(SMPG) (mmol/L)	Number of Imputations	20000
26	PPG	main evening meal	(SMPG) (mmol/L)	Number of Burn-in Iterations	200
27	PPG	main evening meal	(SMPG) (mmol/L)	Seed for random number generator	1711700893

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC

Missing data pattern

Parameter Code=P9PEV Planned Treatment for Period 30 (N)=2

Obs							V i s i t				P e r c e n t		V i s i t		
							B A S E						v i s i t		
							2 2 0 0						2 2 0 0		
							M M M						3 6 0 0		
1	PPG	main	evening	meal	(SMPG)	(mmol/L)	1	X	X	X	287	88.04	9.485058	-0.629185	-0.557055
2	PPG	main	evening	meal	(SMPG)	(mmol/L)	2	X	X	O	11	3.37	7.631214	0.682989	.
3	PPG	main	evening	meal	(SMPG)	(mmol/L)	3	X	.	X	17	5.21	10.942188	.	-0.764989
4	PPG	main	evening	meal	(SMPG)	(mmol/L)	4	X	O	O	11	3.37	8.584171	.	.

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC

Missing data pattern

Parameter Code=P9PEV Planned Treatment for Period 30 (N)=3

O b s	P A R A M						G r o u p	v i s i t B A S E \bar{M} i s s			F r e q	P e r c e n t	B A S E	v i s i t 2 2 0 0	v i s i t 3 6 0 0
	1	2	3	4	5	6		7	8	9					
5	PPG	main	evening	meal	(SMPG)	(mmol/L)	1	X	X	X	297	90.83	9.754516	0.078717	-0.009138
6	PPG	main	evening	meal	(SMPG)	(mmol/L)	2	X	X	O	10	3.06	9.124317	1.289334	.
7	PPG	main	evening	meal	(SMPG)	(mmol/L)	3	X	.	X	14	4.28	10.692812	.	-1.014469
8	PPG	main	evening	meal	(SMPG)	(mmol/L)	4	X	O	O	6	1.83	8.349874	.	.

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC

Missing data pattern

Parameter Code=P9PEV Planned Treatment for Period 30 (N)=4

O b s							G r o u p			F r e q	P e r c e n t	B A S E	v i s i t s		v i s i t s	v i s i t s
	P A R A M						B A S E	B A S E	B A S E				B A S E	B A S E		
9	PPG	main	evening	meal	(SMPG)	(mmol/L)	1	X	X	X	292	89.02	9.292585	-0.058034	-0.128693	
10	PPG	main	evening	meal	(SMPG)	(mmol/L)	2	X	X	O	12	3.66	9.318143	0.028989	.	
11	PPG	main	evening	meal	(SMPG)	(mmol/L)	3	X	.	X	13	3.96	9.650092	.	-0.286337	
12	PPG	main	evening	meal	(SMPG)	(mmol/L)	4	X	O	O	11	3.35	10.262261	.		

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PEV Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG main evening meal (SMPG) (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG main evening meal (SMPG) (mmol/L)	Method	Monotone
3	1	PPG main evening meal (SMPG) (mmol/L)	Number of Imputations	1
4	1	PPG main evening meal (SMPG) (mmol/L)	Seed for random number generator	4321

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression Missing Data Pattern

Parameter Code=P9PEV Planned Treatment for Period 30 (N)=2

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- on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PEV Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG main evening meal (SMPG) (mmol/L)	Intercept	
2	1	PPG main evening meal (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG main evening meal (SMPG) (mmol/L)	REGION1	EUROPE
4	1	PPG main evening meal (SMPG) (mmol/L)	REGION1	JAPAN
5	1	PPG main evening meal (SMPG) (mmol/L)	BOLAD1	
6	1	PPG main evening meal (SMPG) (mmol/L)	BASE	

Obs	BOLAD1	ObsVal	_1
1		0.01327	0.043903
2		0.04076	0.069663
3		-0.03227	-0.153951
4		-0.08595	-0.103258
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.03253	-0.076911
6		-0.65254	-0.684709

Parameter Code=P9PEV Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	PPG main evening meal (SMPG) (mmol/L)	Intercept			-0.02546	-0.054472
8	1	PPG main evening meal (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)		-0.28444	-0.215564
9	1	PPG main evening meal (SMPG) (mmol/L)	REGION1	EUROPE		0.03699	-0.097507

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The MI Procedure with Monotone Regression Regression Information

Parameter Code=P9PEV Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

(continued)

										Input	Obs				
										PAAM	Effect	REGION1	BOLD	ObsVal	
10	1	PPG	main	evening	meal	(SMPG)	(mmol/L)	REGION1	JAPAN					0.06624	0.096643
11	1	PPG	main	evening	meal	(SMPG)	(mmol/L)	BOLAD1		BOLUS	INSULIN	ALGORITHM	(SLIDING SCALE)	-0.01226	0.047799
12	1	PPG	main	evening	meal	(SMPG)	(mmol/L)	BASE						-0.34585	-0.302029
13	1	PPG	main	evening	meal	(SMPG)	(mmol/L)	visit2200						0.38531	0.412365

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PEV Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG main evening meal (SMPG) (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG main evening meal (SMPG) (mmol/L)	Method	Monotone
3	1	PPG main evening meal (SMPG) (mmol/L)	Number of Imputations	1
4	1	PPG main evening meal (SMPG) (mmol/L)	Seed for random number generator	4322

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression Missing Data Pattern

Parameter Code=P9PEV Planned Treatment for Period 30 (N)=3

	O	b s	I m p u t a t i o n —	P A R M	G r o u p	R E G I O N l	B B O L A D l	v v i i s s i i t t 2 3 2 6 0 0	F r e q	P e r c e n t	B A S E	v i s i t 2 0 0	v i s i t 3 6 0 0
1	1	PPG	main evening meal (SMPG) (mmol/L)		1	X X X X X		311	95.11	9.796754	0.049807	-0.054395	
2	1	PPG	main evening meal (SMPG) (mmol/L)		2	X X X X .		10	3.06	9.124317	1.289334	.	
3	1	PPG	main evening meal (SMPG) (mmol/L)		3	X X X . .		6	1.83	8.349874	.	.	

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- on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PEV Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG main evening meal (SMPG) (mmol/L)	Intercept	
2	1	PPG main evening meal (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG main evening meal (SMPG) (mmol/L)	REGION1	EUROPE
4	1	PPG main evening meal (SMPG) (mmol/L)	REGION1	JAPAN
5	1	PPG main evening meal (SMPG) (mmol/L)	BOLAD1	
6	1	PPG main evening meal (SMPG) (mmol/L)	BASE	

Obs	BOLAD1	ObsVal	_1
1		0.03557	0.129919
2		0.07207	0.198060
3		-0.20738	-0.206486
4		0.16887	0.082233
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.05973	-0.033840
6		-0.59079	-0.636161

Parameter Code=P9PEV Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	PPG main evening meal (SMPG) (mmol/L)	Intercept			0.00880	-0.008882
8	1	PPG main evening meal (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)		-0.12271	-0.157552
9	1	PPG main evening meal (SMPG) (mmol/L)	REGION1	EUROPE		-0.12410	-0.139062

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The MI Procedure with Monotone Regression Regression Information

Parameter Code=P9PEV Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

(continued)

	O	P	E	R	B	O	
I	b	A	f	E	O	b	
m	n	R	e	G	L	s	
p	s	A	c	I	A	V	
u	-	M	t	N	D	a	
t <th></th> <th></th> <th></th> <th>l</th> <th>l</th> <th>l</th> <th>I</th>				l	l	l	I
10	1	PPG main evening meal (SMPG) (mmol/L)	REGION1	JAPAN			
11	1	PPG main evening meal (SMPG) (mmol/L)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.27268	0.240275
12	1	PPG main evening meal (SMPG) (mmol/L)	BASE			-0.08298	-0.015833
13	1	PPG main evening meal (SMPG) (mmol/L)	visit2200			-0.48636	-0.502098
						0.30668	0.325662

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PEV Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG main evening meal (SMPG) (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG main evening meal (SMPG) (mmol/L)	Method	Monotone
3	1	PPG main evening meal (SMPG) (mmol/L)	Number of Imputations	1
4	1	PPG main evening meal (SMPG) (mmol/L)	Seed for random number generator	4323

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=P9PEV Planned Treatment for Period 30 (N)=4

I m p u t a t i o n s	P A R A M E T E R S	G R O U P	R E G I O N S	E B G I L B O A A N D S 1 1 E 0 0	F r e q	P e r c e n t	B A S E	v i s i t 2 0 0	v i s i t 3 6 0 0
1	1	PPG main evening meal (SMPG) (mmol/L)	1	X X X X X X	305	92.99	9.307823	-0.033647	-0.135412
2	1	PPG main evening meal (SMPG) (mmol/L)	2	X X X X .	12	3.66	9.318143	0.028989	.
3	1	PPG main evening meal (SMPG) (mmol/L)	3	X X X . .	11	3.35	10.262261	.	.

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- on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PEV Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG main evening meal (SMPG) (mmol/L)	Intercept	
2	1	PPG main evening meal (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG main evening meal (SMPG) (mmol/L)	REGION1	EUROPE
4	1	PPG main evening meal (SMPG) (mmol/L)	REGION1	JAPAN
5	1	PPG main evening meal (SMPG) (mmol/L)	BOLAD1	
6	1	PPG main evening meal (SMPG) (mmol/L)	BASE	

Obs	BOLAD1	ObsVal	_1
1		0.00958	-0.032814
2		-0.09311	-0.044027
3		-0.13446	-0.240822
4		0.29007	0.326518
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.09900	-0.103608
6		-0.63993	-0.715397

Parameter Code=P9PEV Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	PPG main evening meal (SMPG) (mmol/L)	Intercept			0.00512	-0.022945
8	1	PPG main evening meal (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)		0.00742	-0.000625
9	1	PPG main evening meal (SMPG) (mmol/L)	REGION1	EUROPE		-0.09163	-0.141023

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The MI Procedure with Monotone Regression Regression Information

Parameter Code=P9PEV Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

(continued)

	O	P	E	R	B	O	I
b	A	f	E	O	O	b	
n	R	e	G	N	L	s	
s							
10	PPG main evening meal (SMPG) (mmol/L)	REGION1 JAPAN			-0.00160	0.052818	
11	PPG main evening meal (SMPG) (mmol/L)	BOLAD1 BOLUS INSULIN ALGORITHM (SLIDING SCALE)			-0.02432	0.023638	
12	PPG main evening meal (SMPG) (mmol/L)	BASE			-0.45965	-0.464485	
13	PPG main evening meal (SMPG) (mmol/L)	visit2200			0.30695	0.362451	

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- on-treatment - full analysis set

The Mixed procedure
Model Information

Parameter Code=P9PB Parameter=PPG breakfast (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Data Set	WORK.IMPUTE
2	1	NN1218-4131	Dependent Variable	eotVisit
3	1	NN1218-4131	Covariance Structure	Diagonal
4	1	NN1218-4131	Estimation Method	REML
5	1	NN1218-4131	Residual Variance Method	Profile
6	1	NN1218-4131	Fixed Effects SE Method	Model-Based
7	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=P9PEV Parameter=PPG main evening meal (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
8	1	NN1218-4131	Data Set	WORK.IMPUTE
9	1	NN1218-4131	Dependent Variable	eotVisit
10	1	NN1218-4131	Covariance Structure	Diagonal
11	1	NN1218-4131	Estimation Method	REML
12	1	NN1218-4131	Residual Variance Method	Profile
13	1	NN1218-4131	Fixed Effects SE Method	Model-Based
14	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=P9PEVC Parameter=PPG main evening meal (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
15	1	NN1218-4131	Data Set	WORK.IMPUTE
16	1	NN1218-4131	Dependent Variable	eotVisit
17	1	NN1218-4131	Covariance Structure	Diagonal

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The Mixed procedure
Model Information

Parameter Code=P9PEVC Parameter=PPG main evening meal (SMPG) (mg/dL)

(continued)

Obs	_Imputation_	STUDYID	Descr	Value
18	1	NN1218-4131	Estimation Method	REML
19	1	NN1218-4131	Residual Variance Method	Profile
20	1	NN1218-4131	Fixed Effects SE Method	Model-Based
21	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=P9PGBC Parameter=PPG breakfast (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
22	1	NN1218-4131	Data Set	WORK.IMPUTE
23	1	NN1218-4131	Dependent Variable	eotVisit
24	1	NN1218-4131	Covariance Structure	Diagonal
25	1	NN1218-4131	Estimation Method	REML
26	1	NN1218-4131	Residual Variance Method	Profile
27	1	NN1218-4131	Fixed Effects SE Method	Model-Based
28	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=P9PL Parameter=PPG lunch (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
29	1	NN1218-4131	Data Set	WORK.IMPUTE
30	1	NN1218-4131	Dependent Variable	eotVisit
31	1	NN1218-4131	Covariance Structure	Diagonal
32	1	NN1218-4131	Estimation Method	REML

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The Mixed procedure
Model Information

Parameter Code=P9PL Parameter=PPG lunch (SMPG) (mmol/L)

(continued)

Obs	_Imputation_	STUDYID	Descr	Value
33	1	NN1218-4131	Residual Variance Method	Profile
34	1	NN1218-4131	Fixed Effects SE Method	Model-Based
35	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=P9PLC Parameter=PPG lunch (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
36	1	NN1218-4131	Data Set	WORK.IMPUTE
37	1	NN1218-4131	Dependent Variable	eotVisit
38	1	NN1218-4131	Covariance Structure	Diagonal
39	1	NN1218-4131	Estimation Method	REML
40	1	NN1218-4131	Residual Variance Method	Profile
41	1	NN1218-4131	Fixed Effects SE Method	Model-Based
42	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=P9PPRAN Parameter=PPG all meals (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
43	1	NN1218-4131	Data Set	WORK.IMPUTE
44	1	NN1218-4131	Dependent Variable	eotVisit
45	1	NN1218-4131	Covariance Structure	Diagonal
46	1	NN1218-4131	Estimation Method	REML
47	1	NN1218-4131	Residual Variance Method	Profile

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The Mixed procedure
Model Information

Parameter Code=P9PPRAN Parameter=PPG all meals (SMPG) (mmol/L)

(continued)

Obs	_Imputation_	STUDYID	Descr	Value
48	1	NN1218-4131	Fixed Effects SE Method	Model-Based
49	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=P9PPRANC Parameter=PPG all meals (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
50	1	NN1218-4131	Data Set	WORK.IMPUTE
51	1	NN1218-4131	Dependent Variable	eotVisit
52	1	NN1218-4131	Covariance Structure	Diagonal
53	1	NN1218-4131	Estimation Method	REML
54	1	NN1218-4131	Residual Variance Method	Profile
55	1	NN1218-4131	Fixed Effects SE Method	Model-Based
56	1	NN1218-4131	Degrees of Freedom Method	Residual

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Class Level Information

Parameter Code=P9PB Parameter=PPG breakfast (SMPG) (mmol/L)

Ob- s	Input ID	STUDY	Class	Level	Values	min
1	1	NN1218-4131	TRTPN	3	2 3 4	5
2	1	NN1218-4131	REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA	49
3	1	NN1218-4131	BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULI	85


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Class Level Information

Parameter Code=P9PEVC Parameter=PPG main evening meal (SMPG) (mg/dL)

O b s		I n		S t u d y		C o u n t r y		L e v e l		V a r i a b l e		m i n	
7		1		NN1218-4131		TRTPN		3		2		3	
8		1		NN1218-4131		REGION1		4		ASIA (EXCLUDING JAPAN)		EUROPE	
9		1		NN1218-4131		BOLAD1		2		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		CARBOHYDRATE COUNTING (FLEXIBLE)	
												BOLUS INSULI	
												85	

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

The Mixed procedure
Class Level Information

Parameter Code=P9PGBC Parameter=PPG breakfast (SMPG) (mg/dL)

O b s		I m p u t a t i o n s		S t a t i s t i c s		L e v e l s		V a r i a t i o n s		m i n	
10	1	NN1218-4131	TRTPN	3	2	3	4			5	
11	1	NN1218-4131	REGION1	4	ASIA (EXCLUDING JAPAN)	EUROPE	JAPAN	NORTH AMERICA		49	
12	1	NN1218-4131	BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	CARBOHYDRATE COUNTING (FLEXIBLE)	BOLUS INSULI			85	

Fast-acting insulin aspart
NN1218-4131

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- on-treatment - full analysis set

The Mixed procedure
Class Level Information

Parameter Code=P9PL Parameter=PPG lunch (SMPG) (mmol/L)

O b s _		I m p u t a t i o n s		S T U D Y I D		C l a s s e s		L e v e l s		V a r i a b l e s		m i n	
13	1	NN1218-4131	TRTPN					3	2	3	4		5
14	1	NN1218-4131	REGION1					4	ASIA (EXCLUDING JAPAN)	EUROPE	JAPAN	NORTH AMERICA	49
15	1	NN1218-4131	BOLAD1					2	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	CARBOHYDRATE COUNTING (FLEXIBLE)	BOLUS INSULI		85

Fast-acting insulin aspart
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- on-treatment - full analysis set

The Mixed procedure
Class Level Information

Parameter Code=P9PLC Parameter=PPG lunch (SMPG) (mg/dL)

		Input		Status		Level		Variable		Length	
O	b	s	—	D	s	s	s	u	e	s	h
16	1	NN1218-4131	TRTPN			3	2	3	4		5
17	1	NN1218-4131	REGION1			4	ASIA (EXCLUDING JAPAN)	EUROPE	JAPAN	NORTH AMERICA	49
18	1	NN1218-4131	BOLAD1			2	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	CARBOHYDRATE COUNTING (FLEXIBLE)	BOLUS INSULI		85

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

The Mixed procedure
Class Level Information

Parameter Code=P9PPRAN Parameter=PPG all meals (SMPG) (mmol/L)

O b s		I m p u t a t i o n s		S t u d y I D		C l a s s e s		L e v e l s		V a r i a b l e s		m i n	
19	1	NN1218-4131	TRTPN					3	2	3	4		5
20	1	NN1218-4131	REGION1					4	ASIA (EXCLUDING JAPAN)	EUROPE	JAPAN	NORTH AMERICA	49
21	1	NN1218-4131	BOLAD1					2	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	CARBOHYDRATE COUNTING (FLEXIBLE)	BOLUS INSULI		85

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

The Mixed procedure
Class Level Information

Parameter Code=P9PPRANC Parameter=PPG all meals (SMPG) (mg/dL)

O b s		I n		S t u d y		C l a s s		L e v e l s		V a r i a b l e s		m i n	
22	1	NN1218-4131	TRTPN	3	2	3	4					5	
23	1	NN1218-4131	REGION1	4	ASIA (EXCLUDING JAPAN)	EUROPE	JAPAN	NORTH AMERICA				49	
24	1	NN1218-4131	BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	CARBOHYDRATE COUNTING (FLEXIBLE)	BOLUS INSULI	85					

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

The Mixed procedure
Dimensions

Parameter Code=P9PB Parameter=PPG breakfast (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Covariance Parameters	1
2	1	NN1218-4131	Columns in X	10
3	1	NN1218-4131	Columns in Z	0
4	1	NN1218-4131	Subjects	1
5	1	NN1218-4131	Max Obs per Subject	986

Parameter Code=P9PEV Parameter=PPG main evening meal (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
6	1	NN1218-4131	Covariance Parameters	1
7	1	NN1218-4131	Columns in X	10
8	1	NN1218-4131	Columns in Z	0
9	1	NN1218-4131	Subjects	1
10	1	NN1218-4131	Max Obs per Subject	981

Parameter Code=P9PEVC Parameter=PPG main evening meal (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
11	1	NN1218-4131	Covariance Parameters	1
12	1	NN1218-4131	Columns in X	10
13	1	NN1218-4131	Columns in Z	0
14	1	NN1218-4131	Subjects	1
15	1	NN1218-4131	Max Obs per Subject	981

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

The Mixed procedure
Dimensions

Parameter Code=P9PGBC Parameter=PPG breakfast (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
16	1	NN1218-4131	Covariance Parameters	1
17	1	NN1218-4131	Columns in X	10
18	1	NN1218-4131	Columns in Z	0
19	1	NN1218-4131	Subjects	1
20	1	NN1218-4131	Max Obs per Subject	986

Parameter Code=P9PL Parameter=PPG lunch (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
21	1	NN1218-4131	Covariance Parameters	1
22	1	NN1218-4131	Columns in X	10
23	1	NN1218-4131	Columns in Z	0
24	1	NN1218-4131	Subjects	1
25	1	NN1218-4131	Max Obs per Subject	984

Parameter Code=P9PLC Parameter=PPG lunch (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
26	1	NN1218-4131	Covariance Parameters	1
27	1	NN1218-4131	Columns in X	10
28	1	NN1218-4131	Columns in Z	0
29	1	NN1218-4131	Subjects	1
30	1	NN1218-4131	Max Obs per Subject	984

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

The Mixed procedure
Dimensions

Parameter Code=P9PPRAN Parameter=PPG all meals (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
31	1	NN1218-4131	Covariance Parameters	1
32	1	NN1218-4131	Columns in X	10
33	1	NN1218-4131	Columns in Z	0
34	1	NN1218-4131	Subjects	1
35	1	NN1218-4131	Max Obs per Subject	977

Parameter Code=P9PPRANC Parameter=PPG all meals (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
36	1	NN1218-4131	Covariance Parameters	1
37	1	NN1218-4131	Columns in X	10
38	1	NN1218-4131	Columns in Z	0
39	1	NN1218-4131	Subjects	1
40	1	NN1218-4131	Max Obs per Subject	977

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

The Mixed procedure
Number of Observations

Parameter Code=P9PB Parameter=PPG breakfast (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
1	1	NN1218-4131	Number of Observations Read	986	986	986	986	986
2	1	NN1218-4131	Number of Observations Used	986	986	986	986	986
3	1	NN1218-4131	Number of Observations Not Used	0	986	986	986	986

Parameter Code=P9PEV Parameter=PPG main evening meal (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
4	1	NN1218-4131	Number of Observations Read	981	981	981	981	981
5	1	NN1218-4131	Number of Observations Used	981	981	981	981	981
6	1	NN1218-4131	Number of Observations Not Used	0	981	981	981	981

Parameter Code=P9PEVC Parameter=PPG main evening meal (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
7	1	NN1218-4131	Number of Observations Read	981	981	981	981	981
8	1	NN1218-4131	Number of Observations Used	981	981	981	981	981
9	1	NN1218-4131	Number of Observations Not Used	0	981	981	981	981

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

The Mixed procedure
Number of Observations

Parameter Code=P9PGBC Parameter=PPG breakfast (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
10	1	NN1218-4131	Number of Observations Read	986	986	986	986	986
11	1	NN1218-4131	Number of Observations Used	986	986	986	986	986
12	1	NN1218-4131	Number of Observations Not Used	0	986	986	986	986

Parameter Code=P9PL Parameter=PPG lunch (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
13	1	NN1218-4131	Number of Observations Read	984	984	984	984	984
14	1	NN1218-4131	Number of Observations Used	984	984	984	984	984
15	1	NN1218-4131	Number of Observations Not Used	0	984	984	984	984

Parameter Code=P9PLC Parameter=PPG lunch (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
16	1	NN1218-4131	Number of Observations Read	984	984	984	984	984
17	1	NN1218-4131	Number of Observations Used	984	984	984	984	984
18	1	NN1218-4131	Number of Observations Not Used	0	984	984	984	984

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
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The Mixed procedure
Number of Observations

Parameter Code=P9PPRAN Parameter=PPG all meals (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
19	1	NN1218-4131	Number of Observations Read	977	977	977	977	977
20	1	NN1218-4131	Number of Observations Used	977	977	977	977	977
21	1	NN1218-4131	Number of Observations Not Used	0	977	977	977	977

Parameter Code=P9PPRANC Parameter=PPG all meals (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
22	1	NN1218-4131	Number of Observations Read	977	977	977	977	977
23	1	NN1218-4131	Number of Observations Used	977	977	977	977	977
24	1	NN1218-4131	Number of Observations Not Used	0	977	977	977	977

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
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The Mixed procedure
Covariance Parameter Estimates

Parameter Code=P9PB Parameter=PPG breakfast (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	CovParm	Estimate
1	1	NN1218-4131	Residual	6.8505

Parameter Code=P9PEV Parameter=PPG main evening meal (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	CovParm	Estimate
20001	1	NN1218-4131	Residual	7.1747

Parameter Code=P9PEVC Parameter=PPG main evening meal (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	CovParm	Estimate
40001	1	NN1218-4131	Residual	2329.78

Parameter Code=P9PGBC Parameter=PPG breakfast (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	CovParm	Estimate
60001	1	NN1218-4131	Residual	2224.50

Parameter Code=P9PL Parameter=PPG lunch (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	CovParm	Estimate
80001	1	NN1218-4131	Residual	5.6759

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
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The Mixed procedure
Covariance Parameter Estimates

Parameter Code=P9PLC Parameter=PPG lunch (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	CovParm	Estimate
100001	1	NN1218-4131	Residual	1843.07

Parameter Code=P9PPRAN Parameter=PPG all meals (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	CovParm	Estimate
120001	1	NN1218-4131	Residual	3.3166

Parameter Code=P9PPRANC Parameter=PPG all meals (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	CovParm	Estimate
140001	1	NN1218-4131	Residual	1076.97

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The Mixed procedure
Fit Statistics

Parameter Code=P9PB Parameter=PPG breakfast (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	-2 Res Log Likelihood	4704.0
2	1	NN1218-4131	AIC (Smaller is Better)	4706.0
3	1	NN1218-4131	AICC (Smaller is Better)	4706.0
4	1	NN1218-4131	BIC (Smaller is Better)	4710.9

Parameter Code=P9PEV Parameter=PPG main evening meal (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
5	1	NN1218-4131	-2 Res Log Likelihood	4725.2
6	1	NN1218-4131	AIC (Smaller is Better)	4727.2
7	1	NN1218-4131	AICC (Smaller is Better)	4727.2
8	1	NN1218-4131	BIC (Smaller is Better)	4732.1

Parameter Code=P9PEVC Parameter=PPG main evening meal (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
9	1	NN1218-4131	-2 Res Log Likelihood	10357.8
10	1	NN1218-4131	AIC (Smaller is Better)	10359.8
11	1	NN1218-4131	AICC (Smaller is Better)	10359.8
12	1	NN1218-4131	BIC (Smaller is Better)	10364.7

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
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The Mixed procedure
Fit Statistics

Parameter Code=P9PGBC Parameter=PPG breakfast (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
13	1	NN1218-4131	-2 Res Log Likelihood	10365.5
14	1	NN1218-4131	AIC (Smaller is Better)	10367.5
15	1	NN1218-4131	AICC (Smaller is Better)	10367.6
16	1	NN1218-4131	BIC (Smaller is Better)	10372.4

Parameter Code=P9PL Parameter=PPG lunch (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
17	1	NN1218-4131	-2 Res Log Likelihood	4510.8
18	1	NN1218-4131	AIC (Smaller is Better)	4512.8
19	1	NN1218-4131	AICC (Smaller is Better)	4512.8
20	1	NN1218-4131	BIC (Smaller is Better)	4517.7

Parameter Code=P9PLC Parameter=PPG lunch (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
21	1	NN1218-4131	-2 Res Log Likelihood	10160.8
22	1	NN1218-4131	AIC (Smaller is Better)	10162.8
23	1	NN1218-4131	AICC (Smaller is Better)	10162.8
24	1	NN1218-4131	BIC (Smaller is Better)	10167.6

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
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The Mixed procedure
Fit Statistics

Parameter Code=P9PPRAN Parameter=PPG all meals (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
25	1	NN1218-4131	-2 Res Log Likelihood	3957.6
26	1	NN1218-4131	AIC (Smaller is Better)	3959.6
27	1	NN1218-4131	AICC (Smaller is Better)	3959.6
28	1	NN1218-4131	BIC (Smaller is Better)	3964.5

Parameter Code=P9PPRANC Parameter=PPG all meals (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
29	1	NN1218-4131	-2 Res Log Likelihood	9567.1
30	1	NN1218-4131	AIC (Smaller is Better)	9569.1
31	1	NN1218-4131	AICC (Smaller is Better)	9569.1
32	1	NN1218-4131	BIC (Smaller is Better)	9573.9

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- on-treatment - full analysis set

The Mixed procedure
Solution for Fixed Effects

Parameter Code=P9PB Parameter=PPG breakfast (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1			
1	1	NN1218-4131	TRTPN	2					
2	1	NN1218-4131	TRTPN	3					
3	1	NN1218-4131	TRTPN	4					
4	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)				
5	1	NN1218-4131	REGION1	—	EUROPE				
6	1	NN1218-4131	REGION1	—	JAPAN				
7	1	NN1218-4131	REGION1	—	NORTH AMERICA				
8	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)			
9	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY			
10	1	NN1218-4131	BASE	—					
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper	
1	6.0802	0.3516	978	17.29	<.0001	0.05	5.3902	6.7702	
2	6.7812	0.3523	978	19.25	<.0001	0.05	6.0899	7.4724	
3	6.3861	0.3485	978	18.32	<.0001	0.05	5.7022	7.0700	
4	-0.2715	0.3060	978	-0.89	0.3751	0.05	-0.8720	0.3289	
5	-0.3485	0.2174	978	-1.60	0.1092	0.05	-0.7751	0.07808	
6	0.7675	0.2430	978	3.16	0.0016	0.05	0.2907	1.2444	
7	0	
8	-0.5750	0.1892	978	-3.04	0.0024	0.05	-0.9463	-0.2037	
9	0	
10	-0.6605	0.02864	978	-23.06	<.0001	0.05	-0.7167	-0.6043	

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The Mixed procedure
Solution for Fixed Effects

Parameter Code=P9PEV Parameter=PPG main evening meal (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
11	1	NN1218-4131	TRTPN	2				
12	1	NN1218-4131	TRTPN	3				
13	1	NN1218-4131	TRTPN	4				
14	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
15	1	NN1218-4131	REGION1	—	EUROPE			
16	1	NN1218-4131	REGION1	—	JAPAN			
17	1	NN1218-4131	REGION1	—	NORTH AMERICA			
18	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
19	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
20	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
11	6.9668	0.3520	973	19.79	<.0001	0.05	6.2761	7.6575
12	7.6392	0.3601	973	21.21	<.0001	0.05	6.9326	8.3458
13	7.1439	0.3497	973	20.43	<.0001	0.05	6.4576	7.8302
14	-0.7641	0.3143	973	-2.43	0.0152	0.05	-1.3810	-0.1473
15	-0.7760	0.2234	973	-3.47	0.0005	0.05	-1.2144	-0.3376
16	0.1366	0.2475	973	0.55	0.5812	0.05	-0.3492	0.6224
17	0
18	-0.3815	0.1937	973	-1.97	0.0492	0.05	-0.7615	-0.00139
19	0
20	-0.7280	0.02908	973	-25.03	<.0001	0.05	-0.7850	-0.6709

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NN1218-4131

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- on-treatment - full analysis set

The Mixed procedure
Solution for Fixed Effects

Parameter Code=P9PEVC Parameter=PPG main evening meal (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
21	1	NN1218-4131	TRTPN	2				
22	1	NN1218-4131	TRTPN	3				
23	1	NN1218-4131	TRTPN	4				
24	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
25	1	NN1218-4131	REGION1	—	EUROPE			
26	1	NN1218-4131	REGION1	—	JAPAN			
27	1	NN1218-4131	REGION1	—	NORTH AMERICA			
28	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
29	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
30	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
21	125.54	6.3423	973	19.79	<.0001	0.05	113.10	137.99
22	137.66	6.4888	973	21.21	<.0001	0.05	124.92	150.39
23	128.73	6.3019	973	20.43	<.0001	0.05	116.37	141.10
24	-13.7698	5.6645	973	-2.43	0.0152	0.05	-24.8857	-2.6538
25	-13.9829	4.0256	973	-3.47	0.0005	0.05	-21.8827	-6.0831
26	2.4616	4.4606	973	0.55	0.5812	0.05	-6.2919	11.2151
27	0
28	-6.8740	3.4901	973	-1.97	0.0492	0.05	-13.7229	-0.02511
29	0
30	-0.7280	0.02908	973	-25.03	<.0001	0.05	-0.7850	-0.6709

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The Mixed procedure
Solution for Fixed Effects

Parameter Code=P9PGBC Parameter=PPG breakfast (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
31	1	NN1218-4131	TRTPN	2				
32	1	NN1218-4131	TRTPN	3				
33	1	NN1218-4131	TRTPN	4				
34	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
35	1	NN1218-4131	REGION1	—	EUROPE			
36	1	NN1218-4131	REGION1	—	JAPAN			
37	1	NN1218-4131	REGION1	—	NORTH AMERICA			
38	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
39	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
40	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
31	109.56	6.3359	978	17.29	<.0001	0.05	97.1312	122.00
32	122.20	6.3478	978	19.25	<.0001	0.05	109.74	134.65
33	115.08	6.2800	978	18.32	<.0001	0.05	102.75	127.40
34	-4.8930	5.5139	978	-0.89	0.3751	0.05	-15.7134	5.9273
35	-6.2804	3.9174	978	-1.60	0.1092	0.05	-13.9679	1.4071
36	13.8310	4.3790	978	3.16	0.0016	0.05	5.2377	22.4243
37	0
38	-10.3620	3.4096	978	-3.04	0.0024	0.05	-17.0530	-3.6710
39	0
40	-0.6605	0.02864	978	-23.06	<.0001	0.05	-0.7167	-0.6043

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The Mixed procedure
Solution for Fixed Effects

Parameter Code=P9PL Parameter=PPG lunch (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
41	1	NN1218-4131	TRTPN	2				
42	1	NN1218-4131	TRTPN	3				
43	1	NN1218-4131	TRTPN	4				
44	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
45	1	NN1218-4131	REGION1	—	EUROPE			
46	1	NN1218-4131	REGION1	—	JAPAN			
47	1	NN1218-4131	REGION1	—	NORTH AMERICA			
48	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
49	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
50	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
41	6.4937	0.3157	976	20.57	<.0001	0.05	5.8742	7.1131
42	6.9998	0.3136	976	22.32	<.0001	0.05	6.3843	7.6153
43	6.6377	0.3171	976	20.94	<.0001	0.05	6.0155	7.2599
44	-0.04701	0.2784	976	-0.17	0.8660	0.05	-0.5934	0.4994
45	-0.3968	0.1981	976	-2.00	0.0454	0.05	-0.7855	-0.00814
46	0.9443	0.2240	976	4.21	<.0001	0.05	0.5046	1.3839
47	0
48	-0.5868	0.1717	976	-3.42	0.0007	0.05	-0.9237	-0.2499
49	0
50	-0.7186	0.02731	976	-26.31	<.0001	0.05	-0.7722	-0.6650

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The Mixed procedure
Solution for Fixed Effects

Parameter Code=P9PLC Parameter=PPG lunch (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1			BOLAD1
51	1	NN1218-4131	TRTPN	2				
52	1	NN1218-4131	TRTPN	3				
53	1	NN1218-4131	TRTPN	4				
54	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
55	1	NN1218-4131	REGION1	—	EUROPE			
56	1	NN1218-4131	REGION1	—	JAPAN			
57	1	NN1218-4131	REGION1	—	NORTH AMERICA			
58	1	NN1218-4131	BOLAD1	—				BOLUS INSULIN ALGORITHM (SLIDING SCALE)
59	1	NN1218-4131	BOLAD1	—				CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY
60	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
51	117.02	5.6883	976	20.57	<.0001	0.05	105.85	128.18
52	126.14	5.6518	976	22.32	<.0001	0.05	115.04	137.23
53	119.61	5.7134	976	20.94	<.0001	0.05	108.40	130.82
54	-0.8471	5.0173	976	-0.17	0.8660	0.05	-10.6931	8.9988
55	-7.1511	3.5693	976	-2.00	0.0454	0.05	-14.1555	-0.1468
56	17.0160	4.0373	976	4.21	<.0001	0.05	9.0932	24.9387
57	0
58	-10.5742	3.0934	976	-3.42	0.0007	0.05	-16.6447	-4.5036
59	0
60	-0.7186	0.02731	976	-26.31	<.0001	0.05	-0.7722	-0.6650

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The Mixed procedure
Solution for Fixed Effects

Parameter Code=P9PPRAN Parameter=PPG all meals (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1
61	1	NN1218-4131	TRTPN	2		
62	1	NN1218-4131	TRTPN	3		
63	1	NN1218-4131	TRTPN	4		
64	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)	
65	1	NN1218-4131	REGION1	—	EUROPE	
66	1	NN1218-4131	REGION1	—	JAPAN	
67	1	NN1218-4131	REGION1	—	NORTH AMERICA	
68	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)
69	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY
70	1	NN1218-4131	BASE	—		

Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
61	5.6759	0.2988	969	19.00	<.0001	0.05	5.0895	6.2623
62	6.2755	0.3003	969	20.90	<.0001	0.05	5.6862	6.8648
63	5.9365	0.2966	969	20.01	<.0001	0.05	5.3544	6.5186
64	-0.3101	0.2134	969	-1.45	0.1466	0.05	-0.7290	0.1088
65	-0.3691	0.1521	969	-2.43	0.0154	0.05	-0.6676	-0.07062
66	0.6167	0.1706	969	3.61	0.0003	0.05	0.2819	0.9515
67	0
68	-0.4902	0.1322	969	-3.71	0.0002	0.05	-0.7496	-0.2309
69	0
70	-0.6221	0.02709	969	-22.97	<.0001	0.05	-0.6753	-0.5689

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The Mixed procedure
Solution for Fixed Effects

Parameter Code=P9PPRANC Parameter=PPG all meals (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1			BOLAD1
71	1	NN1218-4131	TRTPN	2				
72	1	NN1218-4131	TRTPN	3				
73	1	NN1218-4131	TRTPN	4				
74	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
75	1	NN1218-4131	REGION1	—	EUROPE			
76	1	NN1218-4131	REGION1	—	JAPAN			
77	1	NN1218-4131	REGION1	—	NORTH AMERICA			
78	1	NN1218-4131	BOLAD1	—				BOLUS INSULIN ALGORITHM (SLIDING SCALE)
79	1	NN1218-4131	BOLAD1	—				CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY
80	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
71	102.28	5.3845	969	19.00	<.0001	0.05	91.7126	112.85
72	113.08	5.4109	969	20.90	<.0001	0.05	102.47	123.70
73	106.98	5.3453	969	20.01	<.0001	0.05	96.4856	117.47
74	-5.5881	3.8462	969	-1.45	0.1466	0.05	-13.1360	1.9598
75	-6.6517	2.7410	969	-2.43	0.0154	0.05	-12.0307	-1.2726
76	11.1124	3.0743	969	3.61	0.0003	0.05	5.0793	17.1455
77	0
78	-8.8341	2.3815	969	-3.71	0.0002	0.05	-13.5076	-4.1607
79	0
80	-0.6221	0.02709	969	-22.97	<.0001	0.05	-0.6753	-0.5689

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
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The Mixed procedure
Least Squares Means

Obs	_Imputation_	PARAMCD	PARAM	STUDYID	Effect	TRTPN
1	1	P9PB	PPG breakfast (SMPG) (mmol/L)	NN1218-4131	TRTPN	2
2	1	P9PB	PPG breakfast (SMPG) (mmol/L)	NN1218-4131	TRTPN	3
3	1	P9PB	PPG breakfast (SMPG) (mmol/L)	NN1218-4131	TRTPN	4
4	1	P9PEV	PPG main evening meal (SMPG) (mmol/L)	NN1218-4131	TRTPN	2
5	1	P9PEV	PPG main evening meal (SMPG) (mmol/L)	NN1218-4131	TRTPN	3
6	1	P9PEV	PPG main evening meal (SMPG) (mmol/L)	NN1218-4131	TRTPN	4
7	1	P9PEVC	PPG main evening meal (SMPG) (mg/dL)	NN1218-4131	TRTPN	2
8	1	P9PEVC	PPG main evening meal (SMPG) (mg/dL)	NN1218-4131	TRTPN	3
9	1	P9PEVC	PPG main evening meal (SMPG) (mg/dL)	NN1218-4131	TRTPN	4
10	1	P9PGBC	PPG breakfast (SMPG) (mg/dL)	NN1218-4131	TRTPN	2
11	1	P9PGBC	PPG breakfast (SMPG) (mg/dL)	NN1218-4131	TRTPN	3
12	1	P9PGBC	PPG breakfast (SMPG) (mg/dL)	NN1218-4131	TRTPN	4
13	1	P9PL	PPG lunch (SMPG) (mmol/L)	NN1218-4131	TRTPN	2
14	1	P9PL	PPG lunch (SMPG) (mmol/L)	NN1218-4131	TRTPN	3

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	WORK.IMPUTE	-0.6892	0.1452	978	-4.75	<.0001	0.05	-0.9740	-0.4043
2	WORK.IMPUTE	0.01183	0.1440	978	0.08	0.9345	0.05	-0.2707	0.2944
3	WORK.IMPUTE	-0.3833	0.1445	978	-2.65	0.0081	0.05	-0.6667	-0.09980
4	WORK.IMPUTE	-0.5122	0.1486	973	-3.45	0.0006	0.05	-0.8038	-0.2205
5	WORK.IMPUTE	0.1602	0.1484	973	1.08	0.2806	0.05	-0.1310	0.4515
6	WORK.IMPUTE	-0.3350	0.1481	973	-2.26	0.0239	0.05	-0.6257	-0.04432
7	WORK.IMPUTE	-9.2291	2.6777	973	-3.45	0.0006	0.05	-14.4839	-3.9743
8	WORK.IMPUTE	2.8873	2.6745	973	1.08	0.2806	0.05	-2.3611	8.1358
9	WORK.IMPUTE	-6.0372	2.6694	973	-2.26	0.0239	0.05	-11.2757	-0.7986
10	WORK.IMPUTE	-12.4186	2.6160	978	-4.75	<.0001	0.05	-17.5522	-7.2850
11	WORK.IMPUTE	0.2132	2.5948	978	0.08	0.9345	0.05	-4.8788	5.3052
12	WORK.IMPUTE	-6.9065	2.6031	978	-2.65	0.0081	0.05	-12.0148	-1.7983
13	WORK.IMPUTE	-0.5278	0.1320	976	-4.00	<.0001	0.05	-0.7867	-0.2689
14	WORK.IMPUTE	-0.02166	0.1317	976	-0.16	0.8694	0.05	-0.2801	0.2368

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The Mixed procedure
Least Squares Means

Obs	_Imputation_	PARAMCD	PARAM	STUDYID	Effect	TRTPN
15	1	P9PL	PPG lunch (SMPG) (mmol/L)	NN1218-4131	TRTPN	4
16	1	P9PLC	PPG lunch (SMPG) (mg/dL)	NN1218-4131	TRTPN	2
17	1	P9PLC	PPG lunch (SMPG) (mg/dL)	NN1218-4131	TRTPN	3
18	1	P9PLC	PPG lunch (SMPG) (mg/dL)	NN1218-4131	TRTPN	4
19	1	P9PPRAN	PPG all meals (SMPG) (mmol/L)	NN1218-4131	TRTPN	2
20	1	P9PPRAN	PPG all meals (SMPG) (mmol/L)	NN1218-4131	TRTPN	3
21	1	P9PPRAN	PPG all meals (SMPG) (mmol/L)	NN1218-4131	TRTPN	4
22	1	P9PPRANC	PPG all meals (SMPG) (mg/dL)	NN1218-4131	TRTPN	2
23	1	P9PPRANC	PPG all meals (SMPG) (mg/dL)	NN1218-4131	TRTPN	3
24	1	P9PPRANC	PPG all meals (SMPG) (mg/dL)	NN1218-4131	TRTPN	4

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
15	WORK.IMPUTE	-0.3838	0.1315	976	-2.92	0.0036	0.05	-0.6417	-0.1258
16	WORK.IMPUTE	-9.5109	2.3778	976	-4.00	<.0001	0.05	-14.1770	-4.8447
17	WORK.IMPUTE	-0.3904	2.3732	976	-0.16	0.8694	0.05	-5.0475	4.2667
18	WORK.IMPUTE	-6.9155	2.3689	976	-2.92	0.0036	0.05	-11.5642	-2.2668
19	WORK.IMPUTE	-0.5768	0.1013	969	-5.69	<.0001	0.05	-0.7757	-0.3780
20	WORK.IMPUTE	0.02280	0.1011	969	0.23	0.8216	0.05	-0.1756	0.2212
21	WORK.IMPUTE	-0.3162	0.1007	969	-3.14	0.0017	0.05	-0.5138	-0.1187
22	WORK.IMPUTE	-10.3943	1.8261	969	-5.69	<.0001	0.05	-13.9778	-6.8108
23	WORK.IMPUTE	0.4109	1.8221	969	0.23	0.8216	0.05	-3.1648	3.9867
24	WORK.IMPUTE	-5.6983	1.8140	969	-3.14	0.0017	0.05	-9.2580	-2.1386

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The Mixed procedure
Least Squares Means Estimate

Parameter Code=P9PB Parameter=PPG breakfast (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
1	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
2	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	WORK.IMPUTE	-0.3059	0.2050	978	-1.49	0.1359	0.05	-0.7081	0.09632
2	WORK.IMPUTE	0.3951	0.2040	978	1.94	0.0531	0.05	-0.00527	0.7955

Parameter Code=P9PEV Parameter=PPG main evening meal (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
3	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
4	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
3	WORK.IMPUTE	-0.1771	0.2100	973	-0.84	0.3991	0.05	-0.5892	0.2349
4	WORK.IMPUTE	0.4953	0.2099	973	2.36	0.0185	0.05	0.08335	0.9072

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
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The Mixed procedure
Least Squares Means Estimate

Parameter Code=P9PEVC Parameter=PPG main evening meal (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label				
5	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)				
6	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)				

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
5	WORK.IMPUTE	-3.1920	3.7835	973	-0.84	0.3991	0.05	-10.6167	4.2328
6	WORK.IMPUTE	8.9245	3.7824	973	2.36	0.0185	0.05	1.5019	16.3471

Parameter Code=P9PGBC Parameter=PPG breakfast (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label				
7	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)				
8	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)				

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
7	WORK.IMPUTE	-5.5121	3.6934	978	-1.49	0.1359	0.05	-12.7599	1.7357
8	WORK.IMPUTE	7.1198	3.6765	978	1.94	0.0531	0.05	-0.09489	14.3344

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

The Mixed procedure
Least Squares Means Estimate

Parameter Code=P9PL Parameter=PPG lunch (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
9	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
10	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
9	WORK.IMPUTE	-0.1440	0.1864	976	-0.77	0.4399	0.05	-0.5098	0.2217
10	WORK.IMPUTE	0.3621	0.1861	976	1.95	0.0520	0.05	-0.00314	0.7273

Parameter Code=P9PLC Parameter=PPG lunch (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
11	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
12	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
11	WORK.IMPUTE	-2.5954	3.3586	976	-0.77	0.4399	0.05	-9.1862	3.9955
12	WORK.IMPUTE	6.5251	3.3539	976	1.95	0.0520	0.05	-0.05655	13.1068

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

The Mixed procedure
Least Squares Means Estimate

Parameter Code=P9PPRAN Parameter=PPG all meals (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
13	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
14	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
13	WORK.IMPUTE	-0.2606	0.1430	969	-1.82	0.0686	0.05	-0.5411	0.01993
14	WORK.IMPUTE	0.3390	0.1427	969	2.38	0.0177	0.05	0.05896	0.6191

Parameter Code=P9PPRANC Parameter=PPG all meals (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
15	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
16	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
15	WORK.IMPUTE	-4.6960	2.5760	969	-1.82	0.0686	0.05	-9.7513	0.3592
16	WORK.IMPUTE	6.1092	2.5717	969	2.38	0.0177	0.05	1.0625	11.1560

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2056 of 4425	Novo Nordisk
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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9PB Parameter=PPG breakfast (SMPG) (mmol/L) Study Identifier=NN1218-413

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.001734	0.021034	0.022768	3.45E6	0.082422	0.076146	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.714524	0.150890	-1.01026	-0.41879	3.45E6	-0.876528	-0.548207

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-4.74	<.0001

nn1218/nn1218-4131/ctr_20180214_er
10FEB2018:18:26:18 - a_797pp_stat_diff.sas/a_9pp_ppg_stat_on_fas_app.txt

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9PEV Parameter=PPG main evening meal (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.001641	0.021825	0.023467	4.09E6	0.075210	0.069949	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.512113	0.153189	-0.81236	-0.21187	4.09E6	-0.680158	-0.356281

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-3.34	0.0008

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9PEVC Parameter=PPG main evening meal (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.532994	7.087119	7.620140	4.09E6	0.075210	0.069949	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-9.228280	2.760460	-14.6387	-3.81788	4.09E6	-12.256441	-6.420189

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-3.34	0.0008

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2059 of 4425	Novo Nordisk
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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9PGBC Parameter=PPG breakfast (SMPG) (mg/dL) Study Identifier=NN1218-41

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.562927	6.830174	7.393129	3.45E6	0.082422	0.076146	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-12.875727	2.719031	-18.2049	-7.54652	3.45E6	-15.795030	-9.878692

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-4.74	<.0001

nn1218/nn1218-4131/ctr_20180214_er
10FEB2018:18:26:18 - a_797pp_stat_diff.sas/a_9pp_ppg_stat_on_fas_app.txt

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2060 of 4425	Novo Nordisk
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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9PL Parameter=PPG lunch (SMPG) (mmol/L) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.001266	0.017583	0.018849	4.43E6	0.072021	0.067183	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.529343	0.137293	-0.79843	-0.26025	4.43E6	-0.672012	-0.391929

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-3.86	0.0001

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2061 of 4425	Novo Nordisk
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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9PLC Parameter=PPG lunch (SMPG) (mg/dL) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.411193	5.709594	6.120807	4.43E6	0.072021	0.067183	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-9.538760	2.474026	-14.3878	-4.68976	4.43E6	-12.109648	-7.062558

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-3.86	0.0001

nn1218/nn1218-4131/ctr_20180214_er
10FEB2018:18:26:18 - a_797pp_stat_diff.sas/a_9pp_ppg_stat_on_fas_app.txt

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9PPRAN Parameter=PPG all meals (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000868	0.010305	0.011173	3.32E6	0.084189	0.077653	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.585133	0.105702	-0.79231	-0.37796	3.32E6	-0.708163	-0.461477

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-5.54	<.0001

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9PPRANC Parameter=PPG all meals (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.281713	3.346351	3.628078	3.32E6	0.084189	0.077653	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-10.544101	1.904751	-14.2773	-6.81086	3.32E6	-12.761103	-8.315813

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-5.54	<.0001

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2064 of 4425	Novo Nordisk
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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9PB Parameter=PPG breakfast (SMPG) (mmol/L) Study Identifier=NN1218-413

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.001220	0.020694	0.021915	6.45E6	0.058977	0.055692	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.013599	0.148037	-0.30375	0.276547	6.45E6	-0.141824	0.128105

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-0.09	0.9268

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9PEV Parameter=PPG main evening meal (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.001068	0.021772	0.022840	9.14E6	0.049065	0.046771	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.131069	0.151131	-0.16514	0.427280	9.14E6	-0.000240	0.251116

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	0.87	0.3858

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9PEVC Parameter=PPG main evening meal (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.346869	7.069878	7.416765	9.14E6	0.049065	0.046771	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits	DF	Minimum	Maximum
Estimate	2.361862	2.723374	-2.97585 7.699577	9.14E6	-0.004323	4.525104

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	0.87	0.3858

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2067 of 4425	Novo Nordisk
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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9PGBC Parameter=PPG breakfast (SMPG) (mg/dL) Study Identifier=NN1218-41

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.396297	6.719893	7.116210	6.45E6	0.058977	0.055692	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.245060	2.667623	-5.47351	4.983385	6.45E6	-2.555664	2.308450

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-0.09	0.9268

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2068 of 4425	Novo Nordisk
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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9PL Parameter=PPG lunch (SMPG) (mmol/L) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000932	0.017515	0.018447	7.83E6	0.053241	0.050550	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.039797	0.135821	-0.30600	0.226407	7.83E6	-0.152982	0.079283

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-0.29	0.7695

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2069 of 4425	Novo Nordisk
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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9PLC Parameter=PPG lunch (SMPG) (mg/dL) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.302789	5.687412	5.990217	7.83E6	0.053241	0.050550	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.717137	2.447492	-5.51413	4.079860	7.83E6	-2.756738	1.428673

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-0.29	0.7695

nn1218/nn1218-4131/ctr_20180214_er
10FEB2018:18:26:18 - a_797pp_stat_diff.sas/a_9pp_ppg_stat_on_fas_app.txt

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9PPRAN Parameter=PPG all meals (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000525	0.010261	0.010786	8.45E6	0.051135	0.048648	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.015746	0.103855	-0.18781	0.219298	8.45E6	-0.074433	0.104649

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	0.15	0.8795

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9PPRANC Parameter=PPG all meals (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.170374	3.331994	3.502376	8.45E6	0.051135	0.048648	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.283748	1.871464	-3.38425	3.951750	8.45E6	-1.341287	1.885777

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	0.15	0.8795

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9PB Parameter=PPG breakfast (SMPG) (mmol/L) Study Identifier=NN1218-413

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.001445	0.020827	0.022271	4.75E6	0.069374	0.064874	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.412635	0.149236	-0.70513	-0.12014	4.75E6	-0.565366	-0.267833

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-2.76	0.0057

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9PEV Parameter=PPG main evening meal (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.001463	0.021690	0.023154	5.01E6	0.067467	0.063203	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.282266	0.152163	-0.58050	0.015969	5.01E6	-0.426258	-0.129776

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-1.86	0.0636

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9PEVC Parameter=PPG main evening meal (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.475166	7.043278	7.518469	5.01E6	0.067467	0.063203	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-5.086428	2.741983	-10.4606	0.287761	5.01E6	-7.681174	-2.338572

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-1.86	0.0636

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9PGBC Parameter=PPG breakfast (SMPG) (mg/dL) Study Identifier=NN1218-41

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.469141	6.762793	7.231957	4.75E6	0.069374	0.064874	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-7.435678	2.689230	-12.7065	-2.16488	4.75E6	-10.187895	-4.826357

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-2.76	0.0057

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9PL Parameter=PPG lunch (SMPG) (mmol/L) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.001583	0.017452	0.019036	2.89E6	0.090736	0.083189	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.353775	0.137969	-0.62419	-0.08336	2.89E6	-0.515224	-0.185954

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-2.56	0.0103

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Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2077 of 4425	Novo Nordisk
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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9PLC Parameter=PPG lunch (SMPG) (mg/dL) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.514179	5.667026	6.181230	2.89E6	0.090736	0.083189	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-6.375027	2.486208	-11.2479	-1.50215	2.89E6	-9.284328	-3.350888

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-2.56	0.0103

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9PPRAN Parameter=PPG all meals (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000912	0.010169	0.011082	2.95E6	0.089722	0.082335	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.338373	0.105269	-0.54470	-0.13205	2.95E6	-0.462598	-0.204258

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-3.21	0.0013

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9PPRANC Parameter=PPG all meals (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.296258	3.302126	3.598399	2.95E6	0.089722	0.082335	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-6.097481	1.896945	-9.81543	-2.37954	2.95E6	-8.336011	-3.680726

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-3.21	0.0013

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

Parameter Code=P9PB Label=Faster aspart (meal) - NovoRapid (meal) Parameter=PPG breakfast (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.003250	0.041927	0.045177	3.86E6	0.077513	0.071937	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.301889	0.212548	-0.71848	0.114698	3.86E6	-0.519772	-0.077704

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-1.42	0.1555

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

Parameter Code=P9PB Label=Faster aspart (post) - NovoRapid (meal) Parameter=PPG breakfast (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.002662	0.041544	0.044206	5.52E6	0.064076	0.060218	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.399035	0.210252	-0.01305	0.811123	5.52E6	0.147785	0.619370

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	1.90	0.0577

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

Parameter Code=P9PEV Label=Faster aspart (meal) - NovoRapid (meal) Parameter=PPG main evening meal (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.003132	0.043572	0.046704	4.45E6	0.071879	0.067059	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.229848	0.216111	-0.65342	0.193722	4.45E6	-0.436553	-0.006706

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-1.06	0.2875

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Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2083 of 4425	Novo Nordisk
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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

Parameter Code=P9PEV Label=Faster aspart (post) - NovoRapid (meal) Parameter=PPG main evening meal (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.002545	0.043546	0.046092	6.56E6	0.058446	0.055219	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.413335	0.214689	-0.00745	0.834118	6.56E6	0.220954	0.604061

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	1.93	0.0542

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Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2084 of 4425	Novo Nordisk
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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

Parameter Code=P9PEVC Label=Faster aspart (meal) - NovoRapid (meal) Parameter=PPG main evening meal (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	1.016948	14.148729	15.165728	4.45E6	0.071879	0.067059	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-4.141852	3.894320	-11.7746	3.490876	4.45E6	-7.866691	-0.120844

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-1.06	0.2875

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2085 of 4425	Novo Nordisk
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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

Parameter Code=P9PEVC Label=Faster aspart (post) - NovoRapid (meal) Parameter=PPG main evening meal (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.826402	14.140411	14.966855	6.56E6	0.058446	0.055219	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	7.448289	3.868702	-0.13423	15.03081	6.56E6	3.981594	10.885186

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	1.93	0.0542

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

Parameter Code=P9PGBC Label=Faster aspart (meal) - NovoRapid (meal) Parameter=PPG breakfast (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	1.055246	13.614533	14.669832	3.86E6	0.077513	0.071937	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-5.440048	3.830122	-12.9470	2.066854	3.86E6	-9.366287	-1.400217

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-1.42	0.1555

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

Parameter Code=P9PGBC Label=Faster aspart (post) - NovoRapid (meal) Parameter=PPG breakfast (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.864355	13.490219	14.354618	5.52E6	0.064076	0.060218	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	7.190618	3.788749	-0.23519	14.61643	5.52E6	2.663083	11.161050

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	1.90	0.0577

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

Parameter Code=P9PL Label=Faster aspart (meal) - NovoRapid (meal) Parameter=PPG lunch (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.002866	0.035080	0.037946	3.51E6	0.081705	0.075534	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.175568	0.194797	-0.55736	0.206228	3.51E6	-0.431461	0.022897

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-0.90	0.3674

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

Parameter Code=P9PL Label=Faster aspart (post) - NovoRapid (meal) Parameter=PPG lunch (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.002498	0.034982	0.037481	4.5E6	0.071420	0.066659	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.313978	0.193600	-0.06547	0.693427	4.5E6	0.127796	0.519483

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	1.62	0.1048

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Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2090 of 4425	Novo Nordisk
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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

Parameter Code=P9PLC Label=Faster aspart (meal) - NovoRapid (meal) Parameter=PPG lunch (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.930664	11.391137	12.321847	3.51E6	0.081705	0.075534	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-3.163733	3.510249	-10.0437	3.716231	3.51E6	-7.774927	0.412598

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-0.90	0.3674

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2091 of 4425	Novo Nordisk
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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

Parameter Code=P9PLC Label=Faster aspart (post) - NovoRapid (meal) Parameter=PPG lunch (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.811253	11.359498	12.170791	4.5E6	0.071420	0.066659	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits	DF	Minimum	Maximum
Estimate	5.657890	3.488666	-1.17977 12.49555	4.5E6	2.302891	9.361092

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	1.62	0.1048

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Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2092 of 4425	Novo Nordisk
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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

Parameter Code=P9PPRAN Label=Faster aspart (meal) - NovoRapid (meal) Parameter=PPG all meals (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.001802	0.020509	0.022311	3.06E6	0.087886	0.080786	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.246760	0.149369	-0.53952	0.045997	3.06E6	-0.429635	-0.065256

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-1.65	0.0985

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

Parameter Code=P9PPRAN Label=Faster aspart (post) - NovoRapid (meal) Parameter=PPG all meals (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.001433	0.020440	0.021873	4.66E6	0.070131	0.065535	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.354119	0.147896	0.064248	0.643990	4.66E6	0.178078	0.503628

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	2.39	0.0166

nn1218/nn1218-4131/ctr_20180214_er
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Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2094 of 4425	Novo Nordisk
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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

Parameter Code=P9PPRANC Label=Faster aspart (meal) - NovoRapid (meal) Parameter=PPG all meals (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.585251	6.659577	7.244858	3.06E6	0.087886	0.080786	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-4.446621	2.691627	-9.72212	0.828874	3.06E6	-7.742014	-1.175915

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-1.65	0.0985

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

Parameter Code=P9PPRANC Label=Faster aspart (post) - NovoRapid (meal) Parameter=PPG all meals (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.465449	6.637204	7.102676	4.66E6	0.070131	0.065535	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	6.381229	2.665085	1.157757	11.60470	4.66E6	3.208960	9.075376

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	2.39	0.0166

nn1218/nn1218-4131/ctr_20180214_er
10FEB2018:18:26:18 - a_797pp_stat_diff.sas/a_9pp_ppg_stat_on_fas_app.txt

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NN1218-4131

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The Mixed procedure
Model Information

Parameter Code=P9PB Parameter=PPG breakfast (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Data Set	WORK.IMPUTE_ABS
2	1	NN1218-4131	Dependent Variable	eotVisitAbs
3	1	NN1218-4131	Covariance Structure	Diagonal
4	1	NN1218-4131	Estimation Method	REML
5	1	NN1218-4131	Residual Variance Method	Profile
6	1	NN1218-4131	Fixed Effects SE Method	Model-Based
7	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=P9PEV Parameter=PPG main evening meal (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
8	1	NN1218-4131	Data Set	WORK.IMPUTE_ABS
9	1	NN1218-4131	Dependent Variable	eotVisitAbs
10	1	NN1218-4131	Covariance Structure	Diagonal
11	1	NN1218-4131	Estimation Method	REML
12	1	NN1218-4131	Residual Variance Method	Profile
13	1	NN1218-4131	Fixed Effects SE Method	Model-Based
14	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=P9PEVC Parameter=PPG main evening meal (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
15	1	NN1218-4131	Data Set	WORK.IMPUTE_ABS
16	1	NN1218-4131	Dependent Variable	eotVisitAbs
17	1	NN1218-4131	Covariance Structure	Diagonal

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10FEB2018:18:26:18 - a_797pp_stat_diff.sas/a_9pp_ppg_stat_on_fas_app.txt

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
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The Mixed procedure
Model Information

Parameter Code=P9PEVC Parameter=PPG main evening meal (SMPG) (mg/dL)

(continued)

Obs	_Imputation_	STUDYID	Descr	Value
18	1	NN1218-4131	Estimation Method	REML
19	1	NN1218-4131	Residual Variance Method	Profile
20	1	NN1218-4131	Fixed Effects SE Method	Model-Based
21	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=P9PGBC Parameter=PPG breakfast (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
22	1	NN1218-4131	Data Set	WORK.IMPUTE_ABS
23	1	NN1218-4131	Dependent Variable	eotVisitAbs
24	1	NN1218-4131	Covariance Structure	Diagonal
25	1	NN1218-4131	Estimation Method	REML
26	1	NN1218-4131	Residual Variance Method	Profile
27	1	NN1218-4131	Fixed Effects SE Method	Model-Based
28	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=P9PL Parameter=PPG lunch (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
29	1	NN1218-4131	Data Set	WORK.IMPUTE_ABS
30	1	NN1218-4131	Dependent Variable	eotVisitAbs
31	1	NN1218-4131	Covariance Structure	Diagonal
32	1	NN1218-4131	Estimation Method	REML

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The Mixed procedure
Model Information

Parameter Code=P9PL Parameter=PPG lunch (SMPG) (mmol/L)

(continued)

Obs	_Imputation_	STUDYID	Descr	Value
33	1	NN1218-4131	Residual Variance Method	Profile
34	1	NN1218-4131	Fixed Effects SE Method	Model-Based
35	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=P9PLC Parameter=PPG lunch (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
36	1	NN1218-4131	Data Set	WORK.IMPUTE_ABS
37	1	NN1218-4131	Dependent Variable	eotVisitAbs
38	1	NN1218-4131	Covariance Structure	Diagonal
39	1	NN1218-4131	Estimation Method	REML
40	1	NN1218-4131	Residual Variance Method	Profile
41	1	NN1218-4131	Fixed Effects SE Method	Model-Based
42	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=P9PPRAN Parameter=PPG all meals (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
43	1	NN1218-4131	Data Set	WORK.IMPUTE_ABS
44	1	NN1218-4131	Dependent Variable	eotVisitAbs
45	1	NN1218-4131	Covariance Structure	Diagonal
46	1	NN1218-4131	Estimation Method	REML
47	1	NN1218-4131	Residual Variance Method	Profile

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The Mixed procedure
Model Information

Parameter Code=P9PPRAN Parameter=PPG all meals (SMPG) (mmol/L)

(continued)

Obs	_Imputation_	STUDYID	Descr	Value
48	1	NN1218-4131	Fixed Effects SE Method	Model-Based
49	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=P9PPRANC Parameter=PPG all meals (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
50	1	NN1218-4131	Data Set	WORK.IMPUTE_ABS
51	1	NN1218-4131	Dependent Variable	eotVisitAbs
52	1	NN1218-4131	Covariance Structure	Diagonal
53	1	NN1218-4131	Estimation Method	REML
54	1	NN1218-4131	Residual Variance Method	Profile
55	1	NN1218-4131	Fixed Effects SE Method	Model-Based
56	1	NN1218-4131	Degrees of Freedom Method	Residual

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The Mixed procedure
Class Level Information

Parameter Code=P9PB Parameter=PPG breakfast (SMPG) (mmol/L)

O b s		I n s		D		Y		I		D		S		U		D		C		l		a		s		s		L		e		v		e		l		u		e		s		V		a		l		e		g		t		h		m		i		n		l		e		g		t		h		5		49		85	
1	1	NN1218-4131	TRTPN	3	2	3	4	4	ASIA (EXCLUDING JAPAN)	EUROPE	JAPAN	NORTH AMERICA	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	CARBOHYDRATE COUNTING (FLEXIBLE)	BOLUS INSULI	85																																																														
2	1	NN1218-4131	REGION1	4	ASIA (EXCLUDING JAPAN)	EUROPE	JAPAN	NORTH AMERICA	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	CARBOHYDRATE COUNTING (FLEXIBLE)	BOLUS INSULI	85																																																																		
3	1	NN1218-4131	BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	CARBOHYDRATE COUNTING (FLEXIBLE)	BOLUS INSULI	85																																																																							

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Class Level Information

Parameter Code=P9PEV Parameter=PPG main evening meal (SMPG) (mmol/L)

Ob- s	—	Input ID	STUDY	Class	Level	Values	Unit
4	1	NN1218-4131	TRTPN		3 2 3 4		5
5	1	NN1218-4131	REGION1		4 ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA		49
6	1	NN1218-4131	BOLAD1		2 BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULI		85

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Class Level Information

Parameter Code=P9PEVC Parameter=PPG main evening meal (SMPG) (mg/dL)

Object	Input	STUDY ID	Classes	Levels	Values	min
7	1	NN1218-4131	TRTPN	3 2 3 4		5
8	1	NN1218-4131	REGION1	4 ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA		49
9	1	NN1218-4131	BOLAD1	2 BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULI		85

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The Mixed procedure
Class Level Information

Parameter Code=P9PGBC Parameter=PPG breakfast (SMPG) (mg/dL)

O b s		I m p u t a t i o n s		S t a t i s t i c s		L e v e l s		V a r i a t i o n s		m i n	
10	1	NN1218-4131	TRTPN	3	2	3	4			5	
11	1	NN1218-4131	REGION1	4	ASIA (EXCLUDING JAPAN)	EUROPE	JAPAN	NORTH AMERICA		49	
12	1	NN1218-4131	BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	CARBOHYDRATE COUNTING (FLEXIBLE)	BOLUS INSULI			85	

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The Mixed procedure
Class Level Information

Parameter Code=P9PL Parameter=PPG lunch (SMPG) (mmol/L)

Obs	Inpution	STUDY ID	Classs	Level	Values	min
13	1	NN1218-4131	TRTPN	3 2 3 4		5
14	1	NN1218-4131	REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA	49
15	1	NN1218-4131	BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULI	85

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The Mixed procedure
Class Level Information

Parameter Code=P9PLC Parameter=PPG lunch (SMPG) (mg/dL)

O b s _		I m p u t a t i o n s		S T U D Y I D		C l a s s e s		L e v e l s		V a r i a b l e s		m i n	
16	1	NN1218-4131	TRTPN			3	2	3	4			5	
17	1	NN1218-4131	REGION1			4	ASIA (EXCLUDING JAPAN)	EUROPE	JAPAN	NORTH AMERICA		49	
18	1	NN1218-4131	BOLAD1			2	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	CARBOHYDRATE COUNTING (FLEXIBLE)	BOLUS INSULI			85	

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The Mixed procedure
Class Level Information

Parameter Code=P9PPRAN Parameter=PPG all meals (SMPG) (mmol/L)

O b s _		I m p u t a t i o n s		S T U D Y I D		C l a s s e s		L e v e l s		V a r i a b l e s		m i n i m a l e g t h	
19	1	NN1218-4131	TRTPN			3	2	3	4			5	
20	1	NN1218-4131	REGION1			4	ASIA (EXCLUDING JAPAN)	EUROPE	JAPAN	NORTH AMERICA		49	
21	1	NN1218-4131	BOLAD1			2	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	CARBOHYDRATE COUNTING (FLEXIBLE)	BOLUS INSULI		85		

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The Mixed procedure
Class Level Information

Parameter Code=P9PPRANC Parameter=PPG all meals (SMPG) (mg/dL)

O b s		I n		S t u d y		C l i n i c a l		L e v e l s		V a r i a b l e s		m i n	
22	1	NN1218-4131	TRTPN	3	2	3	4					5	
23	1	NN1218-4131	REGION1	4	ASIA (EXCLUDING JAPAN)	EUROPE	JAPAN	NORTH AMERICA				49	
24	1	NN1218-4131	BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	CARBOHYDRATE COUNTING (FLEXIBLE)	BOLUS INSULI	85					

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The Mixed procedure
Dimensions

Parameter Code=P9PB Parameter=PPG breakfast (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Covariance Parameters	1
2	1	NN1218-4131	Columns in X	10
3	1	NN1218-4131	Columns in Z	0
4	1	NN1218-4131	Subjects	1
5	1	NN1218-4131	Max Obs per Subject	986

Parameter Code=P9PEV Parameter=PPG main evening meal (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
6	1	NN1218-4131	Covariance Parameters	1
7	1	NN1218-4131	Columns in X	10
8	1	NN1218-4131	Columns in Z	0
9	1	NN1218-4131	Subjects	1
10	1	NN1218-4131	Max Obs per Subject	981

Parameter Code=P9PEVC Parameter=PPG main evening meal (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
11	1	NN1218-4131	Covariance Parameters	1
12	1	NN1218-4131	Columns in X	10
13	1	NN1218-4131	Columns in Z	0
14	1	NN1218-4131	Subjects	1
15	1	NN1218-4131	Max Obs per Subject	981

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The Mixed procedure
Dimensions

Parameter Code=P9PGBC Parameter=PPG breakfast (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
16	1	NN1218-4131	Covariance Parameters	1
17	1	NN1218-4131	Columns in X	10
18	1	NN1218-4131	Columns in Z	0
19	1	NN1218-4131	Subjects	1
20	1	NN1218-4131	Max Obs per Subject	986

Parameter Code=P9PL Parameter=PPG lunch (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
21	1	NN1218-4131	Covariance Parameters	1
22	1	NN1218-4131	Columns in X	10
23	1	NN1218-4131	Columns in Z	0
24	1	NN1218-4131	Subjects	1
25	1	NN1218-4131	Max Obs per Subject	984

Parameter Code=P9PLC Parameter=PPG lunch (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
26	1	NN1218-4131	Covariance Parameters	1
27	1	NN1218-4131	Columns in X	10
28	1	NN1218-4131	Columns in Z	0
29	1	NN1218-4131	Subjects	1
30	1	NN1218-4131	Max Obs per Subject	984

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The Mixed procedure
Dimensions

Parameter Code=P9PPRAN Parameter=PPG all meals (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
31	1	NN1218-4131	Covariance Parameters	1
32	1	NN1218-4131	Columns in X	10
33	1	NN1218-4131	Columns in Z	0
34	1	NN1218-4131	Subjects	1
35	1	NN1218-4131	Max Obs per Subject	977

Parameter Code=P9PPRANC Parameter=PPG all meals (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
36	1	NN1218-4131	Covariance Parameters	1
37	1	NN1218-4131	Columns in X	10
38	1	NN1218-4131	Columns in Z	0
39	1	NN1218-4131	Subjects	1
40	1	NN1218-4131	Max Obs per Subject	977

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
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The Mixed procedure
Number of Observations

Parameter Code=P9PB Parameter=PPG breakfast (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
1	1	NN1218-4131	Number of Observations Read	986	986	986	986	986
2	1	NN1218-4131	Number of Observations Used	986	986	986	986	986
3	1	NN1218-4131	Number of Observations Not Used	0	986	986	986	986

Parameter Code=P9PEV Parameter=PPG main evening meal (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
4	1	NN1218-4131	Number of Observations Read	981	981	981	981	981
5	1	NN1218-4131	Number of Observations Used	981	981	981	981	981
6	1	NN1218-4131	Number of Observations Not Used	0	981	981	981	981

Parameter Code=P9PEVC Parameter=PPG main evening meal (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
7	1	NN1218-4131	Number of Observations Read	981	981	981	981	981
8	1	NN1218-4131	Number of Observations Used	981	981	981	981	981
9	1	NN1218-4131	Number of Observations Not Used	0	981	981	981	981

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
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The Mixed procedure
Number of Observations

Parameter Code=P9PGBC Parameter=PPG breakfast (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
10	1	NN1218-4131	Number of Observations Read	986	986	986	986	986
11	1	NN1218-4131	Number of Observations Used	986	986	986	986	986
12	1	NN1218-4131	Number of Observations Not Used	0	986	986	986	986

Parameter Code=P9PL Parameter=PPG lunch (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
13	1	NN1218-4131	Number of Observations Read	984	984	984	984	984
14	1	NN1218-4131	Number of Observations Used	984	984	984	984	984
15	1	NN1218-4131	Number of Observations Not Used	0	984	984	984	984

Parameter Code=P9PLC Parameter=PPG lunch (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
16	1	NN1218-4131	Number of Observations Read	984	984	984	984	984
17	1	NN1218-4131	Number of Observations Used	984	984	984	984	984
18	1	NN1218-4131	Number of Observations Not Used	0	984	984	984	984

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The Mixed procedure
Number of Observations

Parameter Code=P9PPRAN Parameter=PPG all meals (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
19	1	NN1218-4131	Number of Observations Read	977	977	977	977	977
20	1	NN1218-4131	Number of Observations Used	977	977	977	977	977
21	1	NN1218-4131	Number of Observations Not Used	0	977	977	977	977

Parameter Code=P9PPRANC Parameter=PPG all meals (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
22	1	NN1218-4131	Number of Observations Read	977	977	977	977	977
23	1	NN1218-4131	Number of Observations Used	977	977	977	977	977
24	1	NN1218-4131	Number of Observations Not Used	0	977	977	977	977

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The Mixed procedure
Covariance Parameter Estimates

Parameter Code=P9PB Parameter=PPG breakfast (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	CovParm	Estimate
1	1	NN1218-4131	Residual	6.8505

Parameter Code=P9PEV Parameter=PPG main evening meal (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	CovParm	Estimate
20001	1	NN1218-4131	Residual	7.1747

Parameter Code=P9PEVC Parameter=PPG main evening meal (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	CovParm	Estimate
40001	1	NN1218-4131	Residual	2329.78

Parameter Code=P9PGBC Parameter=PPG breakfast (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	CovParm	Estimate
60001	1	NN1218-4131	Residual	2224.50

Parameter Code=P9PL Parameter=PPG lunch (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	CovParm	Estimate
80001	1	NN1218-4131	Residual	5.6759

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The Mixed procedure
Covariance Parameter Estimates

Parameter Code=P9PLC Parameter=PPG lunch (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	CovParm	Estimate
100001	1	NN1218-4131	Residual	1843.07

Parameter Code=P9PPRAN Parameter=PPG all meals (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	CovParm	Estimate
120001	1	NN1218-4131	Residual	3.3166

Parameter Code=P9PPRANC Parameter=PPG all meals (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	CovParm	Estimate
140001	1	NN1218-4131	Residual	1076.97

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The Mixed procedure
Fit Statistics

Parameter Code=P9PB Parameter=PPG breakfast (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	-2 Res Log Likelihood	4704.0
2	1	NN1218-4131	AIC (Smaller is Better)	4706.0
3	1	NN1218-4131	AICC (Smaller is Better)	4706.0
4	1	NN1218-4131	BIC (Smaller is Better)	4710.9

Parameter Code=P9PEV Parameter=PPG main evening meal (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
5	1	NN1218-4131	-2 Res Log Likelihood	4725.2
6	1	NN1218-4131	AIC (Smaller is Better)	4727.2
7	1	NN1218-4131	AICC (Smaller is Better)	4727.2
8	1	NN1218-4131	BIC (Smaller is Better)	4732.1

Parameter Code=P9PEVC Parameter=PPG main evening meal (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
9	1	NN1218-4131	-2 Res Log Likelihood	10357.8
10	1	NN1218-4131	AIC (Smaller is Better)	10359.8
11	1	NN1218-4131	AICC (Smaller is Better)	10359.8
12	1	NN1218-4131	BIC (Smaller is Better)	10364.7

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The Mixed procedure
Fit Statistics

Parameter Code=P9PGBC Parameter=PPG breakfast (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
13	1	NN1218-4131	-2 Res Log Likelihood	10365.5
14	1	NN1218-4131	AIC (Smaller is Better)	10367.5
15	1	NN1218-4131	AICC (Smaller is Better)	10367.6
16	1	NN1218-4131	BIC (Smaller is Better)	10372.4

Parameter Code=P9PL Parameter=PPG lunch (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
17	1	NN1218-4131	-2 Res Log Likelihood	4510.8
18	1	NN1218-4131	AIC (Smaller is Better)	4512.8
19	1	NN1218-4131	AICC (Smaller is Better)	4512.8
20	1	NN1218-4131	BIC (Smaller is Better)	4517.7

Parameter Code=P9PLC Parameter=PPG lunch (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
21	1	NN1218-4131	-2 Res Log Likelihood	10160.8
22	1	NN1218-4131	AIC (Smaller is Better)	10162.8
23	1	NN1218-4131	AICC (Smaller is Better)	10162.8
24	1	NN1218-4131	BIC (Smaller is Better)	10167.6

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The Mixed procedure
Fit Statistics

Parameter Code=P9PPRAN Parameter=PPG all meals (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
25	1	NN1218-4131	-2 Res Log Likelihood	3957.6
26	1	NN1218-4131	AIC (Smaller is Better)	3959.6
27	1	NN1218-4131	AICC (Smaller is Better)	3959.6
28	1	NN1218-4131	BIC (Smaller is Better)	3964.5

Parameter Code=P9PPRANC Parameter=PPG all meals (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
29	1	NN1218-4131	-2 Res Log Likelihood	9567.1
30	1	NN1218-4131	AIC (Smaller is Better)	9569.1
31	1	NN1218-4131	AICC (Smaller is Better)	9569.1
32	1	NN1218-4131	BIC (Smaller is Better)	9573.9

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The Mixed procedure
Solution for Fixed Effects

Parameter Code=P9PB Parameter=PPG breakfast (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1			BOLAD1
1	1	NN1218-4131	TRTPN	2				
2	1	NN1218-4131	TRTPN	3				
3	1	NN1218-4131	TRTPN	4				
4	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
5	1	NN1218-4131	REGION1	—	EUROPE			
6	1	NN1218-4131	REGION1	—	JAPAN			
7	1	NN1218-4131	REGION1	—	NORTH AMERICA			
8	1	NN1218-4131	BOLAD1	—				BOLUS INSULIN ALGORITHM (SLIDING SCALE)
9	1	NN1218-4131	BOLAD1	—				CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY
10	1	NN1218-4131	BASE	—				

Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	6.0802	0.3516	978	17.29	<.0001	0.05	5.3902	6.7702
2	6.7812	0.3523	978	19.25	<.0001	0.05	6.0899	7.4724
3	6.3861	0.3485	978	18.32	<.0001	0.05	5.7022	7.0700
4	-0.2715	0.3060	978	-0.89	0.3751	0.05	-0.8720	0.3289
5	-0.3485	0.2174	978	-1.60	0.1092	0.05	-0.7751	0.07808
6	0.7675	0.2430	978	3.16	0.0016	0.05	0.2907	1.2444
7	0
8	-0.5750	0.1892	978	-3.04	0.0024	0.05	-0.9463	-0.2037
9	0
10	0.3395	0.02864	978	11.85	<.0001	0.05	0.2833	0.3957

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The Mixed procedure
Solution for Fixed Effects

Parameter Code=P9PEV Parameter=PPG main evening meal (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1				BOLAD1
11	1	NN1218-4131	TRTPN	2					
12	1	NN1218-4131	TRTPN	3					
13	1	NN1218-4131	TRTPN	4					
14	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)				
15	1	NN1218-4131	REGION1	—	EUROPE				
16	1	NN1218-4131	REGION1	—	JAPAN				
17	1	NN1218-4131	REGION1	—	NORTH AMERICA				
18	1	NN1218-4131	BOLAD1	—					BOLUS INSULIN ALGORITHM (SLIDING SCALE)
19	1	NN1218-4131	BOLAD1	—					CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY
20	1	NN1218-4131	BASE	—					
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper	
11	6.9668	0.3520	973	19.79	<.0001	0.05	6.2761	7.6575	
12	7.6392	0.3601	973	21.21	<.0001	0.05	6.9326	8.3458	
13	7.1439	0.3497	973	20.43	<.0001	0.05	6.4576	7.8302	
14	-0.7641	0.3143	973	-2.43	0.0152	0.05	-1.3810	-0.1473	
15	-0.7760	0.2234	973	-3.47	0.0005	0.05	-1.2144	-0.3376	
16	0.1366	0.2475	973	0.55	0.5812	0.05	-0.3492	0.6224	
17	0	
18	-0.3815	0.1937	973	-1.97	0.0492	0.05	-0.7615	-0.00139	
19	0	
20	0.2720	0.02908	973	9.36	<.0001	0.05	0.2150	0.3291	

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The Mixed procedure
Solution for Fixed Effects

Parameter Code=P9PEVC Parameter=PPG main evening meal (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1			BOLAD1
21	1	NN1218-4131	TRTPN	2				
22	1	NN1218-4131	TRTPN	3				
23	1	NN1218-4131	TRTPN	4				
24	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
25	1	NN1218-4131	REGION1	—	EUROPE			
26	1	NN1218-4131	REGION1	—	JAPAN			
27	1	NN1218-4131	REGION1	—	NORTH AMERICA			
28	1	NN1218-4131	BOLAD1	—				BOLUS INSULIN ALGORITHM (SLIDING SCALE)
29	1	NN1218-4131	BOLAD1	—				CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY
30	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
21	125.54	6.3423	973	19.79	<.0001	0.05	113.10	137.99
22	137.66	6.4888	973	21.21	<.0001	0.05	124.92	150.39
23	128.73	6.3019	973	20.43	<.0001	0.05	116.37	141.10
24	-13.7698	5.6645	973	-2.43	0.0152	0.05	-24.8857	-2.6538
25	-13.9829	4.0256	973	-3.47	0.0005	0.05	-21.8827	-6.0831
26	2.4616	4.4606	973	0.55	0.5812	0.05	-6.2919	11.2151
27	0
28	-6.8740	3.4901	973	-1.97	0.0492	0.05	-13.7229	-0.02511
29	0
30	0.2720	0.02908	973	9.36	<.0001	0.05	0.2150	0.3291

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The Mixed procedure
Solution for Fixed Effects

Parameter Code=P9PGBC Parameter=PPG breakfast (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
31	1	NN1218-4131	TRTPN	2				
32	1	NN1218-4131	TRTPN	3				
33	1	NN1218-4131	TRTPN	4				
34	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
35	1	NN1218-4131	REGION1	—	EUROPE			
36	1	NN1218-4131	REGION1	—	JAPAN			
37	1	NN1218-4131	REGION1	—	NORTH AMERICA			
38	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
39	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
40	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
31	109.56	6.3359	978	17.29	<.0001	0.05	97.1312	122.00
32	122.20	6.3478	978	19.25	<.0001	0.05	109.74	134.65
33	115.08	6.2800	978	18.32	<.0001	0.05	102.75	127.40
34	-4.8930	5.5139	978	-0.89	0.3751	0.05	-15.7134	5.9273
35	-6.2804	3.9174	978	-1.60	0.1092	0.05	-13.9679	1.4071
36	13.8310	4.3790	978	3.16	0.0016	0.05	5.2377	22.4243
37	0
38	-10.3620	3.4096	978	-3.04	0.0024	0.05	-17.0530	-3.6710
39	0
40	0.3395	0.02864	978	11.85	<.0001	0.05	0.2833	0.3957

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The Mixed procedure
Solution for Fixed Effects

Parameter Code=P9PL Parameter=PPG lunch (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1			BOLAD1
41	1	NN1218-4131	TRTPN	2				
42	1	NN1218-4131	TRTPN	3				
43	1	NN1218-4131	TRTPN	4				
44	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
45	1	NN1218-4131	REGION1	—	EUROPE			
46	1	NN1218-4131	REGION1	—	JAPAN			
47	1	NN1218-4131	REGION1	—	NORTH AMERICA			
48	1	NN1218-4131	BOLAD1	—				BOLUS INSULIN ALGORITHM (SLIDING SCALE)
49	1	NN1218-4131	BOLAD1	—				CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY
50	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
41	6.4937	0.3157	976	20.57	<.0001	0.05	5.8742	7.1131
42	6.9998	0.3136	976	22.32	<.0001	0.05	6.3843	7.6153
43	6.6377	0.3171	976	20.94	<.0001	0.05	6.0155	7.2599
44	-0.04701	0.2784	976	-0.17	0.8660	0.05	-0.5934	0.4994
45	-0.3968	0.1981	976	-2.00	0.0454	0.05	-0.7855	-0.00814
46	0.9443	0.2240	976	4.21	<.0001	0.05	0.5046	1.3839
47	0
48	-0.5868	0.1717	976	-3.42	0.0007	0.05	-0.9237	-0.2499
49	0
50	0.2814	0.02731	976	10.31	<.0001	0.05	0.2278	0.3350

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The Mixed procedure
Solution for Fixed Effects

Parameter Code=P9PLC Parameter=PPG lunch (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
51	1	NN1218-4131	TRTPN	2				
52	1	NN1218-4131	TRTPN	3				
53	1	NN1218-4131	TRTPN	4				
54	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
55	1	NN1218-4131	REGION1	—	EUROPE			
56	1	NN1218-4131	REGION1	—	JAPAN			
57	1	NN1218-4131	REGION1	—	NORTH AMERICA			
58	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
59	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
60	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
51	117.02	5.6883	976	20.57	<.0001	0.05	105.85	128.18
52	126.14	5.6518	976	22.32	<.0001	0.05	115.04	137.23
53	119.61	5.7134	976	20.94	<.0001	0.05	108.40	130.82
54	-0.8471	5.0173	976	-0.17	0.8660	0.05	-10.6931	8.9988
55	-7.1511	3.5693	976	-2.00	0.0454	0.05	-14.1555	-0.1468
56	17.0160	4.0373	976	4.21	<.0001	0.05	9.0932	24.9387
57	0
58	-10.5742	3.0934	976	-3.42	0.0007	0.05	-16.6447	-4.5036
59	0
60	0.2814	0.02731	976	10.31	<.0001	0.05	0.2278	0.3350

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The Mixed procedure
Solution for Fixed Effects

Parameter Code=P9PPRAN Parameter=PPG all meals (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1
61	1	NN1218-4131	TRTPN	2		
62	1	NN1218-4131	TRTPN	3		
63	1	NN1218-4131	TRTPN	4		
64	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)	
65	1	NN1218-4131	REGION1	—	EUROPE	
66	1	NN1218-4131	REGION1	—	JAPAN	
67	1	NN1218-4131	REGION1	—	NORTH AMERICA	
68	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)
69	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY
70	1	NN1218-4131	BASE	—		

Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
61	5.6759	0.2988	969	19.00	<.0001	0.05	5.0895	6.2623
62	6.2755	0.3003	969	20.90	<.0001	0.05	5.6862	6.8648
63	5.9365	0.2966	969	20.01	<.0001	0.05	5.3544	6.5186
64	-0.3101	0.2134	969	-1.45	0.1466	0.05	-0.7290	0.1088
65	-0.3691	0.1521	969	-2.43	0.0154	0.05	-0.6676	-0.07062
66	0.6167	0.1706	969	3.61	0.0003	0.05	0.2819	0.9515
67	0
68	-0.4902	0.1322	969	-3.71	0.0002	0.05	-0.7496	-0.2309
69	0
70	0.3779	0.02709	969	13.95	<.0001	0.05	0.3247	0.4311

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The Mixed procedure
Solution for Fixed Effects

Parameter Code=P9PPRANC Parameter=PPG all meals (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1			BOLAD1
71	1	NN1218-4131	TRTPN	2				
72	1	NN1218-4131	TRTPN	3				
73	1	NN1218-4131	TRTPN	4				
74	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
75	1	NN1218-4131	REGION1	—	EUROPE			
76	1	NN1218-4131	REGION1	—	JAPAN			
77	1	NN1218-4131	REGION1	—	NORTH AMERICA			
78	1	NN1218-4131	BOLAD1	—				BOLUS INSULIN ALGORITHM (SLIDING SCALE)
79	1	NN1218-4131	BOLAD1	—				CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY
80	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
71	102.28	5.3845	969	19.00	<.0001	0.05	91.7126	112.85
72	113.08	5.4109	969	20.90	<.0001	0.05	102.47	123.70
73	106.98	5.3453	969	20.01	<.0001	0.05	96.4856	117.47
74	-5.5881	3.8462	969	-1.45	0.1466	0.05	-13.1360	1.9598
75	-6.6517	2.7410	969	-2.43	0.0154	0.05	-12.0307	-1.2726
76	11.1124	3.0743	969	3.61	0.0003	0.05	5.0793	17.1455
77	0
78	-8.8341	2.3815	969	-3.71	0.0002	0.05	-13.5076	-4.1607
79	0
80	0.3779	0.02709	969	13.95	<.0001	0.05	0.3247	0.4311

nn1218/nn1218-4131/ctr_20180214_er
10FEB2018:18:26:18 - a_797pp_stat_diff.sas/a_9pp_ppg_stat_on_fas_app.txt

Fast-acting insulin aspart
NN1218-4131

Clinical Trial Report
Statistical document

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Novo Nordisk

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

The Mixed procedure
Least Squares Means

Obs	_Imputation_	PARAMCD	PARAM	STUDYID	Effect	TRTPN
1	1	P9PB	PPG breakfast (SMPG) (mmol/L)	NN1218-4131	TRTPN	2
20001	1	P9PEV	PPG main evening meal (SMPG) (mmol/L)	NN1218-4131	TRTPN	2
40001	1	P9PEVC	PPG main evening meal (SMPG) (mg/dL)	NN1218-4131	TRTPN	2
60001	1	P9PGBC	PPG breakfast (SMPG) (mg/dL)	NN1218-4131	TRTPN	2
80001	1	P9PL	PPG lunch (SMPG) (mmol/L)	NN1218-4131	TRTPN	2
100001	1	P9PLC	PPG lunch (SMPG) (mg/dL)	NN1218-4131	TRTPN	2
120001	1	P9PPRAN	PPG all meals (SMPG) (mmol/L)	NN1218-4131	TRTPN	2
140001	1	P9PPRANC	PPG all meals (SMPG) (mg/dL)	NN1218-4131	TRTPN	2
160001	1	P9PB	PPG breakfast (SMPG) (mmol/L)	NN1218-4131	TRTPN	3
180001	1	P9PEV	PPG main evening meal (SMPG) (mmol/L)	NN1218-4131	TRTPN	3
200001	1	P9PEVC	PPG main evening meal (SMPG) (mg/dL)	NN1218-4131	TRTPN	3
220001	1	P9PGBC	PPG breakfast (SMPG) (mg/dL)	NN1218-4131	TRTPN	3
240001	1	P9PL	PPG lunch (SMPG) (mmol/L)	NN1218-4131	TRTPN	3
260001	1	P9PLC	PPG lunch (SMPG) (mg/dL)	NN1218-4131	TRTPN	3

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	WORK.IMPUTE	-0.6892	0.1452	978	-4.75	<.0001	0.05	-0.9740	-0.4043
20001	WORK.IMPUTE	-0.5122	0.1486	973	-3.45	0.0006	0.05	-0.8038	-0.2205
40001	WORK.IMPUTE	-9.2291	2.6777	973	-3.45	0.0006	0.05	-14.4839	-3.9743
60001	WORK.IMPUTE	-12.4186	2.6160	978	-4.75	<.0001	0.05	-17.5522	-7.2850
80001	WORK.IMPUTE	-0.5278	0.1320	976	-4.00	<.0001	0.05	-0.7867	-0.2689
100001	WORK.IMPUTE	-9.5109	2.3778	976	-4.00	<.0001	0.05	-14.1770	-4.8447
120001	WORK.IMPUTE	-0.5768	0.1013	969	-5.69	<.0001	0.05	-0.7757	-0.3780
140001	WORK.IMPUTE	-10.3943	1.8261	969	-5.69	<.0001	0.05	-13.9778	-6.8108
160001	WORK.IMPUTE	0.01183	0.1440	978	0.08	0.9345	0.05	-0.2707	0.2944
180001	WORK.IMPUTE	0.1602	0.1484	973	1.08	0.2806	0.05	-0.1310	0.4515
200001	WORK.IMPUTE	2.8873	2.6745	973	1.08	0.2806	0.05	-2.3611	8.1358
220001	WORK.IMPUTE	0.2132	2.5948	978	0.08	0.9345	0.05	-4.8788	5.3052
240001	WORK.IMPUTE	-0.02166	0.1317	976	-0.16	0.8694	0.05	-0.2801	0.2368
260001	WORK.IMPUTE	-0.3904	2.3732	976	-0.16	0.8694	0.05	-5.0475	4.2667

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Fast-acting insulin aspart
NN1218-4131

Clinical Trial Report
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Novo Nordisk

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

The Mixed procedure
Least Squares Means

Obs	_Imputation_	PARAMCD	PARAM	STUDYID	Effect	TRTPN
280001	1	P9PPRAN	PPG all meals (SMPG) (mmol/L)	NN1218-4131	TRTPN	3
300001	1	P9PPRANC	PPG all meals (SMPG) (mg/dL)	NN1218-4131	TRTPN	3
320001	1	P9PB	PPG breakfast (SMPG) (mmol/L)	NN1218-4131	TRTPN	4
340001	1	P9PEV	PPG main evening meal (SMPG) (mmol/L)	NN1218-4131	TRTPN	4
360001	1	P9PEVC	PPG main evening meal (SMPG) (mg/dL)	NN1218-4131	TRTPN	4
380001	1	P9PGBC	PPG breakfast (SMPG) (mg/dL)	NN1218-4131	TRTPN	4
400001	1	P9PL	PPG lunch (SMPG) (mmol/L)	NN1218-4131	TRTPN	4
420001	1	P9PLC	PPG lunch (SMPG) (mg/dL)	NN1218-4131	TRTPN	4
440001	1	P9PPRAN	PPG all meals (SMPG) (mmol/L)	NN1218-4131	TRTPN	4
460001	1	P9PPRANC	PPG all meals (SMPG) (mg/dL)	NN1218-4131	TRTPN	4

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
280001	WORK.IMPUTE	0.02280	0.1011	969	0.23	0.8216	0.05	-0.1756	0.2212
300001	WORK.IMPUTE	0.4109	1.8221	969	0.23	0.8216	0.05	-3.1648	3.9867
320001	WORK.IMPUTE	-0.3833	0.1445	978	-2.65	0.0081	0.05	-0.6667	-0.09980
340001	WORK.IMPUTE	-0.3350	0.1481	973	-2.26	0.0239	0.05	-0.6257	-0.04432
360001	WORK.IMPUTE	-6.0372	2.6694	973	-2.26	0.0239	0.05	-11.2757	-0.7986
380001	WORK.IMPUTE	-6.9065	2.6031	978	-2.65	0.0081	0.05	-12.0148	-1.7983
400001	WORK.IMPUTE	-0.3838	0.1315	976	-2.92	0.0036	0.05	-0.6417	-0.1258
420001	WORK.IMPUTE	-6.9155	2.3689	976	-2.92	0.0036	0.05	-11.5642	-2.2668
440001	WORK.IMPUTE	-0.3162	0.1007	969	-3.14	0.0017	0.05	-0.5138	-0.1187
460001	WORK.IMPUTE	-5.6983	1.8140	969	-3.14	0.0017	0.05	-9.2580	-2.1386

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

The Mixed procedure
Least Squares Means Estimate

Parameter Code=P9PB Parameter=PPG breakfast (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label				
1	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)				
20001	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)				

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	WORK.IMPUTE	-0.3059	0.2050	978	-1.49	0.1359	0.05	-0.7081	0.09632
20001	WORK.IMPUTE	0.3951	0.2040	978	1.94	0.0531	0.05	-0.00527	0.7955

Parameter Code=P9PEV Parameter=PPG main evening meal (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label				
40001	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)				
60001	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)				

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
40001	WORK.IMPUTE	-0.1771	0.2100	973	-0.84	0.3991	0.05	-0.5892	0.2349
60001	WORK.IMPUTE	0.4953	0.2099	973	2.36	0.0185	0.05	0.08335	0.9072

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

The Mixed procedure
Least Squares Means Estimate

Parameter Code=P9PEVC Parameter=PPG main evening meal (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label				
80001	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)				
100001	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)				

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
80001	WORK.IMPUTE	-3.1920	3.7835	973	-0.84	0.3991	0.05	-10.6167	4.2328
100001	WORK.IMPUTE	8.9245	3.7824	973	2.36	0.0185	0.05	1.5019	16.3471

Parameter Code=P9PGBC Parameter=PPG breakfast (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label				
120001	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)				
140001	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)				

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
120001	WORK.IMPUTE	-5.5121	3.6934	978	-1.49	0.1359	0.05	-12.7599	1.7357
140001	WORK.IMPUTE	7.1198	3.6765	978	1.94	0.0531	0.05	-0.09489	14.3344

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

The Mixed procedure
Least Squares Means Estimate

Parameter Code=P9PL Parameter=PPG lunch (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
160001	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
180001	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
160001	WORK.IMPUTE	-0.1440	0.1864	976	-0.77	0.4399	0.05	-0.5098	0.2217
180001	WORK.IMPUTE	0.3621	0.1861	976	1.95	0.0520	0.05	-0.00314	0.7273

Parameter Code=P9PLC Parameter=PPG lunch (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
200001	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
220001	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
200001	WORK.IMPUTE	-2.5954	3.3586	976	-0.77	0.4399	0.05	-9.1862	3.9955
220001	WORK.IMPUTE	6.5251	3.3539	976	1.95	0.0520	0.05	-0.05655	13.1068

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

The Mixed procedure
Least Squares Means Estimate

Parameter Code=P9PPRAN Parameter=PPG all meals (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label				
240001	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)				
260001	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)				
Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
240001	WORK.IMPUTE	-0.2606	0.1430	969	-1.82	0.0686	0.05	-0.5411	0.01993
260001	WORK.IMPUTE	0.3390	0.1427	969	2.38	0.0177	0.05	0.05896	0.6191

Parameter Code=P9PPRANC Parameter=PPG all meals (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label				
280001	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)				
300001	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)				
Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
280001	WORK.IMPUTE	-4.6960	2.5760	969	-1.82	0.0686	0.05	-9.7513	0.3592
300001	WORK.IMPUTE	6.1092	2.5717	969	2.38	0.0177	0.05	1.0625	11.1560

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2133 of 4425	Novo Nordisk
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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9PB Parameter=PPG breakfast (SMPG) (mmol/L) Study Identifier=NN1218-413

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.001734	0.021034	0.022768	3.45E6	0.082422	0.076146	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	9.084899	0.150890	8.789161	9.380638	3.45E6	8.922896	9.251217

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	60.21	<.0001

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9PEV Parameter=PPG main evening meal (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.001641	0.021825	0.023467	4.09E6	0.075210	0.069949	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	9.007071	0.153189	8.706826	9.307315	4.09E6	8.839026	9.162903

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	58.80	<.0001

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9PEVC Parameter=PPG main evening meal (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.532994	7.087119	7.620140	4.09E6	0.075210	0.069949	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	162.307417	2.760460	156.8970	167.7178	4.09E6	159.279257	165.115509

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	58.80	<.0001

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2136 of 4425	Novo Nordisk
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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9PGBC Parameter=PPG breakfast (SMPG) (mg/dL) Study Identifier=NN1218-41

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.562927	6.830174	7.393129	3.45E6	0.082422	0.076146	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	163.709887	2.719031	158.3807	169.0391	3.45E6	160.790583	166.706921

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	60.21	<.0001

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9PL Parameter=PPG lunch (SMPG) (mmol/L) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.001266	0.017583	0.018849	4.43E6	0.072021	0.067183	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	8.896560	0.137293	8.627470	9.165650	4.43E6	8.753891	9.033974

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	64.80	<.0001

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2138 of 4425	Novo Nordisk
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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9PLC Parameter=PPG lunch (SMPG) (mg/dL) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.411193	5.709594	6.120807	4.43E6	0.072021	0.067183	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	160.316011	2.474026	155.4670	165.1650	4.43E6	157.745122	162.792213

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	64.80	<.0001

nn1218/nn1218-4131/ctr_20180214_er
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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9PPRAN Parameter=PPG all meals (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000868	0.010305	0.011173	3.32E6	0.084189	0.077653	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	8.986723	0.105702	8.779551	9.193895	3.32E6	8.863693	9.110379

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	85.02	<.0001

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9PPRANC Parameter=PPG all meals (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.281713	3.346351	3.628078	3.32E6	0.084189	0.077653	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	161.940750	1.904751	158.2075	165.6740	3.32E6	159.723748	164.169038

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	85.02	<.0001

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2141 of 4425	Novo Nordisk
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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9PB Parameter=PPG breakfast (SMPG) (mmol/L) Study Identifier=NN1218-413

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.001220	0.020694	0.021915	6.45E6	0.058977	0.055692	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits	DF	Minimum	Maximum
Estimate	9.785824	0.148037	9.495677 10.07597	6.45E6	9.657600	9.927528

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	66.10	<.0001

nn1218/nn1218-4131/ctr_20180214_er
10FEB2018:18:26:18 - a_797pp_stat_diff.sas/a_9pp_ppg_stat_on_fas_app.txt

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9PEV Parameter=PPG main evening meal (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.001068	0.021772	0.022840	9.14E6	0.049065	0.046771	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	9.650253	0.151131	9.354042	9.946464	9.14E6	9.518944	9.770300

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	63.85	<.0001

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9PEVC Parameter=PPG main evening meal (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.346869	7.069878	7.416765	9.14E6	0.049065	0.046771	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	173.897559	2.723374	168.5598	179.2353	9.14E6	171.531374	176.060801

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	63.85	<.0001

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2144 of 4425	Novo Nordisk
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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9PGBC Parameter=PPG breakfast (SMPG) (mg/dL) Study Identifier=NN1218-41

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.396297	6.719893	7.116210	6.45E6	0.058977	0.055692	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	176.340554	2.667623	171.1121	181.5690	6.45E6	174.029950	178.894063

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	66.10	<.0001

nn1218/nn1218-4131/ctr_20180214_er
10FEB2018:18:26:18 - a_797pp_stat_diff.sas/a_9pp_ppg_stat_on_fas_app.txt

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2145 of 4425	Novo Nordisk
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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9PL Parameter=PPG lunch (SMPG) (mmol/L) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000932	0.017515	0.018447	7.83E6	0.053241	0.050550	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	9.386106	0.135821	9.119902	9.652310	7.83E6	9.272921	9.505186

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	69.11	<.0001

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2146 of 4425	Novo Nordisk
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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9PLC Parameter=PPG lunch (SMPG) (mg/dL) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.302789	5.687412	5.990217	7.83E6	0.053241	0.050550	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	169.137633	2.447492	164.3406	173.9346	7.83E6	167.098032	171.283443

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	69.11	<.0001

nn1218/nn1218-4131/ctr_20180214_er
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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9PPRAN Parameter=PPG all meals (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000525	0.010261	0.010786	8.45E6	0.051135	0.048648	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	9.587603	0.103855	9.384051	9.791154	8.45E6	9.497423	9.676505

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	92.32	<.0001

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9PPRANC Parameter=PPG all meals (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.170374	3.331994	3.502376	8.45E6	0.051135	0.048648	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	172.768599	1.871464	169.1006	176.4366	8.45E6	171.143564	174.370628

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	92.32	<.0001

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2149 of 4425	Novo Nordisk
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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9PB Parameter=PPG breakfast (SMPG) (mmol/L) Study Identifier=NN1218-413

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.001445	0.020827	0.022271	4.75E6	0.069374	0.064874	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	9.386789	0.149236	9.094292	9.679286	4.75E6	9.234058	9.531590

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	62.90	<.0001

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9PEV Parameter=PPG main evening meal (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.001463	0.021690	0.023154	5.01E6	0.067467	0.063203	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	9.236918	0.152163	8.938684	9.535153	5.01E6	9.092926	9.389408

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	60.70	<.0001

Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9PEVC Parameter=PPG main evening meal (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.475166	7.043278	7.518469	5.01E6	0.067467	0.063203	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	166.449270	2.741983	161.0751	171.8235	5.01E6	163.854523	169.197126

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	60.70	<.0001

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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9PGBC Parameter=PPG breakfast (SMPG) (mg/dL) Study Identifier=NN1218-41

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.469141	6.762793	7.231957	4.75E6	0.069374	0.064874	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	169.149936	2.689230	163.8791	174.4207	4.75E6	166.397719	171.759256

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	62.90	<.0001

nn1218/nn1218-4131/ctr_20180214_er
10FEB2018:18:26:18 - a_797pp_stat_diff.sas/a_9pp_ppg_stat_on_fas_app.txt

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2153 of 4425	Novo Nordisk
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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9PL Parameter=PPG lunch (SMPG) (mmol/L) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.001583	0.017452	0.019036	2.89E6	0.090736	0.083189	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	9.072128	0.137969	8.801713	9.342543	2.89E6	8.910679	9.239949

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	65.75	<.0001

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2154 of 4425	Novo Nordisk
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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9PLC Parameter=PPG lunch (SMPG) (mg/dL) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.514179	5.667026	6.181230	2.89E6	0.090736	0.083189	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	163.479744	2.486208	158.6069	168.3526	2.89E6	160.570442	166.503882

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	65.75	<.0001

nn1218/nn1218-4131/ctr_20180214_er
10FEB2018:18:26:18 - a_797pp_stat_diff.sas/a_9pp_ppg_stat_on_fas_app.txt

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2155 of 4425	Novo Nordisk
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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9PPRAN Parameter=PPG all meals (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000912	0.010169	0.011082	2.95E6	0.089722	0.082335	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	9.233483	0.105269	9.027160	9.439807	2.95E6	9.109259	9.367599

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	87.71	<.0001

nn1218/nn1218-4131/ctr_20180214_er
10FEB2018:18:26:18 - a_797pp_stat_diff.sas/a_9pp_ppg_stat_on_fas_app.txt

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2156 of 4425	Novo Nordisk
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Postprandial glucose in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis
- on-treatment - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9PPRANC Parameter=PPG all meals (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.296258	3.302126	3.598399	2.95E6	0.089722	0.082335	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	166.387370	1.896945	162.6694	170.1053	2.95E6	164.148840	168.804125

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	87.71	<.0001

nn1218/nn1218-4131/ctr_20180214_er
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24: Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=P9PGIU Planned Treatment for Period 30 (N)=2

Obs	PARAM					Description	Value
1	PPG increment	all	meals	(SMPG)	(mg/dL)	Data Set	WORK.ENDPOINT_PARAM
2	PPG increment	all	meals	(SMPG)	(mg/dL)	Method	Monotone-data_MCMC
3	PPG increment	all	meals	(SMPG)	(mg/dL)	Multiple Imputation Chain	Multiple Chains
4	PPG increment	all	meals	(SMPG)	(mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
5	PPG increment	all	meals	(SMPG)	(mg/dL)	Start	Starting Value
6	PPG increment	all	meals	(SMPG)	(mg/dL)	Prior	Jeffreys
7	PPG increment	all	meals	(SMPG)	(mg/dL)	Number of Imputations	20000
8	PPG increment	all	meals	(SMPG)	(mg/dL)	Number of Burn-in Iterations	200
9	PPG increment	all	meals	(SMPG)	(mg/dL)	Seed for random number generator	1234

Parameter Code=P9PGIU Planned Treatment for Period 30 (N)=3

Obs	PARAM					Description	Value
10	PPG increment	all	meals	(SMPG)	(mg/dL)	Data Set	WORK.ENDPOINT_PARAM
11	PPG increment	all	meals	(SMPG)	(mg/dL)	Method	Monotone-data_MCMC
12	PPG increment	all	meals	(SMPG)	(mg/dL)	Multiple Imputation Chain	Multiple Chains
13	PPG increment	all	meals	(SMPG)	(mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
14	PPG increment	all	meals	(SMPG)	(mg/dL)	Start	Starting Value
15	PPG increment	all	meals	(SMPG)	(mg/dL)	Prior	Jeffreys
16	PPG increment	all	meals	(SMPG)	(mg/dL)	Number of Imputations	20000
17	PPG increment	all	meals	(SMPG)	(mg/dL)	Number of Burn-in Iterations	200
18	PPG increment	all	meals	(SMPG)	(mg/dL)	Seed for random number generator	1964087206

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=P9PGIU Planned Treatment for Period 30 (N)=4

Obs	PARAM				Description	Value
19	PPG increment	all meals	(SMPG)	(mg/dL)	Data Set	WORK.ENDPOINT_PARAM
20	PPG increment	all meals	(SMPG)	(mg/dL)	Method	Monotone-data_MCMC
21	PPG increment	all meals	(SMPG)	(mg/dL)	Multiple Imputation Chain	Multiple Chains
22	PPG increment	all meals	(SMPG)	(mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
23	PPG increment	all meals	(SMPG)	(mg/dL)	Start	Starting Value
24	PPG increment	all meals	(SMPG)	(mg/dL)	Prior	Jeffreys
25	PPG increment	all meals	(SMPG)	(mg/dL)	Number of Imputations	20000
26	PPG increment	all meals	(SMPG)	(mg/dL)	Number of Burn-in Iterations	200
27	PPG increment	all meals	(SMPG)	(mg/dL)	Seed for random number generator	671416661

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with MCMC

Missing data pattern

Parameter Code=P9PGIU Planned Treatment for Period 30 (N)=2

								V i s i t	V i s i t					
							B A S E	2 2 0 0	3 6 0 0		P e r c e n t		v i s i t	v i s i t
O b s		P A R A M	G r o u p	M̄ i s s	M̄ i s s	M̄ i s s	F r e q			B A S E	2 2 0 0		3 6 0 0	
1	PPG increment	all meals (SMPG)	(mg/dL)	1	X	X	X	282	87.31	32.577372	-15.964789	-13.709150	.	.
2	PPG increment	all meals (SMPG)	(mg/dL)	2	X	X	O	14	4.33	9.335000	14.020651	.	.	.
3	PPG increment	all meals (SMPG)	(mg/dL)	3	X	.	X	16	4.95	32.565222	.	-6.402069	.	.
4	PPG increment	all meals (SMPG)	(mg/dL)	4	X	O	O	11	3.41	-3.118091

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with MCMC
Missing data pattern

Parameter Code=P9PGIU Planned Treatment for Period 30 (N)=3

O b s	P A R A M		G r o u p			F r e q		P e r c e n t		B A S E		v i s i t 2 0 0		v i s i t 3 6 0 0	
5	PPG increment	all meals	(SMPG)	(mg/dL)	1	X	X	X	290	89.78	32.422897	2.939964	1.144863		
6	PPG increment	all meals	(SMPG)	(mg/dL)	2	X	X	O	11	3.41	9.331495	19.370455	.		
7	PPG increment	all meals	(SMPG)	(mg/dL)	3	X	.	X	16	4.95	19.089750	.	4.728062		
8	PPG increment	all meals	(SMPG)	(mg/dL)	4	X	O	O	6	1.86	1.394981	.	.		

Fast-acting insulin aspart
NN1218-4131

Clinical Trial Report
Statistical document

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14 February 2018
1.0

Status:
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Novo Nordisk

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with MCMC
Missing data pattern

Parameter Code=P9PGIU Planned Treatment for Period 30 (N)=4

O b s	P A R A M	G r o u p	v i s i t t			F r e q	P e r c e n t	B A S E	v i s i t t	v i s i t t
			B	2	3					
			A	2	6					
			S	0	0					
			E	0	0					
			\bar{M}	\bar{M}	\bar{M}					
			i	i	i					
			s	s	s					
			s	s	s					
			1	X	X					
			2	X	X					
			3	X	.					
9	PPG increment	all meals	(SMPG)	(mg/dL)		286	87.20	27.065724	-0.314471	-0.180887
10	PPG increment	all meals	(SMPG)	(mg/dL)		13	3.96	36.377778	-4.353974	.
11	PPG increment	all meals	(SMPG)	(mg/dL)		17	5.18	22.863072	.	-6.931817
12	PPG increment	all meals	(SMPG)	(mg/dL)		12	3.66	20.355296	.	.

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PGIU Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG increment all meals (SMPG) (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG increment all meals (SMPG) (mg/dL)	Method	Monotone
3	1	PPG increment all meals (SMPG) (mg/dL)	Number of Imputations	1
4	1	PPG increment all meals (SMPG) (mg/dL)	Seed for random number generator	4321

nn1218/nn1218-4131/ctr_20180214_er
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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression Missing Data Pattern

Parameter Code=P9PGIU Planned Treatment for Period 30 (N)=2

O b s	I m p u t a t i o n	P A R A M	G r o u p	R E G I O N A L	E B O L D S E	v i s i t s	F r e q	P e r c e n t	B A S E	v i s i t s	v i s i t s	
												M
1	1	PPG increment	all meals	(SMPG)	(mg/dL)	1	X X X X X X	298	92.26	32.576719	-15.911487	-13.316823
2	1	PPG increment	all meals	(SMPG)	(mg/dL)	2	X X X X .	14	4.33	9.335000	14.020651	.
3	1	PPG increment	all meals	(SMPG)	(mg/dL)	3	X X X . .	11	3.41	-3.118091	.	.

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGIU Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG increment all meals (SMPG) (mg/dL)	Intercept	
2	1	PPG increment all meals (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG increment all meals (SMPG) (mg/dL)	REGION1	EUROPE
4	1	PPG increment all meals (SMPG) (mg/dL)	REGION1	JAPAN
5	1	PPG increment all meals (SMPG) (mg/dL)	BOLAD1	
6	1	PPG increment all meals (SMPG) (mg/dL)	BASE	

Obs	BOLAD1	ObsVal	_1
1		0.00254	0.035188
2		-0.06708	-0.037507
3		0.01318	-0.115383
4		0.06745	0.047402
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.05376	0.006476
6		-0.59150	-0.617946

Parameter Code=P9PGIU Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	PPG increment all meals (SMPG) (mg/dL)	Intercept			-0.03238	-0.062737
8	1	PPG increment all meals (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)		-0.24978	-0.176483
9	1	PPG increment all meals (SMPG) (mg/dL)	REGION1	EUROPE		0.10163	-0.035475

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGIU Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

(continued)

Imputed									
Observations									
		P		E	R		B	O	
		A		f	E		O	b	
		R		f	I		L	s	
		A		e	O		A	V	
		M		c	N		D	a	
				t	1		1	1	I
10	1	PPG increment	all meals	(SMPG)	(mg/dL)	REGION1	JAPAN	-0.02735	0.001721
11	1	PPG increment	all meals	(SMPG)	(mg/dL)	BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.11760	0.181391
12	1	PPG increment	all meals	(SMPG)	(mg/dL)	BASE		-0.38698	-0.333094
13	1	PPG increment	all meals	(SMPG)	(mg/dL)	visit2200		0.33633	0.350975

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PGIU Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG increment all meals (SMPG) (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG increment all meals (SMPG) (mg/dL)	Method	Monotone
3	1	PPG increment all meals (SMPG) (mg/dL)	Number of Imputations	1
4	1	PPG increment all meals (SMPG) (mg/dL)	Seed for random number generator	4322

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression Missing Data Pattern

Parameter Code=P9PGIU Planned Treatment for Period 30 (N)=3

O b s	I m p u t a t i o n —	P A R A M	G r o u p	R E G I O N 1	E B O L O N D S 1	B i t t B A A S E	v i s s i t t 2 3 2 6 0 0	F r e q	P e r c e n t	B A S E	v i s i t t 2 2 0 0	v i s i t t 3 6 0 0			
													M	M	M
1	1	PPG increment	all meals (SMPG)	(mg/dL)	1	X	X	X	X	X	306	94.74	31.725739	3.343121	1.332220
2	1	PPG increment	all meals (SMPG)	(mg/dL)	2	X	X	X	X	.	11	3.41	9.331495	19.370455	.
3	1	PPG increment	all meals (SMPG)	(mg/dL)	3	X	X	X	.	.	6	1.86	1.394981	.	.

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGIU Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG increment all meals (SMPG) (mg/dL)	Intercept	
2	1	PPG increment all meals (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG increment all meals (SMPG) (mg/dL)	REGION1	EUROPE
4	1	PPG increment all meals (SMPG) (mg/dL)	REGION1	JAPAN
5	1	PPG increment all meals (SMPG) (mg/dL)	BOLAD1	
6	1	PPG increment all meals (SMPG) (mg/dL)	BASE	

Obs	BOLAD1	ObsVal	_1
1		0.04434	0.144520
2		0.10667	0.238221
3		-0.18643	-0.181576
4		0.26234	0.167011
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.09412	-0.065868
6		-0.50917	-0.542501

Parameter Code=P9PGIU Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	PPG increment all meals (SMPG) (mg/dL)	Intercept			0.00134	-0.016987
8	1	PPG increment all meals (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)		-0.24859	-0.284113
9	1	PPG increment all meals (SMPG) (mg/dL)	REGION1	EUROPE		-0.09444	-0.110729

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PGIU Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG increment all meals (SMPG) (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG increment all meals (SMPG) (mg/dL)	Method	Monotone
3	1	PPG increment all meals (SMPG) (mg/dL)	Number of Imputations	1
4	1	PPG increment all meals (SMPG) (mg/dL)	Seed for random number generator	4323

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGIU Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG increment all meals (SMPG) (mg/dL)	Intercept	
2	1	PPG increment all meals (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG increment all meals (SMPG) (mg/dL)	REGION1	EUROPE
4	1	PPG increment all meals (SMPG) (mg/dL)	REGION1	JAPAN
5	1	PPG increment all meals (SMPG) (mg/dL)	BOLAD1	
6	1	PPG increment all meals (SMPG) (mg/dL)	BASE	

Obs	BOLAD1	ObsVal	_1
1		-0.00426	-0.051336
2		-0.12623	-0.072524
3		-0.01932	-0.138149
4		0.21570	0.257743
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.01417	-0.019807
6		-0.56961	-0.646549

Parameter Code=P9PGIU Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	PPG increment all meals (SMPG) (mg/dL)	Intercept			0.03106	0.035770
8	1	PPG increment all meals (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)		0.17907	0.107141
9	1	PPG increment all meals (SMPG) (mg/dL)	REGION1	EUROPE		-0.13346	-0.085802

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGIU Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

(continued)

Imputed									
Observations									
		P		E	R		B	O	
		A		f	E		O	b	
		R		f	I		L	s	
		A		e	O		A	V	
		M		c	N		D	a	
				t	1		1	1	I
10	1	PPG increment	all meals	(SMPG)	(mg/dL)	REGION1	JAPAN	0.04532	0.119670
11	1	PPG increment	all meals	(SMPG)	(mg/dL)	BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.06640	-0.074792
12	1	PPG increment	all meals	(SMPG)	(mg/dL)	BASE		-0.34227	-0.283995
13	1	PPG increment	all meals	(SMPG)	(mg/dL)	visit2200		0.46298	0.396165

Fast-acting insulin aspart
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Clinical Trial Report
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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=P9PGINC Planned Treatment for Period 30 (N)=2

Obs	PARAM	Description	Value
1	PPG increment all meals (SMPG) (mmol/L)	Data Set	WORK.ENDPOINT_PARAM
2	PPG increment all meals (SMPG) (mmol/L)	Method	Monotone-data_MCMC
3	PPG increment all meals (SMPG) (mmol/L)	Multiple Imputation Chain	Multiple Chains
4	PPG increment all meals (SMPG) (mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
5	PPG increment all meals (SMPG) (mmol/L)	Start	Starting Value
6	PPG increment all meals (SMPG) (mmol/L)	Prior	Jeffreys
7	PPG increment all meals (SMPG) (mmol/L)	Number of Imputations	20000
8	PPG increment all meals (SMPG) (mmol/L)	Number of Burn-in Iterations	200
9	PPG increment all meals (SMPG) (mmol/L)	Seed for random number generator	1234

Parameter Code=P9PGINC Planned Treatment for Period 30 (N)=3

Obs	PARAM	Description	Value
10	PPG increment all meals (SMPG) (mmol/L)	Data Set	WORK.ENDPOINT_PARAM
11	PPG increment all meals (SMPG) (mmol/L)	Method	Monotone-data_MCMC
12	PPG increment all meals (SMPG) (mmol/L)	Multiple Imputation Chain	Multiple Chains
13	PPG increment all meals (SMPG) (mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
14	PPG increment all meals (SMPG) (mmol/L)	Start	Starting Value
15	PPG increment all meals (SMPG) (mmol/L)	Prior	Jeffreys
16	PPG increment all meals (SMPG) (mmol/L)	Number of Imputations	20000
17	PPG increment all meals (SMPG) (mmol/L)	Number of Burn-in Iterations	200
18	PPG increment all meals (SMPG) (mmol/L)	Seed for random number generator	1964087206

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=P9PGINC Planned Treatment for Period 30 (N)=4

Obs	PARAM				Description	Value
19	PPG increment	all meals	(SMPG)	(mmol/L)	Data Set	WORK.ENDPOINT_PARAM
20	PPG increment	all meals	(SMPG)	(mmol/L)	Method	Monotone-data_MCMC
21	PPG increment	all meals	(SMPG)	(mmol/L)	Multiple Imputation Chain	Multiple Chains
22	PPG increment	all meals	(SMPG)	(mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
23	PPG increment	all meals	(SMPG)	(mmol/L)	Start	Starting Value
24	PPG increment	all meals	(SMPG)	(mmol/L)	Prior	Jeffreys
25	PPG increment	all meals	(SMPG)	(mmol/L)	Number of Imputations	20000
26	PPG increment	all meals	(SMPG)	(mmol/L)	Number of Burn-in Iterations	200
27	PPG increment	all meals	(SMPG)	(mmol/L)	Seed for random number generator	671416661

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with MCMC
Missing data pattern

Parameter Code=P9PPGINC Planned Treatment for Period 30 (N)=3

O b s	P A R A M		G r o u p			F r e q		P e r c e n t		B A S E		v i s i t 2 2 0 0		v i s i t 3 6 0 0	
5	PPG increment	all meals	(SMPG)	(mmol/L)	1	X	X	X	290	89.78	1.799273	0.163150		0.063533	
6	PPG increment	all meals	(SMPG)	(mmol/L)	2	X	X	O	11	3.41	0.517841	1.074942		.	
7	PPG increment	all meals	(SMPG)	(mmol/L)	3	X	.	X	16	4.95	1.059365	.		0.262379	
8	PPG increment	all meals	(SMPG)	(mmol/L)	4	X	O	O	6	1.86	0.077413	.		.	

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with MCMC
Missing data pattern

Parameter Code=P9PPGINC Planned Treatment for Period 30 (N)=4

							v i s i t t		B A S E		P e r c e n t		v i s i t t		v i s i t t	
							2 2 0 0		2 2 0 0		A S E		2 2 0 0		3 6 0 0	
							P A R A M		G r o u p		F r e q					
							M̄ M̄ M̄									
							s s s									
9	PPG increment	all	meals	(SMPG)	(mmol/L)		1	X	X	X	286	87.20	1.501982	-0.017451	-0.010038	
10	PPG increment	all	meals	(SMPG)	(mmol/L)		2	X	X	O	13	3.96	2.018745	-0.241619	.	
11	PPG increment	all	meals	(SMPG)	(mmol/L)		3	X	.	X	17	5.18	1.268761	.	-0.384674	
12	PPG increment	all	meals	(SMPG)	(mmol/L)		4	X	O	O	12	3.66	1.129595	.	.	

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PGINC Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG increment all meals (SMPG) (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG increment all meals (SMPG) (mmol/L)	Method	Monotone
3	1	PPG increment all meals (SMPG) (mmol/L)	Number of Imputations	1
4	1	PPG increment all meals (SMPG) (mmol/L)	Seed for random number generator	4321

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression Missing Data Pattern

Parameter Code=P9PGINC Planned Treatment for Period 30 (N)=2

O b s	I m p u t a t i o n s							G r o u p	R E G I O N a l E B O A A S E					F r e q	P e r c e n t	B A S E	v i s i t 2 0 0	v i s i t 3 6 0 0
		P A R A M							M	M	M	M	M					
1	1	PPG	increment	all	meals	(SMPG)	(mmol/L)	1	X	X	X	X	X	298	92.26	1.807809	-0.882990	-0.739002
2	1	PPG	increment	all	meals	(SMPG)	(mmol/L)	2	X	X	X	X	X	14	4.33	0.518036	0.778061	.
3	1	PPG	increment	all	meals	(SMPG)	(mmol/L)	3	X	X	X	X	.	11	3.41	-0.173035	.	.

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGINC Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG increment all meals (SMPG) (mmol/L)	Intercept	
2	1	PPG increment all meals (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG increment all meals (SMPG) (mmol/L)	REGION1	EUROPE
4	1	PPG increment all meals (SMPG) (mmol/L)	REGION1	JAPAN
5	1	PPG increment all meals (SMPG) (mmol/L)	BOLAD1	
6	1	PPG increment all meals (SMPG) (mmol/L)	BASE	

Obs	BOLAD1	ObsVal	_1
1		0.00254	0.035188
2		-0.06708	-0.037507
3		0.01318	-0.115383
4		0.06745	0.047402
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.05376	0.006476
6		-0.59150	-0.617946

Parameter Code=P9PGINC Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	PPG increment all meals (SMPG) (mmol/L)	Intercept			-0.03238	-0.062737
8	1	PPG increment all meals (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)		-0.24978	-0.176483
9	1	PPG increment all meals (SMPG) (mmol/L)	REGION1	EUROPE		0.10163	-0.035475

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PPGINC Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

(continued)

Imputed									
Observations									
		P		E	R		B	O	
		A		f	E		O	b	
		R		f	I		L	s	
		A		e	O		A	V	
		M		c	N		D	a	
				t	1		1	1	\bar{I}
10	1	PPG increment	all meals (SMPG)	(mmol/L)	REGION1	JAPAN		-0.02735	0.001721
11	1	PPG increment	all meals (SMPG)	(mmol/L)	BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.11760	0.181391
12	1	PPG increment	all meals (SMPG)	(mmol/L)	BASE			-0.38698	-0.333094
13	1	PPG increment	all meals (SMPG)	(mmol/L)	visit2200			0.33633	0.350975

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PGINC Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG increment all meals (SMPG) (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG increment all meals (SMPG) (mmol/L)	Method	Monotone
3	1	PPG increment all meals (SMPG) (mmol/L)	Number of Imputations	1
4	1	PPG increment all meals (SMPG) (mmol/L)	Seed for random number generator	4322


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Fast-acting insulin aspart
NN1218-4131

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGINC Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG increment all meals (SMPG) (mmol/L)	Intercept	
2	1	PPG increment all meals (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG increment all meals (SMPG) (mmol/L)	REGION1	EUROPE
4	1	PPG increment all meals (SMPG) (mmol/L)	REGION1	JAPAN
5	1	PPG increment all meals (SMPG) (mmol/L)	BOLAD1	
6	1	PPG increment all meals (SMPG) (mmol/L)	BASE	

Obs	BOLAD1	ObsVal	_1
1		0.04434	0.144520
2		0.10667	0.238221
3		-0.18643	-0.181576
4		0.26234	0.167011
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.09412	-0.065868
6		-0.50917	-0.542501

Parameter Code=P9PGINC Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	PPG increment all meals (SMPG) (mmol/L)	Intercept			0.00134	-0.016987
8	1	PPG increment all meals (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)		-0.24859	-0.284113
9	1	PPG increment all meals (SMPG) (mmol/L)	REGION1	EUROPE		-0.09444	-0.110729

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09FEB2018:20:27:18 - a_797pp_stat_diff.sas/a_9pp_ppginc_stat_in_fas_app.txt

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PPGINC Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

(continued)

Imputed									
Observations									
		P		E	R		B	O	
		A		f	E		O	b	
		R		f	I		L	s	
		A		e	O		A	V	
		M		c	N		D	a	
				t	1		1	1	\bar{I}
10	1	PPG increment	all meals (SMPG)	(mmol/L)	REGION1	JAPAN		0.39406	0.359111
11	1	PPG increment	all meals (SMPG)	(mmol/L)	BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.11535	-0.044175
12	1	PPG increment	all meals (SMPG)	(mmol/L)	BASE			-0.44115	-0.448906
13	1	PPG increment	all meals (SMPG)	(mmol/L)	visit2200			0.36431	0.392766

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2187 of 4425	Novo Nordisk
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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PGINC Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG increment all meals (SMPG) (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG increment all meals (SMPG) (mmol/L)	Method	Monotone
3	1	PPG increment all meals (SMPG) (mmol/L)	Number of Imputations	1
4	1	PPG increment all meals (SMPG) (mmol/L)	Seed for random number generator	4323

nn1218/nn1218-4131/ctr_20180214_er
09FEB2018:20:27:18 - a_797pp_stat_diff.sas/a_9pp_ppginc_stat_in_fas_app.txt

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression Missing Data Pattern

Parameter Code=P9PGINC Planned Treatment for Period 30 (N)=4

[illegible]

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGINC Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG increment all meals (SMPG) (mmol/L)	Intercept	
2	1	PPG increment all meals (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG increment all meals (SMPG) (mmol/L)	REGION1	EUROPE
4	1	PPG increment all meals (SMPG) (mmol/L)	REGION1	JAPAN
5	1	PPG increment all meals (SMPG) (mmol/L)	BOLAD1	
6	1	PPG increment all meals (SMPG) (mmol/L)	BASE	

Obs	BOLAD1	ObsVal	_1
1		-0.00426	-0.051336
2		-0.12623	-0.072524
3		-0.01932	-0.138149
4		0.21570	0.257743
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.01417	-0.019807
6		-0.56961	-0.646549

Parameter Code=P9PGINC Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	PPG increment all meals (SMPG) (mmol/L)	Intercept			0.03106	0.035770
8	1	PPG increment all meals (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)		0.17907	0.107141
9	1	PPG increment all meals (SMPG) (mmol/L)	REGION1	EUROPE		-0.13346	-0.085802

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PPGINC Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

(continued)

Imputed									
Observations									
		P		E	R		B	O	
		A		f	E		O	b	
		R		f	I		L	s	
		A		e	O		A	V	
		M		c	N		D	a	
				t	1		1	1	\bar{I}
10	1	PPG increment	all meals (SMPG)	(mmol/L)	REGION1	JAPAN		0.04532	0.119670
11	1	PPG increment	all meals (SMPG)	(mmol/L)	BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.06640	-0.074792
12	1	PPG increment	all meals (SMPG)	(mmol/L)	BASE			-0.34227	-0.283995
13	1	PPG increment	all meals (SMPG)	(mmol/L)	visit2200			0.46298	0.396165

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=P9PGIBU Planned Treatment for Period 30 (N)=2

Obs	PARAM				Description	Value
1	PPG	increment	breakfast	(SMPG) (mg/dL)	Data Set	WORK.ENDPOINT_PARAM
2	PPG	increment	breakfast	(SMPG) (mg/dL)	Method	Monotone-data_MCMC
3	PPG	increment	breakfast	(SMPG) (mg/dL)	Multiple Imputation Chain	Multiple Chains
4	PPG	increment	breakfast	(SMPG) (mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
5	PPG	increment	breakfast	(SMPG) (mg/dL)	Start	Starting Value
6	PPG	increment	breakfast	(SMPG) (mg/dL)	Prior	Jeffreys
7	PPG	increment	breakfast	(SMPG) (mg/dL)	Number of Imputations	20000
8	PPG	increment	breakfast	(SMPG) (mg/dL)	Number of Burn-in Iterations	200
9	PPG	increment	breakfast	(SMPG) (mg/dL)	Seed for random number generator	1234

Parameter Code=P9PGIBU Planned Treatment for Period 30 (N)=3

Obs	PARAM				Description	Value
10	PPG	increment	breakfast	(SMPG) (mg/dL)	Data Set	WORK.ENDPOINT_PARAM
11	PPG	increment	breakfast	(SMPG) (mg/dL)	Method	Monotone-data_MCMC
12	PPG	increment	breakfast	(SMPG) (mg/dL)	Multiple Imputation Chain	Multiple Chains
13	PPG	increment	breakfast	(SMPG) (mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
14	PPG	increment	breakfast	(SMPG) (mg/dL)	Start	Starting Value
15	PPG	increment	breakfast	(SMPG) (mg/dL)	Prior	Jeffreys
16	PPG	increment	breakfast	(SMPG) (mg/dL)	Number of Imputations	20000
17	PPG	increment	breakfast	(SMPG) (mg/dL)	Number of Burn-in Iterations	200
18	PPG	increment	breakfast	(SMPG) (mg/dL)	Seed for random number generator	1890978291

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=P9PGIBU Planned Treatment for Period 30 (N)=4

Obs	PARAM			Description	Value
19	PPG increment breakfast	(SMPG)	(mg/dL)	Data Set	WORK.ENDPOINT_PARAM
20	PPG increment breakfast	(SMPG)	(mg/dL)	Method	Monotone-data_MCMC
21	PPG increment breakfast	(SMPG)	(mg/dL)	Multiple Imputation Chain	Multiple Chains
22	PPG increment breakfast	(SMPG)	(mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
23	PPG increment breakfast	(SMPG)	(mg/dL)	Start	Starting Value
24	PPG increment breakfast	(SMPG)	(mg/dL)	Prior	Jeffreys
25	PPG increment breakfast	(SMPG)	(mg/dL)	Number of Imputations	20000
26	PPG increment breakfast	(SMPG)	(mg/dL)	Number of Burn-in Iterations	200
27	PPG increment breakfast	(SMPG)	(mg/dL)	Seed for random number generator	91941876

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with MCMC

Missing data pattern

Parameter Code=P9PGIBU Planned Treatment for Period 30 (N)=2

O		P	G	B	V	F	P	B	V	V	
b		A	r	A	i	r	e	A	i	i	
s		M	o	E	s	e	n	S	t	s	
			p	0	s	q	t	E	0	0	
				̄	̄						
				i	i						
				s	s						
1	PPG increment breakfast (SMPG) (mg/dL)		1	X	X	X	289	88.65	42.264205	-20.869008	-20.796249
2	PPG increment breakfast (SMPG) (mg/dL)		2	X	X	O	11	3.37	9.093697	14.312000	.
3	PPG increment breakfast (SMPG) (mg/dL)		3	X	.	X	15	4.60	33.670444	.	-20.940511
4	PPG increment breakfast (SMPG) (mg/dL)		4	X	O	O	11	3.37	-15.597273	.	.

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with MCMC

Missing data pattern

Parameter Code=P9PGIBU Planned Treatment for Period 30 (N)=3

O b s	P A R A M					G r o u p	B A S E			F r e q	P e r c e n t	B A S E	v i s i t 2 0 0	v i s i t 3 6 0
							\bar{M}	\bar{M}	\bar{M}					
5	PPG	increment	breakfast	(SMPG)	(mg/dL)	1	X	X	X	299	90.33	38.574404	0.631658	1.114075
6	PPG	increment	breakfast	(SMPG)	(mg/dL)	2	X	X	O	13	3.93	4.180205	1.680538	.
7	PPG	increment	breakfast	(SMPG)	(mg/dL)	3	X	.	X	15	4.53	18.929511	.	4.539422
8	PPG	increment	breakfast	(SMPG)	(mg/dL)	4	X	O	O	4	1.21	38.476167	.	.

Fast-acting insulin aspart
NN1218-4131

Clinical Trial Report
Statistical document

Date:
Version:

14 February 2018
1.0

Status:
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Novo Nordisk

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation -
statistical analysis - in-trial - full analysis set

The MI Procedure with MCMC
Missing data pattern

Parameter Code=P9PGIBU Planned Treatment for Period 30 (N)=4

O b s	P A R A M	G r o u p	v i s i t t			F r e q	P e r c e n t	B A S E	v i s i t t	v i s i t t
			B	2	3					
			A	2	6					
			S	0	0					
			E	0	0					
			\bar{M}	\bar{M}	\bar{M}					
			i	i	i					
			s	s	s					
9	PPG increment breakfast (SMPG) (mg/dL)	1	X	X	X	292	88.75	38.601793	-4.012583	-6.622506
10	PPG increment breakfast (SMPG) (mg/dL)	2	X	X	O	11	3.34	37.218000	-21.836939	.
11	PPG increment breakfast (SMPG) (mg/dL)	3	X	.	X	14	4.26	7.301381	.	11.436429
12	PPG increment breakfast (SMPG) (mg/dL)	4	X	O	O	12	3.65	22.443667	.	.

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PGIBU Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG increment breakfast (SMPG) (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG increment breakfast (SMPG) (mg/dL)	Method	Monotone
3	1	PPG increment breakfast (SMPG) (mg/dL)	Number of Imputations	1
4	1	PPG increment breakfast (SMPG) (mg/dL)	Seed for random number generator	4321

nn1218/nn1218-4131/ctr_20180214_er
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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGIBU Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG increment breakfast (SMPG) (mg/dL)	Intercept	
2	1	PPG increment breakfast (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG increment breakfast (SMPG) (mg/dL)	REGION1	EUROPE
4	1	PPG increment breakfast (SMPG) (mg/dL)	REGION1	JAPAN
5	1	PPG increment breakfast (SMPG) (mg/dL)	BOLAD1	
6	1	PPG increment breakfast (SMPG) (mg/dL)	BASE	

Obs	BOLAD1	ObsVal	_1
1		0.01966	0.049077
2		0.01836	0.045596
3		0.04348	-0.072233
4		-0.03538	-0.055052
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.00315	-0.039822
6		-0.68302	-0.711298

Parameter Code=P9PGIBU Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	PPG increment breakfast (SMPG) (mg/dL)	Intercept			0.01919	-0.009664
8	1	PPG increment breakfast (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)		-0.10778	-0.039428
9	1	PPG increment breakfast (SMPG) (mg/dL)	REGION1	EUROPE		-0.05629	-0.188571

	O b s _	P A R A M	E f f e c t	R E G I O N	B O L U S	O b s V a l	I
10	1	PPG increment breakfast (SMPG) (mg/dL)	REGION1	JAPAN		0.08052	0.109542
11	1	PPG increment breakfast (SMPG) (mg/dL)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.00262	0.057633
12	1	PPG increment breakfast (SMPG) (mg/dL)	BASE			-0.47094	-0.416971
13	1	PPG increment breakfast (SMPG) (mg/dL)	visit2200			0.30008	0.330608

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PGIBU Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG increment breakfast (SMPG) (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG increment breakfast (SMPG) (mg/dL)	Method	Monotone
3	1	PPG increment breakfast (SMPG) (mg/dL)	Number of Imputations	1
4	1	PPG increment breakfast (SMPG) (mg/dL)	Seed for random number generator	4322

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression Missing Data Pattern

Parameter Code=P9PGIBU Planned Treatment for Period 30 (N)=3

O b s	I m p u t a t i o n —	P A R A M	G r o u p	R E G I O N 1	B E N E F I T 1	B E N E F I T 2	B E N E F I T 3	B E N E F I T 4	B E N E F I T 5	F r e q	P e r c e n t	B A S E	v i s i t 2 0 0	v i s i t 3 0 0
1	1	PPG increment breakfast (SMPG)	(mg/dL)	1	X	X	X	X	X	314	94.86	37.635953	1.837052	1.277706
2	1	PPG increment breakfast (SMPG)	(mg/dL)	2	X	X	X	X	.	13	3.93	4.180205	1.680538	.
3	1	PPG increment breakfast (SMPG)	(mg/dL)	3	X	X	X	.	.	4	1.21	38.476167	.	.

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGIBU Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG increment breakfast (SMPG) (mg/dL)	Intercept	
2	1	PPG increment breakfast (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG increment breakfast (SMPG) (mg/dL)	REGION1	EUROPE
4	1	PPG increment breakfast (SMPG) (mg/dL)	REGION1	JAPAN
5	1	PPG increment breakfast (SMPG) (mg/dL)	BOLAD1	
6	1	PPG increment breakfast (SMPG) (mg/dL)	BASE	

Obs	BOLAD1	ObsVal	_1
1		0.05183	0.144710
2		0.16721	0.291198
3		-0.14916	-0.147429
4		0.18141	0.094926
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.14534	-0.119444
6		-0.58293	-0.620116

Parameter Code=P9PGIBU Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	PPG increment breakfast (SMPG) (mg/dL)	Intercept			0.02643	0.091142
8	1	PPG increment breakfast (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)		-0.03529	-0.090700
9	1	PPG increment breakfast (SMPG) (mg/dL)	REGION1	EUROPE		-0.01090	-0.028448

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression Regression Information

Parameter Code=P9PGIBU Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

(continued)

O b s _										I				
P A R A M										E f f e c t	R E G I O N 1	B O L A D 1	O b s V a l	I
10	1	PPG	increment	breakfast	(SMPG)	(mg/dL)	REGION1	JAPAN					0.21034	0.233716
11	1	PPG	increment	breakfast	(SMPG)	(mg/dL)	BOLAD1		BOLUS	INSULIN	ALGORITHM	(SLIDING SCALE)	-0.16258	-0.179696
12	1	PPG	increment	breakfast	(SMPG)	(mg/dL)	BASE						-0.51082	-0.563606
13	1	PPG	increment	breakfast	(SMPG)	(mg/dL)	visit2200						0.33313	0.354588

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PGIBU Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG increment breakfast (SMPG) (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG increment breakfast (SMPG) (mg/dL)	Method	Monotone
3	1	PPG increment breakfast (SMPG) (mg/dL)	Number of Imputations	1
4	1	PPG increment breakfast (SMPG) (mg/dL)	Seed for random number generator	4323

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGIBU Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG increment breakfast (SMPG) (mg/dL)	Intercept	
2	1	PPG increment breakfast (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG increment breakfast (SMPG) (mg/dL)	REGION1	EUROPE
4	1	PPG increment breakfast (SMPG) (mg/dL)	REGION1	JAPAN
5	1	PPG increment breakfast (SMPG) (mg/dL)	BOLAD1	
6	1	PPG increment breakfast (SMPG) (mg/dL)	BASE	

Obs	BOLAD1	ObsVal	_1
1		0.02774	-0.018703
2		0.04144	0.093908
3		-0.02332	-0.139713
4		0.20484	0.246309
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.08246	-0.087792
6		-0.57190	-0.649985

Parameter Code=P9PGIBU Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	PPG increment breakfast (SMPG) (mg/dL)	Intercept			0.01451	0.019353
8	1	PPG increment breakfast (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)		0.08022	0.006785
9	1	PPG increment breakfast (SMPG) (mg/dL)	REGION1	EUROPE		-0.08485	-0.036155

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression Regression Information

Parameter Code=P9PGIBU Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

(continued)

[illegible]

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=P9PGINCB Planned Treatment for Period 30 (N)=2

Obs	PARAM				Description	Value
1	PPG	increment	breakfast	(SMPG) (mmol/L)	Data Set	WORK.ENDPOINT_PARAM
2	PPG	increment	breakfast	(SMPG) (mmol/L)	Method	Monotone-data_MCMC
3	PPG	increment	breakfast	(SMPG) (mmol/L)	Multiple Imputation Chain	Multiple Chains
4	PPG	increment	breakfast	(SMPG) (mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
5	PPG	increment	breakfast	(SMPG) (mmol/L)	Start	Starting Value
6	PPG	increment	breakfast	(SMPG) (mmol/L)	Prior	Jeffreys
7	PPG	increment	breakfast	(SMPG) (mmol/L)	Number of Imputations	20000
8	PPG	increment	breakfast	(SMPG) (mmol/L)	Number of Burn-in Iterations	200
9	PPG	increment	breakfast	(SMPG) (mmol/L)	Seed for random number generator	1234

Parameter Code=P9PGINCB Planned Treatment for Period 30 (N)=3

Obs	PARAM				Description	Value
10	PPG	increment	breakfast	(SMPG) (mmol/L)	Data Set	WORK.ENDPOINT_PARAM
11	PPG	increment	breakfast	(SMPG) (mmol/L)	Method	Monotone-data_MCMC
12	PPG	increment	breakfast	(SMPG) (mmol/L)	Multiple Imputation Chain	Multiple Chains
13	PPG	increment	breakfast	(SMPG) (mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
14	PPG	increment	breakfast	(SMPG) (mmol/L)	Start	Starting Value
15	PPG	increment	breakfast	(SMPG) (mmol/L)	Prior	Jeffreys
16	PPG	increment	breakfast	(SMPG) (mmol/L)	Number of Imputations	20000
17	PPG	increment	breakfast	(SMPG) (mmol/L)	Number of Burn-in Iterations	200
18	PPG	increment	breakfast	(SMPG) (mmol/L)	Seed for random number generator	1890978291

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=P9PPGINCB Planned Treatment for Period 30 (N)=4

Obs	PARAM				Description	Value
19	PPG increment breakfast	(SMPG)	(mmol/L)		Data Set	WORK.ENDPOINT_PARAM
20	PPG increment breakfast	(SMPG)	(mmol/L)		Method	Monotone-data_MCMC
21	PPG increment breakfast	(SMPG)	(mmol/L)		Multiple Imputation Chain	Multiple Chains
22	PPG increment breakfast	(SMPG)	(mmol/L)		Initial Estimates for MCMC	EM Posterior Mode
23	PPG increment breakfast	(SMPG)	(mmol/L)		Start	Starting Value
24	PPG increment breakfast	(SMPG)	(mmol/L)		Prior	Jeffreys
25	PPG increment breakfast	(SMPG)	(mmol/L)		Number of Imputations	20000
26	PPG increment breakfast	(SMPG)	(mmol/L)		Number of Burn-in Iterations	200
27	PPG increment breakfast	(SMPG)	(mmol/L)		Seed for random number generator	91941876

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with MCMC

Missing data pattern

Parameter Code=P9PGINCB Planned Treatment for Period 30 (N)=2

						v i s i t t						v i s i t t					
						B A S E			P e r c e n t			v i s i t t					
						M̄ i s s			F r e q			B A S E			v i s i t t		
						G r o u p											
						P A R A M											
1	PPG	increment	breakfast	(SMPG)	(mmol/L)	1	X	X	X	289	88.65	2.345405	-1.158103	-1.154065			
2	PPG	increment	breakfast	(SMPG)	(mmol/L)	2	X	X	O	11	3.37	0.504645	0.794229	.			
3	PPG	increment	breakfast	(SMPG)	(mmol/L)	3	X	.	X	15	4.60	1.868504	.	-1.162071			
4	PPG	increment	breakfast	(SMPG)	(mmol/L)	4	X	O	O	11	3.37	-0.865553	.	.			

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with MCMC

Missing data pattern

Parameter Code=P9PGINCB Planned Treatment for Period 30 (N)=3

O b s						P A R A M	G r o u p	v i s i t t v i s i t t			F r e q	P e r c e n t	B A S E	v i s i t t v i s i t t	v i s i t t v i s i t t
								B A S E	2 2 0 0	3 6 0 0					
5	PPG	increment	breakfast	(SMPG)	(mmol/L)	1	X	X	X	299	90.33	2.140644	0.035053	0.061824	
6	PPG	increment	breakfast	(SMPG)	(mmol/L)	2	X	X	O	13	3.93	0.231976	0.093260	.	
7	PPG	increment	breakfast	(SMPG)	(mmol/L)	3	X	.	X	15	4.53	1.050472	.	0.251910	
8	PPG	increment	breakfast	(SMPG)	(mmol/L)	4	X	O	O	4	1.21	2.135192	.	.	

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with MCMC
Missing data pattern

Parameter Code=P9PPGINCB Planned Treatment for Period 30 (N)=4

O b s	P A R A M	G r o u p				F r e q	P e r c e n t	B A S E	v i s i t 2 0 0	v i s i t 3 6 0 0
			B	A	S					
			E	0	0					
			\bar{M}	\bar{M}	\bar{M}					
9	PPG increment breakfast (SMPG) (mmol/L)	1	X	X	X	292	88.75	2.142164	-0.222674	-0.367509
			X	X	O					
			X	.	X					
			X	O	O					
10	PPG increment breakfast (SMPG) (mmol/L)	2	X	X	O	11	3.34	2.065372	-1.211817	.
11	PPG increment breakfast (SMPG) (mmol/L)	3	X	.	X	14	4.26	0.405182	.	0.634652
12	PPG increment breakfast (SMPG) (mmol/L)	4	X	O	O	12	3.65	1.245486	.	.

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2213 of 4425	Novo Nordisk
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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PPGINCB Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG increment breakfast (SMPG) (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG increment breakfast (SMPG) (mmol/L)	Method	Monotone
3	1	PPG increment breakfast (SMPG) (mmol/L)	Number of Imputations	1
4	1	PPG increment breakfast (SMPG) (mmol/L)	Seed for random number generator	4321

nn1218/nn1218-4131/ctr_20180214_er
09FEB2018:20:27:18 - a_797pp_stat_diff.sas/a_9pp_ppginc_stat_in_fas_app.txt

```
nn1218/nn1218-4131/ctr_20180214_er
09FEB2018:20:27:18 - a 797pp stat diff.sas/a 9pp ppginc stat in_fas app.txt
```

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGINCB Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG increment breakfast (SMPG) (mmol/L)	Intercept	
2	1	PPG increment breakfast (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG increment breakfast (SMPG) (mmol/L)	REGION1	EUROPE
4	1	PPG increment breakfast (SMPG) (mmol/L)	REGION1	JAPAN
5	1	PPG increment breakfast (SMPG) (mmol/L)	BOLAD1	
6	1	PPG increment breakfast (SMPG) (mmol/L)	BASE	

Obs	BOLAD1	ObsVal	_1
1		0.01966	0.049077
2		0.01836	0.045596
3		0.04348	-0.072233
4		-0.03538	-0.055052
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.00315	-0.039822
6		-0.68302	-0.711298

Parameter Code=P9PGINCB Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	PPG increment breakfast (SMPG) (mmol/L)	Intercept			0.01919	-0.009664
8	1	PPG increment breakfast (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)		-0.10778	-0.039428
9	1	PPG increment breakfast (SMPG) (mmol/L)	REGION1	EUROPE		-0.05629	-0.188571

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PPGINCB Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

(continued)

Imputed				Region		BOLUS		INSULIN		ALGORITHM		(SLIDING SCALE)		Mean	
Obs	P	A	M	E	R	B	O	L	A	D	N	1	1	1	1
10	1	PPG	increment	breakfast	(SMPG)	(mmol/L)	REGION1	JAPAN						0.08052	0.109542
11	1	PPG	increment	breakfast	(SMPG)	(mmol/L)	BOLAD1		BOLUS	INSULIN	ALGORITHM	(SLIDING	SCALE)	-0.00262	0.057633
12	1	PPG	increment	breakfast	(SMPG)	(mmol/L)	BASE							-0.47094	-0.416971
13	1	PPG	increment	breakfast	(SMPG)	(mmol/L)	visit2200							0.30008	0.330608

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PGINCB Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG increment breakfast (SMPG) (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG increment breakfast (SMPG) (mmol/L)	Method	Monotone
3	1	PPG increment breakfast (SMPG) (mmol/L)	Number of Imputations	1
4	1	PPG increment breakfast (SMPG) (mmol/L)	Seed for random number generator	4322

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGINCB Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG increment breakfast (SMPG) (mmol/L)	Intercept	
2	1	PPG increment breakfast (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG increment breakfast (SMPG) (mmol/L)	REGION1	EUROPE
4	1	PPG increment breakfast (SMPG) (mmol/L)	REGION1	JAPAN
5	1	PPG increment breakfast (SMPG) (mmol/L)	BOLAD1	
6	1	PPG increment breakfast (SMPG) (mmol/L)	BASE	

Obs	BOLAD1	ObsVal	_1
1		0.05183	0.144710
2		0.16721	0.291198
3		-0.14916	-0.147429
4		0.18141	0.094926
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.14534	-0.119444
6		-0.58293	-0.620116

Parameter Code=P9PGINCB Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	PPG increment breakfast (SMPG) (mmol/L)	Intercept			0.02643	0.091142
8	1	PPG increment breakfast (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)		-0.03529	-0.090700
9	1	PPG increment breakfast (SMPG) (mmol/L)	REGION1	EUROPE		-0.01090	-0.028448

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGINCB Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

(continued)

Imputed				Region		BOLUS		INSULIN		ALGORITHM		(SLIDING SCALE)		Slope		Intercept	
Obs	P	A	M	E	R	B	O	I	N	A	D	1	1				
10	1	PPG	increment	breakfast	(SMPG)	(mmol/L)	REGION1	JAPAN						0.21034		0.233716	
11	1	PPG	increment	breakfast	(SMPG)	(mmol/L)	BOLAD1		BOLUS	INSULIN	ALGORITHM	(SLIDING	SCALE)	-0.16258		-0.179696	
12	1	PPG	increment	breakfast	(SMPG)	(mmol/L)	BASE							-0.51082		-0.563606	
13	1	PPG	increment	breakfast	(SMPG)	(mmol/L)	visit2200							0.33313		0.354588	

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PGINCB Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG increment breakfast (SMPG) (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG increment breakfast (SMPG) (mmol/L)	Method	Monotone
3	1	PPG increment breakfast (SMPG) (mmol/L)	Number of Imputations	1
4	1	PPG increment breakfast (SMPG) (mmol/L)	Seed for random number generator	4323

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nn1218/nn1218-4131/ctr_20180214_er
09FEB2018:20:27:18 - a 797pp stat diff.sas/a 9pp ppginc stat in_fas app.txt
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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGINCB Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG increment breakfast (SMPG) (mmol/L)	Intercept	
2	1	PPG increment breakfast (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG increment breakfast (SMPG) (mmol/L)	REGION1	EUROPE
4	1	PPG increment breakfast (SMPG) (mmol/L)	REGION1	JAPAN
5	1	PPG increment breakfast (SMPG) (mmol/L)	BOLAD1	
6	1	PPG increment breakfast (SMPG) (mmol/L)	BASE	

Obs	BOLAD1	ObsVal	_1
1		0.02774	-0.018703
2		0.04144	0.093908
3		-0.02332	-0.139713
4		0.20484	0.246309
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.08246	-0.087792
6		-0.57190	-0.649985

Parameter Code=P9PGINCB Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	PPG increment breakfast (SMPG) (mmol/L)	Intercept			0.01451	0.019353
8	1	PPG increment breakfast (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)		0.08022	0.006785
9	1	PPG increment breakfast (SMPG) (mmol/L)	REGION1	EUROPE		-0.08485	-0.036155

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PPGINCB Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

(continued)

Imputed Observations							Region	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	Observations	Imputed
				Pfizer	Amgen	East of World	Novartis			
10	1	PPG increment breakfast (SMPG)	(mmol/L)	REGION1	JAPAN				0.12813	0.203683
11	1	PPG increment breakfast (SMPG)	(mmol/L)	BOLAD1				BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.00238	-0.010154
12	1	PPG increment breakfast (SMPG)	(mmol/L)	BASE					-0.46293	-0.396663
13	1	PPG increment breakfast (SMPG)	(mmol/L)	visit2200					0.31985	0.247807

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=P9PGILU Planned Treatment for Period 30 (N)=2

Obs	PARAM	Description	Value
1	PPG increment lunch (SMPG) (mg/dL)	Data Set	WORK.ENDPOINT_PARAM
2	PPG increment lunch (SMPG) (mg/dL)	Method	Monotone-data_MCMC
3	PPG increment lunch (SMPG) (mg/dL)	Multiple Imputation Chain	Multiple Chains
4	PPG increment lunch (SMPG) (mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
5	PPG increment lunch (SMPG) (mg/dL)	Start	Starting Value
6	PPG increment lunch (SMPG) (mg/dL)	Prior	Jeffreys
7	PPG increment lunch (SMPG) (mg/dL)	Number of Imputations	20000
8	PPG increment lunch (SMPG) (mg/dL)	Number of Burn-in Iterations	200
9	PPG increment lunch (SMPG) (mg/dL)	Seed for random number generator	1234

Parameter Code=P9PGILU Planned Treatment for Period 30 (N)=3

Obs	PARAM	Description	Value
10	PPG increment lunch (SMPG) (mg/dL)	Data Set	WORK.ENDPOINT_PARAM
11	PPG increment lunch (SMPG) (mg/dL)	Method	Monotone-data_MCMC
12	PPG increment lunch (SMPG) (mg/dL)	Multiple Imputation Chain	Multiple Chains
13	PPG increment lunch (SMPG) (mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
14	PPG increment lunch (SMPG) (mg/dL)	Start	Starting Value
15	PPG increment lunch (SMPG) (mg/dL)	Prior	Jeffreys
16	PPG increment lunch (SMPG) (mg/dL)	Number of Imputations	20000
17	PPG increment lunch (SMPG) (mg/dL)	Number of Burn-in Iterations	200
18	PPG increment lunch (SMPG) (mg/dL)	Seed for random number generator	1964087206

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=P9PGILU Planned Treatment for Period 30 (N)=4

Obs	PARAM			Description	Value
19	PPG increment	lunch	(SMPG) (mg/dL)	Data Set	WORK.ENDPOINT_PARAM
20	PPG increment	lunch	(SMPG) (mg/dL)	Method	Monotone-data_MCMC
21	PPG increment	lunch	(SMPG) (mg/dL)	Multiple Imputation Chain	Multiple Chains
22	PPG increment	lunch	(SMPG) (mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
23	PPG increment	lunch	(SMPG) (mg/dL)	Start	Starting Value
24	PPG increment	lunch	(SMPG) (mg/dL)	Prior	Jeffreys
25	PPG increment	lunch	(SMPG) (mg/dL)	Number of Imputations	20000
26	PPG increment	lunch	(SMPG) (mg/dL)	Number of Burn-in Iterations	200
27	PPG increment	lunch	(SMPG) (mg/dL)	Seed for random number generator	67020607

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with MCMC

Missing data pattern

Parameter Code=P9PGILU Planned Treatment for Period 30 (N)=2

					v i s i t			v i s i t					
					B A S E			2 6 0			v i s i t		
					\bar{M} i s s			\bar{M} i s s			2 2 0		
					P A R A M			G r o u p			P e r c e n t		
					F r e q			B A S E			v i s i t		
					3			6			3		
					0			0			0		
					0			0			0		
1	PPG increment lunch (SMPG) (mg/dL)	1	X	X	X	288	88.07	35.049113	-11.737397	-11.993847	.	.	
2	PPG increment lunch (SMPG) (mg/dL)	2	X	X	O	13	3.98	45.726667	-17.801795	.	.	.	
3	PPG increment lunch (SMPG) (mg/dL)	3	X	.	X	16	4.89	32.447417	.	.	.	-6.601958	
4	PPG increment lunch (SMPG) (mg/dL)	4	X	O	O	10	3.06	-6.926367	

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with MCMC

Missing data pattern

Parameter Code=P9PGILU Planned Treatment for Period 30 (N)=3

O b s					P A R A M	G r o u p	B A S E			F r e q	P e r c e n t	B A S E	v i s i t 2 2 0 0	v i s i t 3 6 0 0
							\bar{M}	\bar{M}	\bar{M}					
5	PPG increment	lunch	(SMPG)	(mg/dL)	1	X	X	X	296	90.80	36.915833	-0.048015	-2.292946	
6	PPG increment	lunch	(SMPG)	(mg/dL)	2	X	X	O	12	3.68	1.961000	22.065417	.	
7	PPG increment	lunch	(SMPG)	(mg/dL)	3	X	.	X	13	3.99	25.808872	.	-2.174590	
8	PPG increment	lunch	(SMPG)	(mg/dL)	4	X	O	O	5	1.53	8.787200	.		

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nn1218/nn1218-4131/ctr_20180214_er
09FEB2018:20:27:18 - a 797pp stat diff.sas/a 9pp ppginc stat in_fas app.txt
```

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PGILU Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG increment lunch (SMPG) (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG increment lunch (SMPG) (mg/dL)	Method	Monotone
3	1	PPG increment lunch (SMPG) (mg/dL)	Number of Imputations	1
4	1	PPG increment lunch (SMPG) (mg/dL)	Seed for random number generator	4321

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression Missing Data Pattern

Parameter Code=P9PGILU Planned Treatment for Period 30 (N)=2

O b s	I m p u t a t i o n —	P A R A M	G r o u p	R E G I O N A L E S					F r e q	P e r c e n t	B A S E	v i s i t 2 0 0	v i s i t 3 6 0 0		
				\bar{M}	\bar{M}	\bar{M}	\bar{M}	\bar{M}							
1	1	PPG increment	lunch (SMPG)	(mg/dL)	1	X	X	X	X	X	304	92.97	34.912182	-11.777396	-11.710064
2	1	PPG increment	lunch (SMPG)	(mg/dL)	2	X	X	X	X	.	13	3.98	45.726667	-17.801795	.
3	1	PPG increment	lunch (SMPG)	(mg/dL)	3	X	X	X	.	.	10	3.06	-6.926367	.	.

Fast-acting insulin aspart
NN1218-4131

Clinical Trial Report
Statistical document

Date:
Version:

14 February 2018
1.0

Status:
Page:

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Novo Nordisk

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGILU Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG increment lunch (SMPG) (mg/dL)	Intercept	
2	1	PPG increment lunch (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG increment lunch (SMPG) (mg/dL)	REGION1	EUROPE
4	1	PPG increment lunch (SMPG) (mg/dL)	REGION1	JAPAN
5	1	PPG increment lunch (SMPG) (mg/dL)	BOLAD1	
6	1	PPG increment lunch (SMPG) (mg/dL)	BASE	

Obs	BOLAD1	ObsVal	_1
1		0.03342	0.066473
2		-0.12081	-0.090309
3		-0.08069	-0.210039
4		0.34223	0.321667
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.05161	-0.097745
6		-0.59318	-0.611487

Parameter Code=P9PGILU Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	PPG increment lunch (SMPG) (mg/dL)	Intercept			-0.03822	-0.065073
8	1	PPG increment lunch (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)		-0.16445	-0.245409
9	1	PPG increment lunch (SMPG) (mg/dL)	REGION1	EUROPE		0.03975	0.130754

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression Regression Information

Parameter Code=P9PGILU Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

(continued)

							Input Observations	Parameters	Effects	Region	Bolus Algorithm	Observations	
10	1	PPG	increment	lunch	(SMPG)	(mg/dL)	REGION1	JAPAN				0.04696	-0.088966
11	1	PPG	increment	lunch	(SMPG)	(mg/dL)	BOLAD1		BOLUS	INSULIN	ALGORITHM (SLIDING SCALE)	0.11745	0.152445
12	1	PPG	increment	lunch	(SMPG)	(mg/dL)	BASE					-0.45232	-0.340475
13	1	PPG	increment	lunch	(SMPG)	(mg/dL)	visit2200					0.26056	0.365874

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PGILU Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG increment lunch (SMPG) (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG increment lunch (SMPG) (mg/dL)	Method	Monotone
3	1	PPG increment lunch (SMPG) (mg/dL)	Number of Imputations	1
4	1	PPG increment lunch (SMPG) (mg/dL)	Seed for random number generator	4322

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression Missing Data Pattern

Parameter Code=P9PGILU Planned Treatment for Period 30 (N)=3

O b s	I m p u t a t i o n —	P A R A M	G r o u p	R E G I O N A L E S					F r e q	P e r c e n t	B A S E	v i s i t 2 0 0	v i s i t 3 6 0 0			
				M	M	M	M	M								
1	1	PPG increment	lunch	(SMPG)	(mg/dL)	1	X	X	X	X	X	309	94.79	36.448550	0.751942	-2.287967
2	1	PPG increment	lunch	(SMPG)	(mg/dL)	2	X	X	X	X	.	12	3.68	1.961000	22.065417	.
3	1	PPG increment	lunch	(SMPG)	(mg/dL)	3	X	X	X	.	.	5	1.53	8.787200	.	.

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGILU Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG increment lunch (SMPG) (mg/dL)	Intercept	
2	1	PPG increment lunch (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG increment lunch (SMPG) (mg/dL)	REGION1	EUROPE
4	1	PPG increment lunch (SMPG) (mg/dL)	REGION1	JAPAN
5	1	PPG increment lunch (SMPG) (mg/dL)	BOLAD1	
6	1	PPG increment lunch (SMPG) (mg/dL)	BASE	

Obs	BOLAD1	ObsVal	_1
1		0.04340	0.136412
2		0.14729	0.271026
3		-0.16875	-0.165199
4		0.15387	0.064927
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.05788	-0.031421
6		-0.60345	-0.634725

Parameter Code=P9PGILU Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	PPG increment lunch (SMPG) (mg/dL)	Intercept			0.01089	-0.051866
8	1	PPG increment lunch (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)		-0.14040	-0.237695
9	1	PPG increment lunch (SMPG) (mg/dL)	REGION1	EUROPE		-0.16186	-0.140054

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression Regression Information

Parameter Code=P9PGILU Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

(continued)

							Input Observations	Parameters	Effects	Region	Bolus Dose	Observed	Interval
10	1	PPG	increment	lunch	(SMPG)	(mg/dL)	REGION1	JAPAN				0.29281	0.291263
11	1	PPG	increment	lunch	(SMPG)	(mg/dL)	BOLAD1		BOLUS	INSULIN	ALGORITHM (SLIDING SCALE)	-0.02597	-0.039362
12	1	PPG	increment	lunch	(SMPG)	(mg/dL)	BASE					-0.51453	-0.443834
13	1	PPG	increment	lunch	(SMPG)	(mg/dL)	visit2200					0.20712	0.231551

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PGILU Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG increment lunch (SMPG) (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG increment lunch (SMPG) (mg/dL)	Method	Monotone
3	1	PPG increment lunch (SMPG) (mg/dL)	Number of Imputations	1
4	1	PPG increment lunch (SMPG) (mg/dL)	Seed for random number generator	4323

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression Missing Data Pattern

Parameter Code=P9PGILU Planned Treatment for Period 30 (N)=4

O b s	I m p u t a t i o n —	P A R A M	G r o u p	R E G I O N A L E S					F r e q	P e r c e n t	B A S E	v i s i t 2 0 0	v i s i t 3 6 0 0			
				M	M	M	M	M								
1	1	PPG increment	lunch	(SMPG)	(mg/dL)	1	X	X	X	X	X	307	93.31	30.855792	-2.120781	-0.490010
2	1	PPG increment	lunch	(SMPG)	(mg/dL)	2	X	X	X	X	.	12	3.65	22.342833	-3.657167	.
3	1	PPG increment	lunch	(SMPG)	(mg/dL)	3	X	X	X	.	.	10	3.04	23.519800	.	.

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGILU Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG increment lunch (SMPG) (mg/dL)	Intercept	
2	1	PPG increment lunch (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG increment lunch (SMPG) (mg/dL)	REGION1	EUROPE
4	1	PPG increment lunch (SMPG) (mg/dL)	REGION1	JAPAN
5	1	PPG increment lunch (SMPG) (mg/dL)	BOLAD1	
6	1	PPG increment lunch (SMPG) (mg/dL)	BASE	

Obs	BOLAD1	ObsVal	_1
1		-0.00706	-0.049627
2		-0.07604	-0.027144
3		-0.07045	-0.177040
4		0.12713	0.164454
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.04250	0.038263
6		-0.65867	-0.727266

Parameter Code=P9PGILU Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	PPG increment lunch (SMPG) (mg/dL)	Intercept			0.04418	0.016743
8	1	PPG increment lunch (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)		0.16408	0.155976
9	1	PPG increment lunch (SMPG) (mg/dL)	REGION1	EUROPE		-0.19935	-0.247569

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression Regression Information

Parameter Code=P9PGILU Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

(continued)

							Input				Obs	
							PARAM	Effect	REGION	BOLD	ObsVal	\bar{I}
10	1	PPG	increment	lunch	(SMPG)	(mg/dL)	REGION1	JAPAN			0.13871	0.191861
11	1	PPG	increment	lunch	(SMPG)	(mg/dL)	BOLAD1		BOLUS	INSULIN ALGORITHM (SLIDING SCALE)	-0.07468	-0.026682
12	1	PPG	increment	lunch	(SMPG)	(mg/dL)	BASE				-0.44655	-0.461085
13	1	PPG	increment	lunch	(SMPG)	(mg/dL)	visit2200				0.31459	0.365404

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=P9PGINCL Planned Treatment for Period 30 (N)=2

Obs	PARAM				Description	Value
1	PPG increment	lunch	(SMPG)	(mmol/L)	Data Set	WORK.ENDPOINT_PARAM
2	PPG increment	lunch	(SMPG)	(mmol/L)	Method	Monotone-data_MCMC
3	PPG increment	lunch	(SMPG)	(mmol/L)	Multiple Imputation Chain	Multiple Chains
4	PPG increment	lunch	(SMPG)	(mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
5	PPG increment	lunch	(SMPG)	(mmol/L)	Start	Starting Value
6	PPG increment	lunch	(SMPG)	(mmol/L)	Prior	Jeffreys
7	PPG increment	lunch	(SMPG)	(mmol/L)	Number of Imputations	20000
8	PPG increment	lunch	(SMPG)	(mmol/L)	Number of Burn-in Iterations	200
9	PPG increment	lunch	(SMPG)	(mmol/L)	Seed for random number generator	1234

Parameter Code=P9PGINCL Planned Treatment for Period 30 (N)=3

Obs	PARAM				Description	Value
10	PPG increment	lunch	(SMPG)	(mmol/L)	Data Set	WORK.ENDPOINT_PARAM
11	PPG increment	lunch	(SMPG)	(mmol/L)	Method	Monotone-data_MCMC
12	PPG increment	lunch	(SMPG)	(mmol/L)	Multiple Imputation Chain	Multiple Chains
13	PPG increment	lunch	(SMPG)	(mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
14	PPG increment	lunch	(SMPG)	(mmol/L)	Start	Starting Value
15	PPG increment	lunch	(SMPG)	(mmol/L)	Prior	Jeffreys
16	PPG increment	lunch	(SMPG)	(mmol/L)	Number of Imputations	20000
17	PPG increment	lunch	(SMPG)	(mmol/L)	Number of Burn-in Iterations	200
18	PPG increment	lunch	(SMPG)	(mmol/L)	Seed for random number generator	1964087206

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=P9PPGINCL Planned Treatment for Period 30 (N)=4

Obs	PARAM				Description	Value
19	PPG increment	lunch	(SMPG)	(mmol/L)	Data Set	WORK.ENDPOINT_PARAM
20	PPG increment	lunch	(SMPG)	(mmol/L)	Method	Monotone-data_MCMC
21	PPG increment	lunch	(SMPG)	(mmol/L)	Multiple Imputation Chain	Multiple Chains
22	PPG increment	lunch	(SMPG)	(mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
23	PPG increment	lunch	(SMPG)	(mmol/L)	Start	Starting Value
24	PPG increment	lunch	(SMPG)	(mmol/L)	Prior	Jeffreys
25	PPG increment	lunch	(SMPG)	(mmol/L)	Number of Imputations	20000
26	PPG increment	lunch	(SMPG)	(mmol/L)	Number of Burn-in Iterations	200
27	PPG increment	lunch	(SMPG)	(mmol/L)	Seed for random number generator	67020607

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The MI Procedure with MCMC
Missing data pattern

Parameter Code=P9PGINCL Planned Treatment for Period 30 (N)=2

O b s							v i s i t 2 3						v i s i t 2 3	
							B A S E						v i s i t 2 3	
							G r o u p						v i s i t 2 3	
							P A R A M						v i s i t 2 3	
							M S S S						v i s i t 2 3	
1	PPG	increment	lunch	(SMPG)	(mmol/L)	1	X	X	X	288	88.07	1.945012	-0.651354	-0.665585
2	PPG	increment	lunch	(SMPG)	(mmol/L)	2	X	X	O	13	3.98	2.537551	-0.987891	.
3	PPG	increment	lunch	(SMPG)	(mmol/L)	3	X	.	X	16	4.89	1.800634	.	-0.366368
4	PPG	increment	lunch	(SMPG)	(mmol/L)	4	X	O	O	10	3.06	-0.384371	.	.

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with MCMC

Missing data pattern

Parameter Code=P9PGINCL Planned Treatment for Period 30 (N)=3

Obs	P A R A M					G r o u p	B A S E M M S			F r e q	P e r c e n t	B A S E	v i s i t 2 2 0 0	v i s i t 3 6 0 0
	1	2	3	4	5		M	M	M					
5	PPG	increment	lunch	(SMPG)	(mmol/L)	1	X	X	X	296	90.80	2.048603	-0.002665	-0.127245
6	PPG	increment	lunch	(SMPG)	(mmol/L)	2	X	X	O	12	3.68	0.108824	1.224496	.
7	PPG	increment	lunch	(SMPG)	(mmol/L)	3	X	.	X	13	3.99	1.432235	.	-0.120676
8	PPG	increment	lunch	(SMPG)	(mmol/L)	4	X	O	O	5	1.53	0.487636	.	.

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with MCMC
Missing data pattern

Parameter Code=P9PPGINCL Planned Treatment for Period 30 (N)=4

						v i s i t t						v i s i t t	
						B A S E						v i s i t t	
						M i s s		M i s s				2 3 6 0 0	
						G r o u p		F r e q		P e r c e n t		B A S E	
						P A R A M						2 2 0 0	
												3 6 0 0	
9	PPG increment	lunch	(SMPG)	(mmol/L)	1	X	X	X	293	89.06	1.741711	-0.122930	0.016175
10	PPG increment	lunch	(SMPG)	(mmol/L)	2	X	X	O	12	3.65	1.239891	-0.202950	.
11	PPG increment	lunch	(SMPG)	(mmol/L)	3	X	.	X	14	4.26	1.096954	.	-0.934822
12	PPG increment	lunch	(SMPG)	(mmol/L)	4	X	O	O	10	3.04	1.305205	.	.

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PGINCL Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG increment lunch (SMPG) (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG increment lunch (SMPG) (mmol/L)	Method	Monotone
3	1	PPG increment lunch (SMPG) (mmol/L)	Number of Imputations	1
4	1	PPG increment lunch (SMPG) (mmol/L)	Seed for random number generator	4321

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGINCL Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG increment lunch (SMPG) (mmol/L)	Intercept	
2	1	PPG increment lunch (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG increment lunch (SMPG) (mmol/L)	REGION1	EUROPE
4	1	PPG increment lunch (SMPG) (mmol/L)	REGION1	JAPAN
5	1	PPG increment lunch (SMPG) (mmol/L)	BOLAD1	
6	1	PPG increment lunch (SMPG) (mmol/L)	BASE	

Obs	BOLAD1	ObsVal	_1
1		0.03342	0.066473
2		-0.12081	-0.090309
3		-0.08069	-0.210039
4		0.34223	0.321667
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.05161	-0.097745
6		-0.59318	-0.611487

Parameter Code=P9PGINCL Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	PPG increment lunch (SMPG) (mmol/L)	Intercept			-0.03822	-0.065073
8	1	PPG increment lunch (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)		-0.16445	-0.245409
9	1	PPG increment lunch (SMPG) (mmol/L)	REGION1	EUROPE		0.03975	0.130754

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PPGINCL Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG increment lunch (SMPG) (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG increment lunch (SMPG) (mmol/L)	Method	Monotone
3	1	PPG increment lunch (SMPG) (mmol/L)	Number of Imputations	1
4	1	PPG increment lunch (SMPG) (mmol/L)	Seed for random number generator	4322

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression Missing Data Pattern

Parameter Code=P9PGINCL Planned Treatment for Period 30 (N)=3

O b s	I m p u t a t i o n s						R E G I O A N D S 1 1 E					v i s s i t t 2 3 2 6 0 0		v i s s i t t 2 3 2 6 0 0			
	P A R A M						G r o u p					F r e q		P e r c e n t			
												B A S E					
1	1	PPG	increment	lunch	(SMPG)	(mmol/L)	1	X	X	X	X	X	309	94.79	2.022672	0.041728	-0.126968
2	1	PPG	increment	lunch	(SMPG)	(mmol/L)	2	X	X	X	X	X	12	3.68	0.108824	1.224496	.
3	1	PPG	increment	lunch	(SMPG)	(mmol/L)	3	X	X	X	X	.	5	1.53	0.487636	.	.

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGINCL Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG increment lunch (SMPG) (mmol/L)	Intercept	
2	1	PPG increment lunch (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG increment lunch (SMPG) (mmol/L)	REGION1	EUROPE
4	1	PPG increment lunch (SMPG) (mmol/L)	REGION1	JAPAN
5	1	PPG increment lunch (SMPG) (mmol/L)	BOLAD1	
6	1	PPG increment lunch (SMPG) (mmol/L)	BASE	

Obs	BOLAD1	ObsVal	_1
1		0.04340	0.136412
2		0.14729	0.271026
3		-0.16875	-0.165199
4		0.15387	0.064927
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.05788	-0.031421
6		-0.60345	-0.634725

Parameter Code=P9PGINCL Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	PPG increment lunch (SMPG) (mmol/L)	Intercept			0.01089	-0.051866
8	1	PPG increment lunch (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)		-0.14040	-0.237695
9	1	PPG increment lunch (SMPG) (mmol/L)	REGION1	EUROPE		-0.16186	-0.140054

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The MI Procedure with Monotone Regression Regression Information

Parameter Code=P9PGINCL Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

(continued)

	O o b s _	P A R A M	E f f e c t	R E G I O N	B O L U S	O b s V a l	I
10	1	PPG increment lunch (SMPG) (mmol/L)	REGION1	JAPAN		0.29281	0.291263
11	1	PPG increment lunch (SMPG) (mmol/L)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.02597	-0.039362
12	1	PPG increment lunch (SMPG) (mmol/L)	BASE			-0.51453	-0.443834
13	1	PPG increment lunch (SMPG) (mmol/L)	visit2200			0.20712	0.231551

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PGINCL Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG increment lunch (SMPG) (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG increment lunch (SMPG) (mmol/L)	Method	Monotone
3	1	PPG increment lunch (SMPG) (mmol/L)	Number of Imputations	1
4	1	PPG increment lunch (SMPG) (mmol/L)	Seed for random number generator	4323

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGINCL Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG increment lunch (SMPG) (mmol/L)	Intercept	
2	1	PPG increment lunch (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG increment lunch (SMPG) (mmol/L)	REGION1	EUROPE
4	1	PPG increment lunch (SMPG) (mmol/L)	REGION1	JAPAN
5	1	PPG increment lunch (SMPG) (mmol/L)	BOLAD1	
6	1	PPG increment lunch (SMPG) (mmol/L)	BASE	

Obs	BOLAD1	ObsVal	_1
1		-0.00706	-0.049627
2		-0.07604	-0.027144
3		-0.07045	-0.177040
4		0.12713	0.164454
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.04250	0.038263
6		-0.65867	-0.727266

Parameter Code=P9PGINCL Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	PPG increment lunch (SMPG) (mmol/L)	Intercept			0.04418	0.016743
8	1	PPG increment lunch (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)		0.16408	0.155976
9	1	PPG increment lunch (SMPG) (mmol/L)	REGION1	EUROPE		-0.19935	-0.247569

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression Regression Information

Parameter Code=P9PGINCL Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

(continued)

							Output				Obs	
							PAAM	Effect	Region	BOLUS	Obs	
10	1	PPG	increment	lunch	(SMPG)	(mmol/L)	REGION1	JAPAN			0.13871	0.191861
11	1	PPG	increment	lunch	(SMPG)	(mmol/L)	BOLAD1		BOLUS	INSULIN ALGORITHM (SLIDING SCALE)	-0.07468	-0.026682
12	1	PPG	increment	lunch	(SMPG)	(mmol/L)	BASE				-0.44655	-0.461085
13	1	PPG	increment	lunch	(SMPG)	(mmol/L)	visit2200				0.31459	0.365404

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=P9PGIEU Planned Treatment for Period 30 (N)=2

Obs	PARAM	Description	Value
1	PPG increment main evening meal (SMPG) (mg/dL)	Data Set	WORK.ENDPOINT_PARAM
2	PPG increment main evening meal (SMPG) (mg/dL)	Method	Monotone-data_MCMC
3	PPG increment main evening meal (SMPG) (mg/dL)	Multiple Imputation Chain	Multiple Chains
4	PPG increment main evening meal (SMPG) (mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
5	PPG increment main evening meal (SMPG) (mg/dL)	Start	Starting Value
6	PPG increment main evening meal (SMPG) (mg/dL)	Prior	Jeffreys
7	PPG increment main evening meal (SMPG) (mg/dL)	Number of Imputations	20000
8	PPG increment main evening meal (SMPG) (mg/dL)	Number of Burn-in Iterations	200
9	PPG increment main evening meal (SMPG) (mg/dL)	Seed for random number generator	1234

Parameter Code=P9PGIEU Planned Treatment for Period 30 (N)=3

Obs	PARAM	Description	Value
10	PPG increment main evening meal (SMPG) (mg/dL)	Data Set	WORK.ENDPOINT_PARAM
11	PPG increment main evening meal (SMPG) (mg/dL)	Method	Monotone-data_MCMC
12	PPG increment main evening meal (SMPG) (mg/dL)	Multiple Imputation Chain	Multiple Chains
13	PPG increment main evening meal (SMPG) (mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
14	PPG increment main evening meal (SMPG) (mg/dL)	Start	Starting Value
15	PPG increment main evening meal (SMPG) (mg/dL)	Prior	Jeffreys
16	PPG increment main evening meal (SMPG) (mg/dL)	Number of Imputations	20000
17	PPG increment main evening meal (SMPG) (mg/dL)	Number of Burn-in Iterations	200
18	PPG increment main evening meal (SMPG) (mg/dL)	Seed for random number generator	662580315

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=P9PGIEU Planned Treatment for Period 30 (N)=4

Obs	PARAM	Description	Value
19	PPG increment main evening meal (SMPG) (mg/dL)	Data Set	WORK.ENDPOINT_PARAM
20	PPG increment main evening meal (SMPG) (mg/dL)	Method	Monotone-data_MCMC
21	PPG increment main evening meal (SMPG) (mg/dL)	Multiple Imputation Chain	Multiple Chains
22	PPG increment main evening meal (SMPG) (mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
23	PPG increment main evening meal (SMPG) (mg/dL)	Start	Starting Value
24	PPG increment main evening meal (SMPG) (mg/dL)	Prior	Jeffreys
25	PPG increment main evening meal (SMPG) (mg/dL)	Number of Imputations	20000
26	PPG increment main evening meal (SMPG) (mg/dL)	Number of Burn-in Iterations	200
27	PPG increment main evening meal (SMPG) (mg/dL)	Seed for random number generator	116507659

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with MCMC

Missing data pattern

Parameter Code=P9PGIEU Planned Treatment for Period 30 (N)=2

	O	b	s	P A R M	G r o u p	v v i i s s i i t t B A S E 2 2 0 0 3 6 0 0 \bar{M} \bar{M} \bar{M} i i i s s s s s s	F r e q	P e r c e n t	B A S E	v i s i t 2 2 0 0	v i s i t 3 6 0 0
1 PPG increment main evening meal (SMPG) (mg/dL)	1	X	X	X	286	88.00	19.170593	-14.264094	-6.659429		
2 PPG increment main evening meal (SMPG) (mg/dL)	2	X	X	O	11	3.38	-8.456485	25.231818	.		
3 PPG increment main evening meal (SMPG) (mg/dL)	3	X	. X		18	5.54	28.884185	.	0.052204		
4 PPG increment main evening meal (SMPG) (mg/dL)	4	X	O	O	10	3.08	-1.530267	.			

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The MI Procedure with MCMC

Missing data pattern

Parameter Code=P9PGIEU Planned Treatment for Period 30 (N)=4

	O	b	s	P A R A M	G r o u p	v v i i s s i i t t B 2 3 A 2 6 S 0 0 E 0 0	F r e q	P e r c e n t	B A S E	v v i s i t 2 2 0 0	v v i s i t 3 6 0 0
9 PPG increment main evening meal (SMPG) (mg/dL)	1	X	X	X	294	89.63	13.176347	4.378954	4.711452		
10 PPG increment main evening meal (SMPG) (mg/dL)	2	X	X	0	11	3.35	24.838303	5.950364	.		
11 PPG increment main evening meal (SMPG) (mg/dL)	3	X	.	X	14	4.27	16.027929	.	3.169357		
12 PPG increment main evening meal (SMPG) (mg/dL)	4	X	0	0	9	2.74	20.289111	.			

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The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PGIEU Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG increment main evening meal (SMPG) (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG increment main evening meal (SMPG) (mg/dL)	Method	Monotone
3	1	PPG increment main evening meal (SMPG) (mg/dL)	Number of Imputations	1
4	1	PPG increment main evening meal (SMPG) (mg/dL)	Seed for random number generator	4321

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The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=P9PGIEU Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM				Group	REGION1_ Miss	BOLAD1_ Miss	BASE_ Miss
1	1	PPG increment main evening meal (SMPG) (mg/dL)				1	X	X	X
2	1	PPG increment main evening meal (SMPG) (mg/dL)				2	X	X	X
3	1	PPG increment main evening meal (SMPG) (mg/dL)				3	X	X	X

Obs	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
1	X	X	304	93.54	19.745740	-14.787810	-6.262030
2	X	.	11	3.38	-8.456485	25.231818	.
3	.	.	10	3.08	-1.530267	.	.

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGIEU Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG increment main evening meal (SMPG) (mg/dL)	Intercept	
2	1	PPG increment main evening meal (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG increment main evening meal (SMPG) (mg/dL)	REGION1	EUROPE
4	1	PPG increment main evening meal (SMPG) (mg/dL)	REGION1	JAPAN
5	1	PPG increment main evening meal (SMPG) (mg/dL)	BOLAD1	
6	1	PPG increment main evening meal (SMPG) (mg/dL)	BASE	

Obs	BOLAD1	ObsVal	_1
1		-0.02802	0.001547
2		-0.08136	-0.053983
3		0.01406	-0.102029
4		-0.04712	-0.065533
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.10794	0.066725
6		-0.65356	-0.674024

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGIEU Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

Obs	Imputed												
								P	E	R	B	O	
								A	f	E	O	b	
								R	e	I	L	s	
								A	c	O	A	V	
								M	t	N	D	a	
										1	1	1	\bar{I}
7	1	PPG increment	main	evening	meal	(SMPG)	(mg/dL)	Intercept				-0.05165	-0.077043
8	1	PPG increment	main	evening	meal	(SMPG)	(mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)			-0.26934	-0.345088
9	1	PPG increment	main	evening	meal	(SMPG)	(mg/dL)	REGION1	EUROPE			0.17244	0.258332

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGIEU Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM	Effect	REGION1
10	1	PPG increment main evening meal (SMPG) (mg/dL)	REGION1	JAPAN
11	1	PPG increment main evening meal (SMPG) (mg/dL)	BOLAD1	
12	1	PPG increment main evening meal (SMPG) (mg/dL)	BASE	
13	1	PPG increment main evening meal (SMPG) (mg/dL)	visit2200	
Obs		BOLAD1	ObsVal	_1
10			-0.04717	-0.172806
11		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.09553	0.127658
12			-0.56457	-0.478711
13			0.11664	0.204449

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The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PGIEU Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG increment main evening meal (SMPG) (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG increment main evening meal (SMPG) (mg/dL)	Method	Monotone
3	1	PPG increment main evening meal (SMPG) (mg/dL)	Number of Imputations	1
4	1	PPG increment main evening meal (SMPG) (mg/dL)	Seed for random number generator	4322

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=P9PGIEU Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM				Group	REGION1_ Miss	BOLAD1_ Miss	BASE_ Miss
1	1	PPG increment main evening meal (SMPG) (mg/dL)				1	X	X	X
2	1	PPG increment main evening meal (SMPG) (mg/dL)				2	X	X	X
3	1	PPG increment main evening meal (SMPG) (mg/dL)				3	X	X	X

Obs	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
1	X	X	311	95.40	20.981390	9.014783	5.579492
2	X	.	10	3.07	-6.221467	37.402967	.
3	.	.	5	1.53	-31.457000	.	.

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGIEU Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG increment main evening meal (SMPG) (mg/dL)	Intercept	
2	1	PPG increment main evening meal (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG increment main evening meal (SMPG) (mg/dL)	REGION1	EUROPE
4	1	PPG increment main evening meal (SMPG) (mg/dL)	REGION1	JAPAN
5	1	PPG increment main evening meal (SMPG) (mg/dL)	BOLAD1	
6	1	PPG increment main evening meal (SMPG) (mg/dL)	BASE	
Obs		BOLAD1	ObsVal	_1
1			0.00772	0.095335
2			-0.08669	0.029213
3			-0.14830	-0.144993
4			0.23273	0.150839
5		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.02254	0.001725
6			-0.65127	-0.686700

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGIEU Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

Obs	Imputed											Obs	I		
				P				E		R		B		O	
				A				f		E		O		b	
				R				e		G		L		s	
				A				c		I		A		V	
				M				t		N		D		a	
										1		1		1	
7	1	PPG increment main evening meal	(SMPG)	(mg/dL)	Intercept									-0.02397	-0.081599
8	1	PPG increment main evening meal	(SMPG)	(mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)								-0.29794	-0.388903
9	1	PPG increment main evening meal	(SMPG)	(mg/dL)	REGION1	EUROPE								0.0002476	0.019714

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGIEU Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM	Effect	REGION1
10	1	PPG increment main evening meal (SMPG) (mg/dL)	REGION1	JAPAN
11	1	PPG increment main evening meal (SMPG) (mg/dL)	BOLAD1	
12	1	PPG increment main evening meal (SMPG) (mg/dL)	BASE	
13	1	PPG increment main evening meal (SMPG) (mg/dL)	visit2200	
Obs		BOLAD1	ObsVal	_1
10			0.31445	0.315405
11		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.03196	-0.044899
12			-0.57050	-0.508787
13			0.17883	0.197876

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The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PGIEU Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG increment main evening meal (SMPG) (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG increment main evening meal (SMPG) (mg/dL)	Method	Monotone
3	1	PPG increment main evening meal (SMPG) (mg/dL)	Number of Imputations	1
4	1	PPG increment main evening meal (SMPG) (mg/dL)	Seed for random number generator	4323

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=P9PGIEU Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM				Group	REGION1_ Miss	BOLAD1_ Miss	BASE_ Miss
1	1	PPG increment main evening meal (SMPG) (mg/dL)				1	X	X	X
2	1	PPG increment main evening meal (SMPG) (mg/dL)				2	X	X	X
3	1	PPG increment main evening meal (SMPG) (mg/dL)				3	X	X	X

Obs	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
1	X	X	308	93.90	13.305964	3.673204	4.641357
2	X	.	11	3.35	24.838303	5.950364	.
3	.	.	9	2.74	20.289111	.	.

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGIEU Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG increment main evening meal (SMPG) (mg/dL)	Intercept	
2	1	PPG increment main evening meal (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG increment main evening meal (SMPG) (mg/dL)	REGION1	EUROPE
4	1	PPG increment main evening meal (SMPG) (mg/dL)	REGION1	JAPAN
5	1	PPG increment main evening meal (SMPG) (mg/dL)	BOLAD1	
6	1	PPG increment main evening meal (SMPG) (mg/dL)	BASE	
Obs		BOLAD1	ObsVal	_1
1			-0.02490	-0.071601
2			-0.21233	-0.158982
3			0.05757	-0.059459
4			0.14944	0.190372
5		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.00935	-0.013773
6			-0.55875	-0.632822

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Regression Information

Parameter Code=P9PGIEU Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

Obs	Imputed														
				P				E		R		B		O	
				A				f		E		O		b	
				R				e		O		A		s	
				A				c		N		D		V	
				M				t		1		1		a	
															\bar{I}
7	1	PPG increment	main evening meal	(SMPG)	(mg/dL)			Intercept						-0.00248	0.074543
8	1	PPG increment	main evening meal	(SMPG)	(mg/dL)			REGION1	ASIA (EXCLUDING JAPAN)					0.0009690	0.009348
9	1	PPG increment	main evening meal	(SMPG)	(mg/dL)			REGION1	EUROPE					0.02874	-0.022162

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGIEU Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM	Effect	REGION1
10	1	PPG increment main evening meal (SMPG) (mg/dL)	REGION1	JAPAN
11	1	PPG increment main evening meal (SMPG) (mg/dL)	BOLAD1	
12	1	PPG increment main evening meal (SMPG) (mg/dL)	BASE	
13	1	PPG increment main evening meal (SMPG) (mg/dL)	visit2200	
Obs		BOLAD1	ObsVal	_1
10			-0.09732	-0.063383
11		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.02129	-0.072818
12			-0.43921	-0.416081
13			0.31343	0.372261

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=P9PGINCE Planned Treatment for Period 30 (N)=2

Obs	PARAM	Description	Value
1	PPG increment main evening meal (SMPG) (mmol/L)	Data Set	WORK.ENDPOINT_PARAM
2	PPG increment main evening meal (SMPG) (mmol/L)	Method	Monotone-data_MCMC
3	PPG increment main evening meal (SMPG) (mmol/L)	Multiple Imputation Chain	Multiple Chains
4	PPG increment main evening meal (SMPG) (mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
5	PPG increment main evening meal (SMPG) (mmol/L)	Start	Starting Value
6	PPG increment main evening meal (SMPG) (mmol/L)	Prior	Jeffreys
7	PPG increment main evening meal (SMPG) (mmol/L)	Number of Imputations	20000
8	PPG increment main evening meal (SMPG) (mmol/L)	Number of Burn-in Iterations	200
9	PPG increment main evening meal (SMPG) (mmol/L)	Seed for random number generator	1234

Parameter Code=P9PGINCE Planned Treatment for Period 30 (N)=3

Obs	PARAM	Description	Value
10	PPG increment main evening meal (SMPG) (mmol/L)	Data Set	WORK.ENDPOINT_PARAM
11	PPG increment main evening meal (SMPG) (mmol/L)	Method	Monotone-data_MCMC
12	PPG increment main evening meal (SMPG) (mmol/L)	Multiple Imputation Chain	Multiple Chains
13	PPG increment main evening meal (SMPG) (mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
14	PPG increment main evening meal (SMPG) (mmol/L)	Start	Starting Value
15	PPG increment main evening meal (SMPG) (mmol/L)	Prior	Jeffreys
16	PPG increment main evening meal (SMPG) (mmol/L)	Number of Imputations	20000
17	PPG increment main evening meal (SMPG) (mmol/L)	Number of Burn-in Iterations	200
18	PPG increment main evening meal (SMPG) (mmol/L)	Seed for random number generator	662580315

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=P9PGINCE Planned Treatment for Period 30 (N)=4

Obs	PARAM				Description	Value
19	PPG increment	main evening meal	(SMPG)	(mmol/L)	Data Set	WORK.ENDPOINT_PARAM
20	PPG increment	main evening meal	(SMPG)	(mmol/L)	Method	Monotone-data_MCMC
21	PPG increment	main evening meal	(SMPG)	(mmol/L)	Multiple Imputation Chain	Multiple Chains
22	PPG increment	main evening meal	(SMPG)	(mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
23	PPG increment	main evening meal	(SMPG)	(mmol/L)	Start	Starting Value
24	PPG increment	main evening meal	(SMPG)	(mmol/L)	Prior	Jeffreys
25	PPG increment	main evening meal	(SMPG)	(mmol/L)	Number of Imputations	20000
26	PPG increment	main evening meal	(SMPG)	(mmol/L)	Number of Burn-in Iterations	200
27	PPG increment	main evening meal	(SMPG)	(mmol/L)	Seed for random number generator	116507659

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with MCMC

Missing data pattern

Parameter Code=P9PGINCE Planned Treatment for Period 30 (N)=3

O b s							v v																			
							i i																			
							s s																			
							i i																			
							t t																			
							B	2	3							v										
							A	2	6							i										
							S	0	0							s										
							E	0	0							i										
																t										
							P	A	R							2										
							G	R	A							2										
							o	i	i							0										
							u	s	s							0										
							p	s	s							0										
							\bar{M}	\bar{M}	\bar{M}							3										
							i	i	i							6										
							s	s	s							0										
							s	s	s							0										

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with MCMC

Missing data pattern

Parameter Code=P9PGINCE Planned Treatment for Period 30 (N)=4

							v v								
							i i								
							s s								
							i i								
							t t								
							B 2 3						v		
							A 2 6						i		
							S 0 0						s		
							E 0 0						i		
										P			t		
P							G			B			v		
A							o			A			i		
R							u			S			s		
A							p			E			i		
M							s			t			t		
							̄M̄M̄M̄			F			3		
							i i i			r			0		
							s s s			e			6		
							s s s			q			0		
9	PPG	increment	main	evening	meal	(SMPG) (mmol/L)	1	X	X	X	294	89.63	0.731207	0.243005	0.261457
10	PPG	increment	main	evening	meal	(SMPG) (mmol/L)	2	X	X	O	11	3.35	1.378374	0.330209	.
11	PPG	increment	main	evening	meal	(SMPG) (mmol/L)	3	X	.	X	14	4.27	0.889452	.	0.175880
12	PPG	increment	main	evening	meal	(SMPG) (mmol/L)	4	X	O	O	9	2.74	1.125922	.	

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The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PGINCE Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG increment main evening meal (SMPG) (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG increment main evening meal (SMPG) (mmol/L)	Method	Monotone
3	1	PPG increment main evening meal (SMPG) (mmol/L)	Number of Imputations	1
4	1	PPG increment main evening meal (SMPG) (mmol/L)	Seed for random number generator	4321

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=P9PGINCE Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM				Group	REGION1_ Miss	BOLAD1_ Miss
1	1	PPG increment main evening meal	(SMPG)	(mmol/L)		1	X	X
2	1	PPG increment main evening meal	(SMPG)	(mmol/L)		2	X	X
3	1	PPG increment main evening meal	(SMPG)	(mmol/L)		3	X	X

Obs	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
1	X	X	X	304	93.54	1.095768	-0.820633	-0.347504
2	X	X	.	11	3.38	-0.469283	1.400212	.
3	X	.	.	10	3.08	-0.084920	.	.

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGINCE Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG increment main evening meal (SMPG) (mmol/L)	Intercept	
2	1	PPG increment main evening meal (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG increment main evening meal (SMPG) (mmol/L)	REGION1	EUROPE
4	1	PPG increment main evening meal (SMPG) (mmol/L)	REGION1	JAPAN
5	1	PPG increment main evening meal (SMPG) (mmol/L)	BOLAD1	
6	1	PPG increment main evening meal (SMPG) (mmol/L)	BASE	

Obs	BOLAD1	ObsVal	_1
1		-0.02802	0.001547
2		-0.08136	-0.053983
3		0.01406	-0.102029
4		-0.04712	-0.065533
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.10794	0.066725
6		-0.65356	-0.674024

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGINCE Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM						Effect
10	1	PPG increment main evening meal (SMPG)	(mmol/L)				REGION1	
11	1	PPG increment main evening meal (SMPG)	(mmol/L)				BOLAD1	
12	1	PPG increment main evening meal (SMPG)	(mmol/L)				BASE	
13	1	PPG increment main evening meal (SMPG)	(mmol/L)				visit2200	
Obs	REGION1	BOLAD1			ObsVal	_1		
10	JAPAN				-0.04717	-0.172806		
11	BOLUS INSULIN ALGORITHM (SLIDING SCALE)				0.09553	0.127658		
12					-0.56457	-0.478711		
13					0.11664	0.204449		

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The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PGINCE Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG increment main evening meal (SMPG) (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG increment main evening meal (SMPG) (mmol/L)	Method	Monotone
3	1	PPG increment main evening meal (SMPG) (mmol/L)	Number of Imputations	1
4	1	PPG increment main evening meal (SMPG) (mmol/L)	Seed for random number generator	4322

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The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=P9PGINCE Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM				Group	REGION1_ Miss	BOLAD1_ Miss
1	1	PPG increment main evening meal	(SMPG)	(mmol/L)		1	X	X
2	1	PPG increment main evening meal	(SMPG)	(mmol/L)		2	X	X
3	1	PPG increment main evening meal	(SMPG)	(mmol/L)		3	X	X

Obs	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
1	X	X	X	311	95.40	1.164339	0.500265	0.309628
2	X	X	.	10	3.07	-0.345253	2.075636	.
3	X	.	.	5	1.53	-1.745671	.	.

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGINCE Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG increment main evening meal (SMPG) (mmol/L)	Intercept	
2	1	PPG increment main evening meal (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG increment main evening meal (SMPG) (mmol/L)	REGION1	EUROPE
4	1	PPG increment main evening meal (SMPG) (mmol/L)	REGION1	JAPAN
5	1	PPG increment main evening meal (SMPG) (mmol/L)	BOLAD1	
6	1	PPG increment main evening meal (SMPG) (mmol/L)	BASE	

Obs	BOLAD1	ObsVal	_1
1		0.00772	0.095335
2		-0.08669	0.029213
3		-0.14830	-0.144993
4		0.23273	0.150839
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.02254	0.001725
6		-0.65127	-0.686700

Parameter Code=P9PGINCE Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

Obs		Input								Effect	REGION1	BO1	Obs	Mean
7	1	PPG	increment	main	evening	meal	(SMPG)	(mmol/L)	Intercept				-0.02397	-0.081599
8	1	PPG	increment	main	evening	meal	(SMPG)	(mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)			-0.29794	-0.388903
9	1	PPG	increment	main	evening	meal	(SMPG)	(mmol/L)	REGION1	EUROPE			0.0002476	0.019714

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PPGINCE Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM						Effect	
10	1	PPG increment main evening meal (SMPG)	(mmol/L)					REGION1	
11	1	PPG increment main evening meal (SMPG)	(mmol/L)					BOLAD1	
12	1	PPG increment main evening meal (SMPG)	(mmol/L)					BASE	
13	1	PPG increment main evening meal (SMPG)	(mmol/L)					visit2200	
Obs	REGION1	BOLAD1						ObsVal	_1
10	JAPAN							0.31445	0.315405
11		BOLUS INSULIN ALGORITHM (SLIDING SCALE)						-0.03196	-0.044899
12								-0.57050	-0.508787
13								0.17883	0.197876

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The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PGINCE Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG increment main evening meal (SMPG) (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG increment main evening meal (SMPG) (mmol/L)	Method	Monotone
3	1	PPG increment main evening meal (SMPG) (mmol/L)	Number of Imputations	1
4	1	PPG increment main evening meal (SMPG) (mmol/L)	Seed for random number generator	4323

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The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=P9PGINCE Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM				Group	REGION1_ Miss	BOLAD1_ Miss
1	1	PPG increment main evening meal	(SMPG)	(mmol/L)		1	X	X
2	1	PPG increment main evening meal	(SMPG)	(mmol/L)		2	X	X
3	1	PPG increment main evening meal	(SMPG)	(mmol/L)		3	X	X

Obs	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
1	X	X	X	308	93.90	0.738400	0.203840	0.257567
2	X	X	.	11	3.35	1.378374	0.330209	.
3	X	.	.	9	2.74	1.125922	.	.

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGINCE Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG increment main evening meal (SMPG) (mmol/L)	Intercept	
2	1	PPG increment main evening meal (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG increment main evening meal (SMPG) (mmol/L)	REGION1	EUROPE
4	1	PPG increment main evening meal (SMPG) (mmol/L)	REGION1	JAPAN
5	1	PPG increment main evening meal (SMPG) (mmol/L)	BOLAD1	
6	1	PPG increment main evening meal (SMPG) (mmol/L)	BASE	

Obs	BOLAD1	ObsVal	_1
1		-0.02490	-0.071601
2		-0.21233	-0.158982
3		0.05757	-0.059459
4		0.14944	0.190372
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.00935	-0.013773
6		-0.55875	-0.632822

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGINCE Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

Obs	Imputed						P A R A M	E f f e c t			R E G I O N 1	B O L A D 1	O b s V a l		
7	1	PPG increment	main	evening	meal	(SMPG)	(mmol/L)	Intercept							
8	1	PPG increment	main	evening	meal	(SMPG)	(mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)					-0.00248	0.074543
9	1	PPG increment	main	evening	meal	(SMPG)	(mmol/L)	REGION1	EUROPE					0.0009690	0.009348
														0.02874	-0.022162

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGINCE Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM	Effect
10	1	PPG increment main evening meal (SMPG) (mmol/L)	REGION1
11	1	PPG increment main evening meal (SMPG) (mmol/L)	BOLAD1
12	1	PPG increment main evening meal (SMPG) (mmol/L)	BASE
13	1	PPG increment main evening meal (SMPG) (mmol/L)	visit2200

Obs	REGION1	BOLAD1	ObsVal	_1
10	JAPAN		-0.09732	-0.063383
11		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.02129	-0.072818
12			-0.43921	-0.416081
13			0.31343	0.372261

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure Model Information

Parameter Code=P9PGIBU Parameter=PPG increment breakfast (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Data Set	WORK.IMPUTE
2	1	NN1218-4131	Dependent Variable	eotVisit
3	1	NN1218-4131	Covariance Structure	Diagonal
4	1	NN1218-4131	Estimation Method	REML
5	1	NN1218-4131	Residual Variance Method	Profile
6	1	NN1218-4131	Fixed Effects SE Method	Model-Based
7	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=P9PGIEU Parameter=PPG increment main evening meal (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
8	1	NN1218-4131	Data Set	WORK.IMPUTE
9	1	NN1218-4131	Dependent Variable	eotVisit
10	1	NN1218-4131	Covariance Structure	Diagonal
11	1	NN1218-4131	Estimation Method	REML
12	1	NN1218-4131	Residual Variance Method	Profile
13	1	NN1218-4131	Fixed Effects SE Method	Model-Based
14	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=P9PGILU Parameter=PPG increment lunch (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
15	1	NN1218-4131	Data Set	WORK.IMPUTE
16	1	NN1218-4131	Dependent Variable	eotVisit
17	1	NN1218-4131	Covariance Structure	Diagonal

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Model Information

Parameter Code=P9PGILU Parameter=PPG increment lunch (SMPG) (mg/dL)

(continued)

Obs	_Imputation_	STUDYID	Descr	Value
18	1	NN1218-4131	Estimation Method	REML
19	1	NN1218-4131	Residual Variance Method	Profile
20	1	NN1218-4131	Fixed Effects SE Method	Model-Based
21	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=P9PGINC Parameter=PPG increment all meals (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
22	1	NN1218-4131	Data Set	WORK.IMPUTE
23	1	NN1218-4131	Dependent Variable	eotVisit
24	1	NN1218-4131	Covariance Structure	Diagonal
25	1	NN1218-4131	Estimation Method	REML
26	1	NN1218-4131	Residual Variance Method	Profile
27	1	NN1218-4131	Fixed Effects SE Method	Model-Based
28	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=P9PGINCB Parameter=PPG increment breakfast (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
29	1	NN1218-4131	Data Set	WORK.IMPUTE
30	1	NN1218-4131	Dependent Variable	eotVisit
31	1	NN1218-4131	Covariance Structure	Diagonal
32	1	NN1218-4131	Estimation Method	REML

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The Mixed procedure
Model Information

Parameter Code=P9PGINCB Parameter=PPG increment breakfast (SMPG) (mmol/L)

(continued)

Obs	_Imputation_	STUDYID	Descr	Value
33	1	NN1218-4131	Residual Variance Method	Profile
34	1	NN1218-4131	Fixed Effects SE Method	Model-Based
35	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=P9PGINCE Parameter=PPG increment main evening meal (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
36	1	NN1218-4131	Data Set	WORK.IMPUTE
37	1	NN1218-4131	Dependent Variable	eotVisit
38	1	NN1218-4131	Covariance Structure	Diagonal
39	1	NN1218-4131	Estimation Method	REML
40	1	NN1218-4131	Residual Variance Method	Profile
41	1	NN1218-4131	Fixed Effects SE Method	Model-Based
42	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=P9PGINCL Parameter=PPG increment lunch (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
43	1	NN1218-4131	Data Set	WORK.IMPUTE
44	1	NN1218-4131	Dependent Variable	eotVisit
45	1	NN1218-4131	Covariance Structure	Diagonal
46	1	NN1218-4131	Estimation Method	REML
47	1	NN1218-4131	Residual Variance Method	Profile

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Model Information

Parameter Code=P9PGINCL Parameter=PPG increment lunch (SMPG) (mmol/L)

(continued)

Obs	_Imputation_	STUDYID	Descr	Value
48	1	NN1218-4131	Fixed Effects SE Method	Model-Based
49	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=P9PGIU Parameter=PPG increment all meals (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
50	1	NN1218-4131	Data Set	WORK.IMPUTE
51	1	NN1218-4131	Dependent Variable	eotVisit
52	1	NN1218-4131	Covariance Structure	Diagonal
53	1	NN1218-4131	Estimation Method	REML
54	1	NN1218-4131	Residual Variance Method	Profile
55	1	NN1218-4131	Fixed Effects SE Method	Model-Based
56	1	NN1218-4131	Degrees of Freedom Method	Residual

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Class Level Information

Parameter Code=P9PGIBU Parameter=PPG increment breakfast (SMPG) (mg/dL)

Ob- s	Input ID	STUDY	Class	Level	Values	min
1	1	NN1218-4131	TRTPN	3	2 3 4	5
2	1	NN1218-4131	REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA	49
3	1	NN1218-4131	BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULI	85

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Class Level Information

Parameter Code=P9PGIEU Parameter=PPG increment main evening meal (SMPG) (mg/dL)

Ob- s	—	Input ID	STUDY	Class	Level	Values	min
4	1	NN1218-4131	TRTPN		3 2 3 4		5
5	1	NN1218-4131	REGION1		4 ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA		49
6	1	NN1218-4131	BOLAD1		2 BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULI		85

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Class Level Information

Parameter Code=P9PGILU Parameter=PPG increment lunch (SMPG) (mg/dL)

		Input data				Output	
		SUTCLV				Vale	
		OonIDass				Obs	
7	1	NN1218-4131	TRTPN	3	2	3	4
8	1	NN1218-4131	REGION1	4	ASIA (EXCLUDING JAPAN)	EUROPE	JAPAN
9	1	NN1218-4131	BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	CARBOHYDRATE COUNTING (FLEXIBLE)	BOLUS INSULI

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Class Level Information

Parameter Code=P9PGINC Parameter=PPG increment all meals (SMPG) (mmol/L)

Obs	Input	STUDY ID	Classes	Levels	Values	min
10	1	NN1218-4131	TRTPN	3 2 3 4		5
11	1	NN1218-4131	REGION1	4 ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA		49
12	1	NN1218-4131	BOLAD1	2 BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULI		85

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Class Level Information

Parameter Code=P9PGINCB Parameter=PPG increment breakfast (SMPG) (mmol/L)

		Input		Stat		Level		Variable		Missing	
O	b	S	o	Y	I	D	C	U	D	a	l
s	—										
13	1	NN1218-4131	TRTPN				3	2	3	4	5
14	1	NN1218-4131	REGION1				4	ASIA (EXCLUDING JAPAN)	EUROPE	JAPAN	NORTH AMERICA
15	1	NN1218-4131	BOLAD1				2	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	CARBOHYDRATE COUNTING (FLEXIBLE)	BOLUS	INSULI

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Class Level Information

Parameter Code=P9PGINCE Parameter=PPG increment main evening meal (SMPG) (mmol/L)

Obs	Input	STUDY ID	Class	Level	Values	Unit
16	1	NN1218-4131	TRTPN	3 2 3 4		5
17	1	NN1218-4131	REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA	49
18	1	NN1218-4131	BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULI	85

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Class Level Information

Parameter Code=P9PGINCL Parameter=PPG increment lunch (SMPG) (mmol/L)

Obs	Input	STUDY ID	Class	Level	Values	min
19	1	NN1218-4131	TRTPN	3 2 3 4		5
20	1	NN1218-4131	REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA	49
21	1	NN1218-4131	BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULI	85

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Class Level Information

Parameter Code=P9PGIU Parameter=PPG increment all meals (SMPG) (mg/dL)

		Input		Stat		Level		Variable		Missing	
O	b	S	o	Y	I	D	C	U	D	a	l
s	—										
22	1	NN1218-4131	TRTPN				3	2	3	4	5
23	1	NN1218-4131	REGION1				4	ASIA (EXCLUDING JAPAN)	EUROPE	JAPAN	NORTH AMERICA
24	1	NN1218-4131	BOLAD1				2	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	CARBOHYDRATE COUNTING (FLEXIBLE)	BOLUS	INSULI
											85

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Dimensions

Parameter Code=P9PGIBU Parameter=PPG increment breakfast (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Covariance Parameters	1
2	1	NN1218-4131	Columns in X	10
3	1	NN1218-4131	Columns in Z	0
4	1	NN1218-4131	Subjects	1
5	1	NN1218-4131	Max Obs per Subject	986

Parameter Code=P9PGIEU Parameter=PPG increment main evening meal (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
6	1	NN1218-4131	Covariance Parameters	1
7	1	NN1218-4131	Columns in X	10
8	1	NN1218-4131	Columns in Z	0
9	1	NN1218-4131	Subjects	1
10	1	NN1218-4131	Max Obs per Subject	979

Parameter Code=P9PGILU Parameter=PPG increment lunch (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
11	1	NN1218-4131	Covariance Parameters	1
12	1	NN1218-4131	Columns in X	10
13	1	NN1218-4131	Columns in Z	0
14	1	NN1218-4131	Subjects	1
15	1	NN1218-4131	Max Obs per Subject	982

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Dimensions

Parameter Code=P9PGINC Parameter=PPG increment all meals (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
16	1	NN1218-4131	Covariance Parameters	1
17	1	NN1218-4131	Columns in X	10
18	1	NN1218-4131	Columns in Z	0
19	1	NN1218-4131	Subjects	1
20	1	NN1218-4131	Max Obs per Subject	974

Parameter Code=P9PGINCB Parameter=PPG increment breakfast (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
21	1	NN1218-4131	Covariance Parameters	1
22	1	NN1218-4131	Columns in X	10
23	1	NN1218-4131	Columns in Z	0
24	1	NN1218-4131	Subjects	1
25	1	NN1218-4131	Max Obs per Subject	986

Parameter Code=P9PGINCE Parameter=PPG increment main evening meal (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
26	1	NN1218-4131	Covariance Parameters	1
27	1	NN1218-4131	Columns in X	10
28	1	NN1218-4131	Columns in Z	0
29	1	NN1218-4131	Subjects	1
30	1	NN1218-4131	Max Obs per Subject	979

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Dimensions

Parameter Code=P9PGINCL Parameter=PPG increment lunch (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
31	1	NN1218-4131	Covariance Parameters	1
32	1	NN1218-4131	Columns in X	10
33	1	NN1218-4131	Columns in Z	0
34	1	NN1218-4131	Subjects	1
35	1	NN1218-4131	Max Obs per Subject	982

Parameter Code=P9PGIU Parameter=PPG increment all meals (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
36	1	NN1218-4131	Covariance Parameters	1
37	1	NN1218-4131	Columns in X	10
38	1	NN1218-4131	Columns in Z	0
39	1	NN1218-4131	Subjects	1
40	1	NN1218-4131	Max Obs per Subject	974

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Number of Observations

Parameter Code=P9PGIBU Parameter=PPG increment breakfast (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
1	1	NN1218-4131	Number of Observations Read	986	986	986	986	986
2	1	NN1218-4131	Number of Observations Used	986	986	986	986	986
3	1	NN1218-4131	Number of Observations Not Used	0	986	986	986	986

Parameter Code=P9PGIEU Parameter=PPG increment main evening meal (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
4	1	NN1218-4131	Number of Observations Read	979	979	979	979	979
5	1	NN1218-4131	Number of Observations Used	979	979	979	979	979
6	1	NN1218-4131	Number of Observations Not Used	0	979	979	979	979

Parameter Code=P9PGILU Parameter=PPG increment lunch (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
7	1	NN1218-4131	Number of Observations Read	982	982	982	982	982
8	1	NN1218-4131	Number of Observations Used	982	982	982	982	982
9	1	NN1218-4131	Number of Observations Not Used	0	982	982	982	982

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Number of Observations

Parameter Code=P9PGINC Parameter=PPG increment all meals (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
10	1	NN1218-4131	Number of Observations Read	974	974	974	974	974
11	1	NN1218-4131	Number of Observations Used	974	974	974	974	974
12	1	NN1218-4131	Number of Observations Not Used	0	974	974	974	974

Parameter Code=P9PGINCB Parameter=PPG increment breakfast (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
13	1	NN1218-4131	Number of Observations Read	986	986	986	986	986
14	1	NN1218-4131	Number of Observations Used	986	986	986	986	986
15	1	NN1218-4131	Number of Observations Not Used	0	986	986	986	986

Parameter Code=P9PGINCE Parameter=PPG increment main evening meal (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
16	1	NN1218-4131	Number of Observations Read	979	979	979	979	979
17	1	NN1218-4131	Number of Observations Used	979	979	979	979	979
18	1	NN1218-4131	Number of Observations Not Used	0	979	979	979	979

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Number of Observations

Parameter Code=P9PGINCL Parameter=PPG increment lunch (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
19	1	NN1218-4131	Number of Observations Read	982	982	982	982	982
20	1	NN1218-4131	Number of Observations Used	982	982	982	982	982
21	1	NN1218-4131	Number of Observations Not Used	0	982	982	982	982

Parameter Code=P9PGIU Parameter=PPG increment all meals (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
22	1	NN1218-4131	Number of Observations Read	974	974	974	974	974
23	1	NN1218-4131	Number of Observations Used	974	974	974	974	974
24	1	NN1218-4131	Number of Observations Not Used	0	974	974	974	974

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Covariance Parameter Estimates

Parameter Code=P9PGIBU Parameter=PPG increment breakfast (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	CovParm	Estimate
1	1	NN1218-4131	Residual	2183.07

Parameter Code=P9PGIEU Parameter=PPG increment main evening meal (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	CovParm	Estimate
20001	1	NN1218-4131	Residual	2452.71

Parameter Code=P9PGILU Parameter=PPG increment lunch (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	CovParm	Estimate
40001	1	NN1218-4131	Residual	2083.15

Parameter Code=P9PGINC Parameter=PPG increment all meals (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	CovParm	Estimate
60001	1	NN1218-4131	Residual	2.7167

Parameter Code=P9PGINCB Parameter=PPG increment breakfast (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	CovParm	Estimate
80001	1	NN1218-4131	Residual	6.7229

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Covariance Parameter Estimates

Parameter Code=P9PGINCE Parameter=PPG increment main evening meal (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	CovParm	Estimate
100001	1	NN1218-4131	Residual	7.5533

Parameter Code=P9PGINCL Parameter=PPG increment lunch (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	CovParm	Estimate
120001	1	NN1218-4131	Residual	6.4152

Parameter Code=P9PGIU Parameter=PPG increment all meals (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	CovParm	Estimate
140001	1	NN1218-4131	Residual	882.16

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Fit Statistics

Parameter Code=P9PGIBU Parameter=PPG increment breakfast (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	-2 Res Log Likelihood	10347.3
2	1	NN1218-4131	AIC (Smaller is Better)	10349.3
3	1	NN1218-4131	AICC (Smaller is Better)	10349.3
4	1	NN1218-4131	BIC (Smaller is Better)	10354.2

Parameter Code=P9PGIEU Parameter=PPG increment main evening meal (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
5	1	NN1218-4131	-2 Res Log Likelihood	10386.6
6	1	NN1218-4131	AIC (Smaller is Better)	10388.6
7	1	NN1218-4131	AICC (Smaller is Better)	10388.6
8	1	NN1218-4131	BIC (Smaller is Better)	10393.5

Parameter Code=P9PGILU Parameter=PPG increment lunch (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
9	1	NN1218-4131	-2 Res Log Likelihood	10259.2
10	1	NN1218-4131	AIC (Smaller is Better)	10261.2
11	1	NN1218-4131	AICC (Smaller is Better)	10261.2
12	1	NN1218-4131	BIC (Smaller is Better)	10266.1

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Fit Statistics

Parameter Code=P9PGINC Parameter=PPG increment all meals (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
13	1	NN1218-4131	-2 Res Log Likelihood	3752.5
14	1	NN1218-4131	AIC (Smaller is Better)	3754.5
15	1	NN1218-4131	AICC (Smaller is Better)	3754.5
16	1	NN1218-4131	BIC (Smaller is Better)	3759.4

Parameter Code=P9PGINCB Parameter=PPG increment breakfast (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
17	1	NN1218-4131	-2 Res Log Likelihood	4685.8
18	1	NN1218-4131	AIC (Smaller is Better)	4687.8
19	1	NN1218-4131	AICC (Smaller is Better)	4687.8
20	1	NN1218-4131	BIC (Smaller is Better)	4692.7

Parameter Code=P9PGINCE Parameter=PPG increment main evening meal (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
21	1	NN1218-4131	-2 Res Log Likelihood	4765.5
22	1	NN1218-4131	AIC (Smaller is Better)	4767.5
23	1	NN1218-4131	AICC (Smaller is Better)	4767.5
24	1	NN1218-4131	BIC (Smaller is Better)	4772.4

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Fit Statistics

Parameter Code=P9PGINCL Parameter=PPG increment lunch (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
25	1	NN1218-4131	-2 Res Log Likelihood	4620.8
26	1	NN1218-4131	AIC (Smaller is Better)	4622.8
27	1	NN1218-4131	AICC (Smaller is Better)	4622.8
28	1	NN1218-4131	BIC (Smaller is Better)	4627.7

Parameter Code=P9PGIU Parameter=PPG increment all meals (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
29	1	NN1218-4131	-2 Res Log Likelihood	9344.7
30	1	NN1218-4131	AIC (Smaller is Better)	9346.7
31	1	NN1218-4131	AICC (Smaller is Better)	9346.7
32	1	NN1218-4131	BIC (Smaller is Better)	9351.5

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Solution for Fixed Effects

Parameter Code=P9PGIBU Parameter=PPG increment breakfast (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
1	1	NN1218-4131	TRTPN	2				
2	1	NN1218-4131	TRTPN	3				
3	1	NN1218-4131	TRTPN	4				
4	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
5	1	NN1218-4131	REGION1	—	EUROPE			
6	1	NN1218-4131	REGION1	—	JAPAN			
7	1	NN1218-4131	REGION1	—	NORTH AMERICA			
8	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
9	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
10	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	10.5857	3.8079	978	2.78	0.0055	0.05	3.1131	18.0583
2	28.7728	3.8203	978	7.53	<.0001	0.05	21.2758	36.2698
3	20.5616	3.8296	978	5.37	<.0001	0.05	13.0464	28.0767
4	5.9702	5.4584	978	1.09	0.2743	0.05	-4.7414	16.6818
5	0.5710	3.8808	978	0.15	0.8831	0.05	-7.0446	8.1865
6	16.1528	4.3227	978	3.74	0.0002	0.05	7.6701	24.6356
7	0
8	-9.6620	3.3711	978	-2.87	0.0042	0.05	-16.2774	-3.0466
9	0
10	-0.7204	0.02651	978	-27.17	<.0001	0.05	-0.7724	-0.6684

Fast-acting insulin aspart
NN1218-4131

Clinical Trial Report
Statistical document

Date:
Version:

14 February 2018
1.0

Status:
Page:

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Solution for Fixed Effects

Parameter Code=P9PGIEU Parameter=PPG increment main evening meal (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1			BOLAD1
11	1	NN1218-4131	TRTPN	2				
12	1	NN1218-4131	TRTPN	3				
13	1	NN1218-4131	TRTPN	4				
14	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
15	1	NN1218-4131	REGION1	—	EUROPE			
16	1	NN1218-4131	REGION1	—	JAPAN			
17	1	NN1218-4131	REGION1	—	NORTH AMERICA			
18	1	NN1218-4131	BOLAD1	—				BOLUS INSULIN ALGORITHM (SLIDING SCALE)
19	1	NN1218-4131	BOLAD1	—				CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY
20	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
11	12.0045	3.8883	971	3.09	0.0021	0.05	4.3740	19.6350
12	23.6379	3.9566	971	5.97	<.0001	0.05	15.8734	31.4025
13	16.9190	3.9294	971	4.31	<.0001	0.05	9.2079	24.6301
14	-19.7407	5.7977	971	-3.40	0.0007	0.05	-31.1181	-8.3632
15	-2.7801	4.1311	971	-0.67	0.5011	0.05	-10.8869	5.3267
16	-0.03821	4.5938	971	-0.01	0.9934	0.05	-9.0532	8.9767
17	0
18	2.7859	3.5846	971	0.78	0.4372	0.05	-4.2485	9.8203
19	0
20	-0.7701	0.02914	971	-26.42	<.0001	0.05	-0.8273	-0.7129

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The Mixed procedure
Solution for Fixed Effects

Parameter Code=P9PGILU Parameter=PPG increment lunch (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
21	1	NN1218-4131	TRTPN	2				
22	1	NN1218-4131	TRTPN	3				
23	1	NN1218-4131	TRTPN	4				
24	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
25	1	NN1218-4131	REGION1	—	EUROPE			
26	1	NN1218-4131	REGION1	—	JAPAN			
27	1	NN1218-4131	REGION1	—	NORTH AMERICA			
28	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
29	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
30	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
21	15.4132	3.6620	974	4.21	<.0001	0.05	8.2269	22.5995
22	24.6608	3.7121	974	6.64	<.0001	0.05	17.3761	31.9454
23	21.0486	3.6796	974	5.72	<.0001	0.05	13.8277	28.2694
24	-3.0775	5.3349	974	-0.58	0.5642	0.05	-13.5468	7.3918
25	-9.8293	3.7998	974	-2.59	0.0098	0.05	-17.2861	-2.3725
26	11.0559	4.3100	974	2.57	0.0105	0.05	2.5979	19.5138
27	0
28	1.1076	3.2965	974	0.34	0.7369	0.05	-5.3615	7.5768
29	0
30	-0.7388	0.03022	974	-24.45	<.0001	0.05	-0.7981	-0.6795

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The Mixed procedure
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Parameter Code=P9PGINC Parameter=PPG increment all meals (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
31	1	NN1218-4131	TRTPN	2				
32	1	NN1218-4131	TRTPN	3				
33	1	NN1218-4131	TRTPN	4				
34	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
35	1	NN1218-4131	REGION1	—	EUROPE			
36	1	NN1218-4131	REGION1	—	JAPAN			
37	1	NN1218-4131	REGION1	—	NORTH AMERICA			
38	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
39	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
40	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
31	0.4450	0.1369	966	3.25	0.0012	0.05	0.1764	0.7136
32	1.1960	0.1384	966	8.64	<.0001	0.05	0.9244	1.4676
33	0.9053	0.1363	966	6.64	<.0001	0.05	0.6378	1.1728
34	-0.2194	0.1931	966	-1.14	0.2562	0.05	-0.5983	0.1595
35	-0.1984	0.1379	966	-1.44	0.1507	0.05	-0.4691	0.07228
36	0.4039	0.1554	966	2.60	0.0095	0.05	0.09894	0.7088
37	0
38	-0.09837	0.1201	966	-0.82	0.4130	0.05	-0.3341	0.1373
39	0
40	-0.6091	0.02689	966	-22.65	<.0001	0.05	-0.6619	-0.5564

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The Mixed procedure
Solution for Fixed Effects

Parameter Code=P9PGINCB Parameter=PPG increment breakfast (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
41	1	NN1218-4131	TRTPN	2				
42	1	NN1218-4131	TRTPN	3				
43	1	NN1218-4131	TRTPN	4				
44	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
45	1	NN1218-4131	REGION1	—	EUROPE			
46	1	NN1218-4131	REGION1	—	JAPAN			
47	1	NN1218-4131	REGION1	—	NORTH AMERICA			
48	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
49	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
50	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
41	0.5874	0.2113	978	2.78	0.0055	0.05	0.1728	1.0021
42	1.5967	0.2120	978	7.53	<.0001	0.05	1.1807	2.0128
43	1.1410	0.2125	978	5.37	<.0001	0.05	0.7240	1.5581
44	0.3313	0.3029	978	1.09	0.2743	0.05	-0.2631	0.9257
45	0.03169	0.2154	978	0.15	0.8831	0.05	-0.3909	0.4543
46	0.8964	0.2399	978	3.74	0.0002	0.05	0.4256	1.3671
47	0
48	-0.5362	0.1871	978	-2.87	0.0042	0.05	-0.9033	-0.1691
49	0
50	-0.7204	0.02651	978	-27.17	<.0001	0.05	-0.7724	-0.6684

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The Mixed procedure
Solution for Fixed Effects

Parameter Code=P9PGINCE Parameter=PPG increment main evening meal (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1			BOLAD1
51	1	NN1218-4131	TRTPN	2				
52	1	NN1218-4131	TRTPN	3				
53	1	NN1218-4131	TRTPN	4				
54	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
55	1	NN1218-4131	REGION1	—	EUROPE			
56	1	NN1218-4131	REGION1	—	JAPAN			
57	1	NN1218-4131	REGION1	—	NORTH AMERICA			
58	1	NN1218-4131	BOLAD1	—				BOLUS INSULIN ALGORITHM (SLIDING SCALE)
59	1	NN1218-4131	BOLAD1	—				CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY
60	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
51	0.6662	0.2158	971	3.09	0.0021	0.05	0.2427	1.0896
52	1.3118	0.2196	971	5.97	<.0001	0.05	0.8809	1.7426
53	0.9389	0.2181	971	4.31	<.0001	0.05	0.5110	1.3668
54	-1.0955	0.3217	971	-3.40	0.0007	0.05	-1.7269	-0.4641
55	-0.1543	0.2292	971	-0.67	0.5011	0.05	-0.6042	0.2956
56	-0.00212	0.2549	971	-0.01	0.9934	0.05	-0.5024	0.4982
57	0
58	0.1546	0.1989	971	0.78	0.4372	0.05	-0.2358	0.5450
59	0
60	-0.7701	0.02914	971	-26.42	<.0001	0.05	-0.8273	-0.7129

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The Mixed procedure
Solution for Fixed Effects

Parameter Code=P9PGINCL Parameter=PPG increment lunch (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1
61	1	NN1218-4131	TRTPN	2		
62	1	NN1218-4131	TRTPN	3		
63	1	NN1218-4131	TRTPN	4		
64	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)	
65	1	NN1218-4131	REGION1	—	EUROPE	
66	1	NN1218-4131	REGION1	—	JAPAN	
67	1	NN1218-4131	REGION1	—	NORTH AMERICA	
68	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)
69	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY
70	1	NN1218-4131	BASE	—		

Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
61	0.8553	0.2032	974	4.21	<.0001	0.05	0.4565	1.2541
62	1.3685	0.2060	974	6.64	<.0001	0.05	0.9643	1.7728
63	1.1681	0.2042	974	5.72	<.0001	0.05	0.7674	1.5688
64	-0.1708	0.2961	974	-0.58	0.5642	0.05	-0.7518	0.4102
65	-0.5455	0.2109	974	-2.59	0.0098	0.05	-0.9593	-0.1317
66	0.6135	0.2392	974	2.57	0.0105	0.05	0.1442	1.0829
67	0
68	0.06147	0.1829	974	0.34	0.7369	0.05	-0.2975	0.4205
69	0
70	-0.7388	0.03022	974	-24.45	<.0001	0.05	-0.7981	-0.6795

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Solution for Fixed Effects

Parameter Code=P9PGIU Parameter=PPG increment all meals (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
71	1	NN1218-4131	TRTPN	2				
72	1	NN1218-4131	TRTPN	3				
73	1	NN1218-4131	TRTPN	4				
74	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
75	1	NN1218-4131	REGION1	—	EUROPE			
76	1	NN1218-4131	REGION1	—	JAPAN			
77	1	NN1218-4131	REGION1	—	NORTH AMERICA			
78	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
79	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
80	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
71	8.0192	2.4665	966	3.25	0.0012	0.05	3.1789	12.8594
72	21.5524	2.4939	966	8.64	<.0001	0.05	16.6583	26.4465
73	16.3133	2.4565	966	6.64	<.0001	0.05	11.4926	21.1341
74	-3.9533	3.4794	966	-1.14	0.2562	0.05	-10.7814	2.8748
75	-3.5750	2.4854	966	-1.44	0.1507	0.05	-8.4525	1.3025
76	7.2774	2.7999	966	2.60	0.0095	0.05	1.7829	12.7719
77	0
78	-1.7726	2.1642	966	-0.82	0.4130	0.05	-6.0196	2.4745
79	0
80	-0.6091	0.02689	966	-22.65	<.0001	0.05	-0.6619	-0.5564

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The Mixed procedure
Least Squares Means

Obs	_Imputation_	PARAMCD	PARAM	STUDYID	Effect
1	1	P9PGIBU	PPG increment breakfast (SMPG) (mg/dL)	NN1218-4131	TRTPN
2	1	P9PGIBU	PPG increment breakfast (SMPG) (mg/dL)	NN1218-4131	TRTPN
3	1	P9PGIBU	PPG increment breakfast (SMPG) (mg/dL)	NN1218-4131	TRTPN
4	1	P9PGIEU	PPG increment main evening meal (SMPG) (mg/dL)	NN1218-4131	TRTPN
5	1	P9PGIEU	PPG increment main evening meal (SMPG) (mg/dL)	NN1218-4131	TRTPN
6	1	P9PGIEU	PPG increment main evening meal (SMPG) (mg/dL)	NN1218-4131	TRTPN
7	1	P9PGILU	PPG increment lunch (SMPG) (mg/dL)	NN1218-4131	TRTPN
8	1	P9PGILU	PPG increment lunch (SMPG) (mg/dL)	NN1218-4131	TRTPN
9	1	P9PGILU	PPG increment lunch (SMPG) (mg/dL)	NN1218-4131	TRTPN
10	1	P9PGINC	PPG increment all meals (SMPG) (mmol/L)	NN1218-4131	TRTPN
11	1	P9PGINC	PPG increment all meals (SMPG) (mmol/L)	NN1218-4131	TRTPN
12	1	P9PGINC	PPG increment all meals (SMPG) (mmol/L)	NN1218-4131	TRTPN
13	1	P9PGINCB	PPG increment breakfast (SMPG) (mmol/L)	NN1218-4131	TRTPN
14	1	P9PGINCB	PPG increment breakfast (SMPG) (mmol/L)	NN1218-4131	TRTPN

Obs	TRTPN	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	2	WORK.IMPUTE	-16.8536	2.5918	978	-6.50	<.0001	0.05	-21.9397	-11.7675
2	3	WORK.IMPUTE	1.3335	2.5706	978	0.52	0.6040	0.05	-3.7111	6.3781
3	4	WORK.IMPUTE	-6.8777	2.5780	978	-2.67	0.0078	0.05	-11.9368	-1.8187
4	2	WORK.IMPUTE	-3.1691	2.7517	971	-1.15	0.2497	0.05	-8.5690	2.2308
5	3	WORK.IMPUTE	8.4643	2.7459	971	3.08	0.0021	0.05	3.0757	13.8528
6	4	WORK.IMPUTE	1.7453	2.7381	971	0.64	0.5240	0.05	-3.6280	7.1186
7	2	WORK.IMPUTE	-9.3579	2.5284	974	-3.70	0.0002	0.05	-14.3196	-4.3962
8	3	WORK.IMPUTE	-0.1103	2.5301	974	-0.04	0.9652	0.05	-5.0754	4.8549
9	4	WORK.IMPUTE	-3.7225	2.5196	974	-1.48	0.1399	0.05	-8.6669	1.2219
10	2	WORK.IMPUTE	-0.5965	0.09187	966	-6.49	<.0001	0.05	-0.7768	-0.4162
11	3	WORK.IMPUTE	0.1545	0.09179	966	1.68	0.0927	0.05	-0.02563	0.3346
12	4	WORK.IMPUTE	-0.1362	0.09114	966	-1.49	0.1353	0.05	-0.3151	0.04261
13	2	WORK.IMPUTE	-0.9353	0.1438	978	-6.50	<.0001	0.05	-1.2175	-0.6530
14	3	WORK.IMPUTE	0.07400	0.1427	978	0.52	0.6040	0.05	-0.2059	0.3539

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The Mixed procedure
Least Squares Means

Obs	_Imputation_	PARAMCD	PARAM	STUDYID	Effect
15	1	P9PGINCB	PPG increment breakfast (SMPG) (mmol/L)	NN1218-4131	TRTPN
16	1	P9PGINCE	PPG increment main evening meal (SMPG) (mmol/L)	NN1218-4131	TRTPN
17	1	P9PGINCE	PPG increment main evening meal (SMPG) (mmol/L)	NN1218-4131	TRTPN
18	1	P9PGINCE	PPG increment main evening meal (SMPG) (mmol/L)	NN1218-4131	TRTPN
19	1	P9PGINCL	PPG increment lunch (SMPG) (mmol/L)	NN1218-4131	TRTPN
20	1	P9PGINCL	PPG increment lunch (SMPG) (mmol/L)	NN1218-4131	TRTPN
21	1	P9PGINCL	PPG increment lunch (SMPG) (mmol/L)	NN1218-4131	TRTPN
22	1	P9PGIU	PPG increment all meals (SMPG) (mg/dL)	NN1218-4131	TRTPN
23	1	P9PGIU	PPG increment all meals (SMPG) (mg/dL)	NN1218-4131	TRTPN
24	1	P9PGIU	PPG increment all meals (SMPG) (mg/dL)	NN1218-4131	TRTPN

Obs	TRTPN	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
15	4	WORK.IMPUTE	-0.3817	0.1431	978	-2.67	0.0078	0.05	-0.6624	-0.1009
16	2	WORK.IMPUTE	-0.1759	0.1527	971	-1.15	0.2497	0.05	-0.4755	0.1238
17	3	WORK.IMPUTE	0.4697	0.1524	971	3.08	0.0021	0.05	0.1707	0.7687
18	4	WORK.IMPUTE	0.09685	0.1519	971	0.64	0.5240	0.05	-0.2013	0.3950
19	2	WORK.IMPUTE	-0.5193	0.1403	974	-3.70	0.0002	0.05	-0.7946	-0.2440
20	3	WORK.IMPUTE	-0.00612	0.1404	974	-0.04	0.9652	0.05	-0.2817	0.2694
21	4	WORK.IMPUTE	-0.2066	0.1398	974	-1.48	0.1399	0.05	-0.4810	0.06781
22	2	WORK.IMPUTE	-10.7492	1.6556	966	-6.49	<.0001	0.05	-13.9982	-7.5003
23	3	WORK.IMPUTE	2.7840	1.6540	966	1.68	0.0927	0.05	-0.4619	6.0299
24	4	WORK.IMPUTE	-2.4551	1.6423	966	-1.49	0.1353	0.05	-5.6779	0.7678

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The Mixed procedure
Least Squares Means Estimate

Parameter Code=P9PGIBU Parameter=PPG increment breakfast (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
1	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
2	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	WORK.IMPUTE	-9.9759	3.6581	978	-2.73	0.0065	0.05	-17.1546	-2.7972
2	WORK.IMPUTE	8.2113	3.6411	978	2.26	0.0243	0.05	1.0660	15.3565

Parameter Code=P9PGIEU Parameter=PPG increment main evening meal (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
3	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
4	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
3	WORK.IMPUTE	-4.9144	3.8855	971	-1.26	0.2062	0.05	-12.5393	2.7105
4	WORK.IMPUTE	6.7190	3.8792	971	1.73	0.0836	0.05	-0.8936	14.3315

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Least Squares Means Estimate

Parameter Code=P9PGILU Parameter=PPG increment lunch (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
5	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
6	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
5	WORK.IMPUTE	-5.6354	3.5733	974	-1.58	0.1151	0.05	-12.6475	1.3768
6	WORK.IMPUTE	3.6122	3.5715	974	1.01	0.3121	0.05	-3.3966	10.6210

Parameter Code=P9PGINC Parameter=PPG increment all meals (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
7	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
8	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
7	WORK.IMPUTE	-0.4603	0.1296	966	-3.55	0.0004	0.05	-0.7145	-0.2060
8	WORK.IMPUTE	0.2907	0.1294	966	2.25	0.0249	0.05	0.03684	0.5446

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Least Squares Means Estimate

Parameter Code=P9PGINCB Parameter=PPG increment breakfast (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
9	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
10	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
9	WORK.IMPUTE	-0.5536	0.2030	978	-2.73	0.0065	0.05	-0.9520	-0.1552
10	WORK.IMPUTE	0.4557	0.2021	978	2.26	0.0243	0.05	0.05916	0.8522

Parameter Code=P9PGINCE Parameter=PPG increment main evening meal (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
11	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
12	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
11	WORK.IMPUTE	-0.2727	0.2156	971	-1.26	0.2062	0.05	-0.6959	0.1504
12	WORK.IMPUTE	0.3729	0.2153	971	1.73	0.0836	0.05	-0.04959	0.7953

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Least Squares Means Estimate

Parameter Code=P9PGINCL Parameter=PPG increment lunch (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
13	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
14	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
13	WORK.IMPUTE	-0.3127	0.1983	974	-1.58	0.1151	0.05	-0.7019	0.07640
14	WORK.IMPUTE	0.2005	0.1982	974	1.01	0.3121	0.05	-0.1885	0.5894

Parameter Code=P9PGIU Parameter=PPG increment all meals (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
15	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
16	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
15	WORK.IMPUTE	-8.2942	2.3347	966	-3.55	0.0004	0.05	-12.8759	-3.7125
16	WORK.IMPUTE	5.2390	2.3314	966	2.25	0.0249	0.05	0.6638	9.8143

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9PGIBU Parameter=PPG increment breakfast (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.551593	6.677561	7.229182	3.43E6	0.082608	0.076305	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-16.826937	2.688714	-22.0967	-11.5572	3.43E6	-19.883163	-14.015489

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-6.26	<.0001

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9PGIEU Parameter=PPG increment main evening meal (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.544136	7.616168	8.160331	4.5E6	0.071448	0.066684	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-3.955880	2.856629	-9.55477	1.643012	4.5E6	-7.032684	-0.663812

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-1.38	0.1661

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9PGILU Parameter=PPG increment lunch (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.494120	6.375845	6.869989	3.87E6	0.077503	0.071928	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-9.800083	2.621066	-14.9373	-4.66289	3.87E6	-12.840039	-7.081754

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-3.74	0.0002

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9PGINC Parameter=PPG increment all meals (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000725	0.008463	0.009188	3.21E6	0.085704	0.078939	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.596212	0.095856	-0.78409	-0.40834	3.21E6	-0.709601	-0.486204

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-6.22	<.0001

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9PGINCB Parameter=PPG increment breakfast (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.001699	0.020564	0.022263	3.43E6	0.082608	0.076305	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.933792	0.149207	-1.22623	-0.64135	3.43E6	-1.103394	-0.777774

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-6.26	<.0001

nn1218/nn1218-4131/ctr_20180214_er
09FEB2018:20:27:18 - a_797pp_stat_diff.sas/a_9pp_ppginc_stat_in_fas_app.txt

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2341 of 4425	Novo Nordisk
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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9PGINCE Parameter=PPG increment main evening meal (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.001676	0.023455	0.025130	4.5E6	0.071448	0.066684	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.219527	0.158525	-0.53023	0.091177	4.5E6	-0.390271	-0.036838

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-1.38	0.1661

nn1218/nn1218-4131/ctr_20180214_er
09FEB2018:20:27:18 - a_797pp_stat_diff.sas/a_9pp_ppginc_stat_in_fas_app.txt

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9PGINCL Parameter=PPG increment lunch (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.001522	0.019635	0.021157	3.87E6	0.077503	0.071928	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.543845	0.145453	-0.82893	-0.25876	3.87E6	-0.712544	-0.392994

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-3.74	0.0002

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9PGIU Parameter=PPG increment all meals (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.235511	2.748099	2.983621	3.21E6	0.085704	0.078939	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-10.743748	1.727316	-14.1292	-7.35827	3.21E6	-12.787015	-8.761396

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-6.22	<.0001

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9PGIBU Parameter=PPG increment breakfast (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.303049	6.568968	6.872033	1.03E7	0.046136	0.044101	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.775759	2.621456	-4.36220	5.913720	1.03E7	-1.594764	3.054198

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	0.30	0.7673

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2345 of 4425	Novo Nordisk
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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9PGIEU Parameter=PPG increment main evening meal (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.334930	7.584158	7.919105	1.12E7	0.044164	0.042296	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits	DF	Minimum	Maximum
Estimate	8.206075	2.814090	2.690559 13.72159	1.12E7	6.020451	10.618985

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	2.92	0.0035

nn1218/nn1218-4131/ctr_20180214_er
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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9PGILU Parameter=PPG increment lunch (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.332660	6.384763	6.717440	8.15E6	0.052105	0.049525	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits	DF	Minimum	Maximum
Estimate	-0.378441	2.591802	-5.45828 4.701399	8.15E6	-2.948869	2.271113

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-0.15	0.8839

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2347 of 4425	Novo Nordisk
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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9PGINC Parameter=PPG increment all meals (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000386	0.008447	0.008833	1.05E7	0.045737	0.043737	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.133513	0.093986	-0.05070	0.317722	1.05E7	0.055065	0.218846

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	1.42	0.1554

nn1218/nn1218-4131/ctr_20180214_er
09FEB2018:20:27:18 - a_797pp_stat_diff.sas/a_9pp_ppginc_stat_in_fas_app.txt

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9PGINCB Parameter=PPG increment breakfast (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000933	0.020230	0.021163	1.03E7	0.046136	0.044101	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.043050	0.145475	-0.24208	0.328175	1.03E7	-0.088500	0.169489

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	0.30	0.7673

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2349 of 4425	Novo Nordisk
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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9PGINCE Parameter=PPG increment main evening meal (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.001031	0.023356	0.024387	1.12E7	0.044164	0.042296	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.455387	0.156165	0.149310	0.761465	1.12E7	0.334098	0.589289

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	2.92	0.0035

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2350 of 4425	Novo Nordisk
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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9PGINCL Parameter=PPG increment lunch (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.001024	0.019662	0.020687	8.15E6	0.052105	0.049525	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.021001	0.143829	-0.30290	0.260899	8.15E6	-0.163644	0.126033

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-0.15	0.8839

nn1218/nn1218-4131/ctr_20180214_er
09FEB2018:20:27:18 - a_797pp_stat_diff.sas/a_9pp_ppginc_stat_in_fas_app.txt

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9PGIU Parameter=PPG increment all meals (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.125447	2.742919	2.868373	1.05E7	0.045737	0.043737	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	2.405896	1.693627	-0.91355	5.725344	1.05E7	0.992274	3.943604

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	1.42	0.1554

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9PGIBU Parameter=PPG increment breakfast (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.451549	6.606725	7.058297	4.89E6	0.068350	0.063978	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-6.395166	2.656746	-11.6023	-1.18804	4.89E6	-9.573064	-3.627735

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-2.41	0.0161

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9PGIEU Parameter=PPG increment main evening meal (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.513762	7.541242	8.055029	4.92E6	0.068130	0.063785	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	2.290124	2.838138	-3.27253	7.852774	4.92E6	-0.356938	5.622226

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	0.81	0.4197

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Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2354 of 4425	Novo Nordisk
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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9PGILU Parameter=PPG increment lunch (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.450622	6.331596	6.782240	4.53E6	0.071174	0.066445	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-2.618925	2.604273	-7.72321	2.485359	4.53E6	-5.118036	0.093210

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-1.01	0.3146

nn1218/nn1218-4131/ctr_20180214_er
09FEB2018:20:27:18 - a_797pp_stat_diff.sas/a_9pp_ppginc_stat_in_fas_app.txt

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9PGINC Parameter=PPG increment all meals (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000644	0.008328	0.008972	3.88E6	0.077369	0.071813	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.120058	0.094721	-0.30571	0.065591	3.88E6	-0.222063	-0.016154

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-1.27	0.2050

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2356 of 4425	Novo Nordisk
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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9PGINCB Parameter=PPG increment breakfast (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.001391	0.020346	0.021737	4.89E6	0.068350	0.063978	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.354893	0.147433	-0.64386	-0.06593	4.89E6	-0.531247	-0.201317

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-2.41	0.0161

nn1218/nn1218-4131/ctr_20180214_er
09FEB2018:20:27:18 - a_797pp_stat_diff.sas/a_9pp_ppginc_stat_in_fas_app.txt

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2357 of 4425	Novo Nordisk
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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9PGINCE Parameter=PPG increment main evening meal (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.001582	0.023224	0.024806	4.92E6	0.068130	0.063785	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.127088	0.157499	-0.18161	0.435781	4.92E6	-0.019808	0.311999

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	0.81	0.4197

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9PGINCL Parameter=PPG increment lunch (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.001388	0.019499	0.020886	4.53E6	0.071174	0.066445	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.145334	0.144521	-0.42859	0.137922	4.53E6	-0.284020	0.005173

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-1.01	0.3146

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2359 of 4425	Novo Nordisk
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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9PGIU Parameter=PPG increment all meals (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.209208	2.704178	2.913397	3.88E6	0.077369	0.071813	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-2.163446	1.706868	-5.50885	1.181954	3.88E6	-4.001569	-0.291094

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-1.27	0.2050

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2360 of 4425	Novo Nordisk
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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=P9PGIBU Label=Faster aspart (meal) - NovoRapid (meal) Parameter=PPG increment breakfast (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	1.004511	13.302586	14.307147	4.06E6	0.075516	0.070214	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-10.431771	3.782479	-17.8453	-3.01825	4.06E6	-14.192512	-6.530818

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-2.76	0.0058

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Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2361 of 4425	Novo Nordisk
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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=P9PGIBU Label=Faster aspart (post) - NovoRapid (meal) Parameter=PPG increment breakfast (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.757451	13.178796	13.936285	6.77E6	0.057478	0.054354	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	7.170926	3.733133	-0.14588	14.48773	6.77E6	3.914832	10.643228

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	1.92	0.0547

nn1218/nn1218-4131/ctr_20180214_er
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Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2362 of 4425	Novo Nordisk
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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=P9PGIEU Label=Faster aspart (meal) - NovoRapid (meal) Parameter=PPG increment main evening meal (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	1.095258	15.185639	16.280951	4.42E6	0.072128	0.067276	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits	DF	Minimum	Maximum
Estimate	-6.246004	4.034966	-14.1544 1.662387	4.42E6	-10.280933	-1.916074

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-1.55	0.1216

nn1218/nn1218-4131/ctr_20180214_er
09FEB2018:20:27:18 - a_797pp_stat_diff.sas/a_9pp_ppginc_stat_in_fas_app.txt

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2363 of 4425	Novo Nordisk
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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=P9PGIEU Label=Faster aspart (post) - NovoRapid (meal) Parameter=PPG increment main evening meal (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.859985	15.136506	15.996535	6.92E6	0.056818	0.053764	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	5.915951	3.999567	-1.92306	13.75496	6.92E6	1.746793	9.289319

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	1.48	0.1391

nn1218/nn1218-4131/ctr_20180214_er
09FEB2018:20:27:18 - a_797pp_stat_diff.sas/a_9pp_ppginc_stat_in_fas_app.txt

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2364 of 4425	Novo Nordisk
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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=P9PGILU Label=Faster aspart (meal) - NovoRapid (meal) Parameter=PPG increment lunch (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.950786	12.734594	13.685427	4.14E6	0.074665	0.069478	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-7.181158	3.699382	-14.4318	0.069499	4.14E6	-11.333015	-2.887330

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-1.94	0.0522

nn1218/nn1218-4131/ctr_20180214_er
09FEB2018:20:27:18 - a_797pp_stat_diff.sas/a_9pp_ppginc_stat_in_fas_app.txt

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2365 of 4425	Novo Nordisk
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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=P9PGILU Label=Faster aspart (post) - NovoRapid (meal) Parameter=PPG increment lunch (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.786546	12.722377	13.508962	5.9E6	0.061827	0.058227	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	2.240483	3.675454	-4.96328	9.444242	5.9E6	-1.315730	5.841189

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	0.61	0.5421

nn1218/nn1218-4131/ctr_20180214_er
09FEB2018:20:27:18 - a_797pp_stat_diff.sas/a_9pp_ppginc_stat_in_fas_app.txt

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2366 of 4425	Novo Nordisk
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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=P9PGINC Label=Faster aspart (meal) - NovoRapid (meal) Parameter=PPG increment all meals (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.001420	0.016830	0.018250	3.3E6	0.084377	0.077812	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.476154	0.135094	-0.74093	-0.21138	3.3E6	-0.636194	-0.306838

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-3.52	0.0004

nn1218/nn1218-4131/ctr_20180214_er
09FEB2018:20:27:18 - a_797pp_stat_diff.sas/a_9pp_ppginc_stat_in_fas_app.txt

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2367 of 4425	Novo Nordisk
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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=P9PGINC Label=Faster aspart (post) - NovoRapid (meal) Parameter=PPG increment all meals (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.001019	0.016783	0.017802	6.1E6	0.060712	0.057237	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.253571	0.133423	-0.00793	0.515076	6.1E6	0.134726	0.376675

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	1.90	0.0574

nn1218/nn1218-4131/ctr_20180214_er
09FEB2018:20:27:18 - a_797pp_stat_diff.sas/a_9pp_ppginc_stat_in_fas_app.txt

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2368 of 4425	Novo Nordisk
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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=P9PGINCB Label=Faster aspart (meal) - NovoRapid (meal) Parameter=PPG increment breakfast (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.003093	0.040966	0.044060	4.06E6	0.075516	0.070214	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.578900	0.209904	-0.99030	-0.16749	4.06E6	-0.787598	-0.362421

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-2.76	0.0058

nn1218/nn1218-4131/ctr_20180214_er
09FEB2018:20:27:18 - a_797pp_stat_diff.sas/a_9pp_ppginc_stat_in_fas_app.txt

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2369 of 4425	Novo Nordisk
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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=P9PGINCB Label=Faster aspart (post) - NovoRapid (meal) Parameter=PPG increment breakfast (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.002333	0.040585	0.042918	6.77E6	0.057478	0.054354	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.397943	0.207166	-0.00810	0.803981	6.77E6	0.217249	0.590634

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	1.92	0.0547

nn1218/nn1218-4131/ctr_20180214_er
09FEB2018:20:27:18 - a_797pp_stat_diff.sas/a_9pp_ppginc_stat_in_fas_app.txt

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2370 of 4425	Novo Nordisk
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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=P9PGINCE Label=Faster aspart (meal) - NovoRapid (meal) Parameter=PPG increment main evening meal (SMPG) (mmol/

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.003373	0.046765	0.050138	4.42E6	0.072128	0.067276	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.346615	0.223916	-0.78548	0.092252	4.42E6	-0.570529	-0.106330

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-1.55	0.1216

nn1218/nn1218-4131/ctr_20180214_er
09FEB2018:20:27:18 - a_797pp_stat_diff.sas/a_9pp_ppginc_stat_in_fas_app.txt

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2371 of 4425	Novo Nordisk
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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=P9PGINCE Label=Faster aspart (post) - NovoRapid (meal) Parameter=PPG increment main evening meal (SMPG) (mmol/

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.002648	0.046614	0.049262	6.92E6	0.056818	0.053764	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.328299	0.221952	-0.10672	0.763316	6.92E6	0.096936	0.515500

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	1.48	0.1391

nn1218/nn1218-4131/ctr_20180214_er
09FEB2018:20:27:18 - a_797pp_stat_diff.sas/a_9pp_ppginc_stat_in_fas_app.txt

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2372 of 4425	Novo Nordisk
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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=P9PGINCL Label=Faster aspart (meal) - NovoRapid (meal) Parameter=PPG increment lunch (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.002928	0.039217	0.042145	4.14E6	0.074665	0.069478	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.398510	0.205293	-0.80088	0.003857	4.14E6	-0.628913	-0.160229

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-1.94	0.0522

nn1218/nn1218-4131/ctr_20180214_er
09FEB2018:20:27:18 - a_797pp_stat_diff.sas/a_9pp_ppginc_stat_in_fas_app.txt

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2373 of 4425	Novo Nordisk
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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=P9PGINCL Label=Faster aspart (post) - NovoRapid (meal) Parameter=PPG increment lunch (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.002422	0.039179	0.041602	5.9E6	0.061827	0.058227	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.124333	0.203965	-0.27543	0.524098	5.9E6	-0.073015	0.324150

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	0.61	0.5421

nn1218/nn1218-4131/ctr_20180214_er
09FEB2018:20:27:18 - a_797pp_stat_diff.sas/a_9pp_ppginc_stat_in_fas_app.txt

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2374 of 4425	Novo Nordisk
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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=P9PGIU Label=Faster aspart (meal) - NovoRapid (meal) Parameter=PPG increment all meals (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.461108	5.465131	5.926262	3.3E6	0.084377	0.077812	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-8.580302	2.434392	-13.3516	-3.80898	3.3E6	-11.464210	-5.529224

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-3.52	0.0004

nn1218/nn1218-4131/ctr_20180214_er
09FEB2018:20:27:18 - a_797pp_stat_diff.sas/a_9pp_ppginc_stat_in_fas_app.txt

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2375 of 4425	Novo Nordisk
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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=P9PGIU Label=Faster aspart (post) - NovoRapid (meal) Parameter=PPG increment all meals (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.330846	5.449752	5.780615	6.1E6	0.060712	0.057237	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	4.569342	2.404291	-0.14298	9.281666	6.1E6	2.427755	6.787677

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	1.90	0.0574

nn1218/nn1218-4131/ctr_20180214_er
09FEB2018:20:27:18 - a_797pp_stat_diff.sas/a_9pp_ppginc_stat_in_fas_app.txt

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure Model Information

Parameter Code=P9PGIBU Parameter=PPG increment breakfast (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Data Set	WORK.IMPUTE_ABS
2	1	NN1218-4131	Dependent Variable	eotVisitAbs
3	1	NN1218-4131	Covariance Structure	Diagonal
4	1	NN1218-4131	Estimation Method	REML
5	1	NN1218-4131	Residual Variance Method	Profile
6	1	NN1218-4131	Fixed Effects SE Method	Model-Based
7	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=P9PGIEU Parameter=PPG increment main evening meal (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
8	1	NN1218-4131	Data Set	WORK.IMPUTE_ABS
9	1	NN1218-4131	Dependent Variable	eotVisitAbs
10	1	NN1218-4131	Covariance Structure	Diagonal
11	1	NN1218-4131	Estimation Method	REML
12	1	NN1218-4131	Residual Variance Method	Profile
13	1	NN1218-4131	Fixed Effects SE Method	Model-Based
14	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=P9PGILU Parameter=PPG increment lunch (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
15	1	NN1218-4131	Data Set	WORK.IMPUTE_ABS
16	1	NN1218-4131	Dependent Variable	eotVisitAbs
17	1	NN1218-4131	Covariance Structure	Diagonal

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Model Information

Parameter Code=P9PGILU Parameter=PPG increment lunch (SMPG) (mg/dL)

(continued)

Obs	_Imputation_	STUDYID	Descr	Value
18	1	NN1218-4131	Estimation Method	REML
19	1	NN1218-4131	Residual Variance Method	Profile
20	1	NN1218-4131	Fixed Effects SE Method	Model-Based
21	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=P9PGINC Parameter=PPG increment all meals (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
22	1	NN1218-4131	Data Set	WORK.IMPUTE_ABS
23	1	NN1218-4131	Dependent Variable	eotVisitAbs
24	1	NN1218-4131	Covariance Structure	Diagonal
25	1	NN1218-4131	Estimation Method	REML
26	1	NN1218-4131	Residual Variance Method	Profile
27	1	NN1218-4131	Fixed Effects SE Method	Model-Based
28	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=P9PGINCB Parameter=PPG increment breakfast (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
29	1	NN1218-4131	Data Set	WORK.IMPUTE_ABS
30	1	NN1218-4131	Dependent Variable	eotVisitAbs
31	1	NN1218-4131	Covariance Structure	Diagonal
32	1	NN1218-4131	Estimation Method	REML

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Model Information

Parameter Code=P9PGINCB Parameter=PPG increment breakfast (SMPG) (mmol/L)

(continued)

Obs	_Imputation_	STUDYID	Descr	Value
33	1	NN1218-4131	Residual Variance Method	Profile
34	1	NN1218-4131	Fixed Effects SE Method	Model-Based
35	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=P9PGINCE Parameter=PPG increment main evening meal (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
36	1	NN1218-4131	Data Set	WORK.IMPUTE_ABS
37	1	NN1218-4131	Dependent Variable	eotVisitAbs
38	1	NN1218-4131	Covariance Structure	Diagonal
39	1	NN1218-4131	Estimation Method	REML
40	1	NN1218-4131	Residual Variance Method	Profile
41	1	NN1218-4131	Fixed Effects SE Method	Model-Based
42	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=P9PGINCL Parameter=PPG increment lunch (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
43	1	NN1218-4131	Data Set	WORK.IMPUTE_ABS
44	1	NN1218-4131	Dependent Variable	eotVisitAbs
45	1	NN1218-4131	Covariance Structure	Diagonal
46	1	NN1218-4131	Estimation Method	REML
47	1	NN1218-4131	Residual Variance Method	Profile

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Model Information

Parameter Code=P9PGINCL Parameter=PPG increment lunch (SMPG) (mmol/L)

(continued)

Obs	_Imputation_	STUDYID	Descr	Value
48	1	NN1218-4131	Fixed Effects SE Method	Model-Based
49	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=P9PGIU Parameter=PPG increment all meals (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
50	1	NN1218-4131	Data Set	WORK.IMPUTE_ABS
51	1	NN1218-4131	Dependent Variable	eotVisitAbs
52	1	NN1218-4131	Covariance Structure	Diagonal
53	1	NN1218-4131	Estimation Method	REML
54	1	NN1218-4131	Residual Variance Method	Profile
55	1	NN1218-4131	Fixed Effects SE Method	Model-Based
56	1	NN1218-4131	Degrees of Freedom Method	Residual

Fast-acting insulin aspart
NN1218-4131

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Class Level Information

Parameter Code=P9PGIBU Parameter=PPG increment breakfast (SMPG) (mg/dL)

O b s		I n		S t		C l		L e		V a		L e		g t	
_		D		s		s		s		s		h			
1	1	NN1218-4131	TRTPN			3	2	3	4						5
2	1	NN1218-4131	REGION1			4	ASIA (EXCLUDING JAPAN)	EUROPE	JAPAN	NORTH AMERICA					49
3	1	NN1218-4131	BOLAD1			2	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	CARBOHYDRATE COUNTING (FLEXIBLE)	BOLUS INSULI						85

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Class Level Information

Parameter Code=P9PGIEU Parameter=PPG increment main evening meal (SMPG) (mg/dL)

Ob- s	—	Input ID	STUDY	Class	Levels	Val- ues	mi- n
4	1	NN1218-4131	TRTPN		3 2 3 4		5
5	1	NN1218-4131	REGION1		4 ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA		49
6	1	NN1218-4131	BOLAD1		2 BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULI		85

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Class Level Information

Parameter Code=P9PGILU Parameter=PPG increment lunch (SMPG) (mg/dL)

Ob- s	—	Input on ID	STUDY ID	Class s	Lev- els	Val- ues	mi- n
7	1	NN1218-4131	TRTPN		3 2 3 4		5
8	1	NN1218-4131	REGION1		4 ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA		49
9	1	NN1218-4131	BOLAD1		2 BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULI		85

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nn1218/nn1218-4131/ctr_20180214_er
09FEB2018:20:27:18 - a 797pp stat diff.sas/a 9pp ppginc stat in_fas app.txt
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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Class Level Information

Parameter Code=P9PGINCB Parameter=PPG increment breakfast (SMPG) (mmol/L)

O b s		I n		S t		C l		L e		V a		L e		g t	
_		D		Y		I		s		e		s		h	
13	1	NN1218-4131	TRTPN					3	2	3	4				5
14	1	NN1218-4131	REGION1					4	ASIA (EXCLUDING JAPAN)	EUROPE	JAPAN	NORTH AMERICA			49
15	1	NN1218-4131	BOLAD1					2	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	CARBOHYDRATE COUNTING (FLEXIBLE)	BOLUS	INSULI			85

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Class Level Information

Parameter Code=P9PGINCE Parameter=PPG increment main evening meal (SMPG) (mmol/L)

Obs	Input	STUDY ID	Class	Level	Values	min
16	1	NN1218-4131	TRTPN	3 2 3 4		5
17	1	NN1218-4131	REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA	49
18	1	NN1218-4131	BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULI	85

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Class Level Information

Parameter Code=P9PGINCL Parameter=PPG increment lunch (SMPG) (mmol/L)

Obs	Inpution	STUDY ID	Classs	Level	Values	min
19	1	NN1218-4131	TRTPN	3 2 3 4		5
20	1	NN1218-4131	REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA	49
21	1	NN1218-4131	BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULI	85

Fast-acting insulin aspart
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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Class Level Information

Parameter Code=P9PGIU Parameter=PPG increment all meals (SMPG) (mg/dL)

O b s		I n		S t		C l		L e		V a		L e		g t	
_		D		Y		I		s		e		s		h	
22	1	NN1218-4131	TRTPN	3	2	3	4								5
23	1	NN1218-4131	REGION1	4	ASIA (EXCLUDING JAPAN)	EUROPE	JAPAN	NORTH AMERICA							49
24	1	NN1218-4131	BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	CARBOHYDRATE COUNTING (FLEXIBLE)	BOLUS INSULI								85

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Dimensions

Parameter Code=P9PGIBU Parameter=PPG increment breakfast (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Covariance Parameters	1
2	1	NN1218-4131	Columns in X	10
3	1	NN1218-4131	Columns in Z	0
4	1	NN1218-4131	Subjects	1
5	1	NN1218-4131	Max Obs per Subject	986

Parameter Code=P9PGIEU Parameter=PPG increment main evening meal (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
6	1	NN1218-4131	Covariance Parameters	1
7	1	NN1218-4131	Columns in X	10
8	1	NN1218-4131	Columns in Z	0
9	1	NN1218-4131	Subjects	1
10	1	NN1218-4131	Max Obs per Subject	979

Parameter Code=P9PGILU Parameter=PPG increment lunch (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
11	1	NN1218-4131	Covariance Parameters	1
12	1	NN1218-4131	Columns in X	10
13	1	NN1218-4131	Columns in Z	0
14	1	NN1218-4131	Subjects	1
15	1	NN1218-4131	Max Obs per Subject	982

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Dimensions

Parameter Code=P9PGINC Parameter=PPG increment all meals (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
16	1	NN1218-4131	Covariance Parameters	1
17	1	NN1218-4131	Columns in X	10
18	1	NN1218-4131	Columns in Z	0
19	1	NN1218-4131	Subjects	1
20	1	NN1218-4131	Max Obs per Subject	974

Parameter Code=P9PGINCB Parameter=PPG increment breakfast (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
21	1	NN1218-4131	Covariance Parameters	1
22	1	NN1218-4131	Columns in X	10
23	1	NN1218-4131	Columns in Z	0
24	1	NN1218-4131	Subjects	1
25	1	NN1218-4131	Max Obs per Subject	986

Parameter Code=P9PGINCE Parameter=PPG increment main evening meal (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
26	1	NN1218-4131	Covariance Parameters	1
27	1	NN1218-4131	Columns in X	10
28	1	NN1218-4131	Columns in Z	0
29	1	NN1218-4131	Subjects	1
30	1	NN1218-4131	Max Obs per Subject	979

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Dimensions

Parameter Code=P9PGINCL Parameter=PPG increment lunch (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
31	1	NN1218-4131	Covariance Parameters	1
32	1	NN1218-4131	Columns in X	10
33	1	NN1218-4131	Columns in Z	0
34	1	NN1218-4131	Subjects	1
35	1	NN1218-4131	Max Obs per Subject	982

Parameter Code=P9PGIU Parameter=PPG increment all meals (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
36	1	NN1218-4131	Covariance Parameters	1
37	1	NN1218-4131	Columns in X	10
38	1	NN1218-4131	Columns in Z	0
39	1	NN1218-4131	Subjects	1
40	1	NN1218-4131	Max Obs per Subject	974

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Number of Observations

Parameter Code=P9PGIBU Parameter=PPG increment breakfast (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
1	1	NN1218-4131	Number of Observations Read	986	986	986	986	986
2	1	NN1218-4131	Number of Observations Used	986	986	986	986	986
3	1	NN1218-4131	Number of Observations Not Used	0	986	986	986	986

Parameter Code=P9PGIEU Parameter=PPG increment main evening meal (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
4	1	NN1218-4131	Number of Observations Read	979	979	979	979	979
5	1	NN1218-4131	Number of Observations Used	979	979	979	979	979
6	1	NN1218-4131	Number of Observations Not Used	0	979	979	979	979

Parameter Code=P9PGILU Parameter=PPG increment lunch (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
7	1	NN1218-4131	Number of Observations Read	982	982	982	982	982
8	1	NN1218-4131	Number of Observations Used	982	982	982	982	982
9	1	NN1218-4131	Number of Observations Not Used	0	982	982	982	982

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Number of Observations

Parameter Code=P9PGINC Parameter=PPG increment all meals (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
10	1	NN1218-4131	Number of Observations Read	974	974	974	974	974
11	1	NN1218-4131	Number of Observations Used	974	974	974	974	974
12	1	NN1218-4131	Number of Observations Not Used	0	974	974	974	974

Parameter Code=P9PGINCB Parameter=PPG increment breakfast (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
13	1	NN1218-4131	Number of Observations Read	986	986	986	986	986
14	1	NN1218-4131	Number of Observations Used	986	986	986	986	986
15	1	NN1218-4131	Number of Observations Not Used	0	986	986	986	986

Parameter Code=P9PGINCE Parameter=PPG increment main evening meal (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
16	1	NN1218-4131	Number of Observations Read	979	979	979	979	979
17	1	NN1218-4131	Number of Observations Used	979	979	979	979	979
18	1	NN1218-4131	Number of Observations Not Used	0	979	979	979	979

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Number of Observations

Parameter Code=P9PGINCL Parameter=PPG increment lunch (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
19	1	NN1218-4131	Number of Observations Read	982	982	982	982	982
20	1	NN1218-4131	Number of Observations Used	982	982	982	982	982
21	1	NN1218-4131	Number of Observations Not Used	0	982	982	982	982

Parameter Code=P9PGIU Parameter=PPG increment all meals (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
22	1	NN1218-4131	Number of Observations Read	974	974	974	974	974
23	1	NN1218-4131	Number of Observations Used	974	974	974	974	974
24	1	NN1218-4131	Number of Observations Not Used	0	974	974	974	974

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Covariance Parameter Estimates

Parameter Code=P9PGIBU Parameter=PPG increment breakfast (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	CovParm	Estimate
1	1	NN1218-4131	Residual	2183.07

Parameter Code=P9PGIEU Parameter=PPG increment main evening meal (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	CovParm	Estimate
20001	1	NN1218-4131	Residual	2452.71

Parameter Code=P9PGILU Parameter=PPG increment lunch (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	CovParm	Estimate
40001	1	NN1218-4131	Residual	2083.15

Parameter Code=P9PGINC Parameter=PPG increment all meals (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	CovParm	Estimate
60001	1	NN1218-4131	Residual	2.7167

Parameter Code=P9PGINCB Parameter=PPG increment breakfast (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	CovParm	Estimate
80001	1	NN1218-4131	Residual	6.7229

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The Mixed procedure
Covariance Parameter Estimates

Parameter Code=P9PGINCE Parameter=PPG increment main evening meal (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	CovParm	Estimate
100001	1	NN1218-4131	Residual	7.5533

Parameter Code=P9PGINCL Parameter=PPG increment lunch (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	CovParm	Estimate
120001	1	NN1218-4131	Residual	6.4152

Parameter Code=P9PGIU Parameter=PPG increment all meals (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	CovParm	Estimate
140001	1	NN1218-4131	Residual	882.16

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Fit Statistics

Parameter Code=P9PGIBU Parameter=PPG increment breakfast (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	-2 Res Log Likelihood	10347.3
2	1	NN1218-4131	AIC (Smaller is Better)	10349.3
3	1	NN1218-4131	AICC (Smaller is Better)	10349.3
4	1	NN1218-4131	BIC (Smaller is Better)	10354.2

Parameter Code=P9PGIEU Parameter=PPG increment main evening meal (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
5	1	NN1218-4131	-2 Res Log Likelihood	10386.6
6	1	NN1218-4131	AIC (Smaller is Better)	10388.6
7	1	NN1218-4131	AICC (Smaller is Better)	10388.6
8	1	NN1218-4131	BIC (Smaller is Better)	10393.5

Parameter Code=P9PGILU Parameter=PPG increment lunch (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
9	1	NN1218-4131	-2 Res Log Likelihood	10259.2
10	1	NN1218-4131	AIC (Smaller is Better)	10261.2
11	1	NN1218-4131	AICC (Smaller is Better)	10261.2
12	1	NN1218-4131	BIC (Smaller is Better)	10266.1

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The Mixed procedure
Fit Statistics

Parameter Code=P9PGINC Parameter=PPG increment all meals (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
13	1	NN1218-4131	-2 Res Log Likelihood	3752.5
14	1	NN1218-4131	AIC (Smaller is Better)	3754.5
15	1	NN1218-4131	AICC (Smaller is Better)	3754.5
16	1	NN1218-4131	BIC (Smaller is Better)	3759.4

Parameter Code=P9PGINCB Parameter=PPG increment breakfast (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
17	1	NN1218-4131	-2 Res Log Likelihood	4685.8
18	1	NN1218-4131	AIC (Smaller is Better)	4687.8
19	1	NN1218-4131	AICC (Smaller is Better)	4687.8
20	1	NN1218-4131	BIC (Smaller is Better)	4692.7

Parameter Code=P9PGINCE Parameter=PPG increment main evening meal (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
21	1	NN1218-4131	-2 Res Log Likelihood	4765.5
22	1	NN1218-4131	AIC (Smaller is Better)	4767.5
23	1	NN1218-4131	AICC (Smaller is Better)	4767.5
24	1	NN1218-4131	BIC (Smaller is Better)	4772.4

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The Mixed procedure
Fit Statistics

Parameter Code=P9PGINCL Parameter=PPG increment lunch (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
25	1	NN1218-4131	-2 Res Log Likelihood	4620.8
26	1	NN1218-4131	AIC (Smaller is Better)	4622.8
27	1	NN1218-4131	AICC (Smaller is Better)	4622.8
28	1	NN1218-4131	BIC (Smaller is Better)	4627.7

Parameter Code=P9PGIU Parameter=PPG increment all meals (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
29	1	NN1218-4131	-2 Res Log Likelihood	9344.7
30	1	NN1218-4131	AIC (Smaller is Better)	9346.7
31	1	NN1218-4131	AICC (Smaller is Better)	9346.7
32	1	NN1218-4131	BIC (Smaller is Better)	9351.5

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The Mixed procedure
Solution for Fixed Effects

Parameter Code=P9PGIBU Parameter=PPG increment breakfast (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
1	1	NN1218-4131	TRTPN	2				
2	1	NN1218-4131	TRTPN	3				
3	1	NN1218-4131	TRTPN	4				
4	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
5	1	NN1218-4131	REGION1	—	EUROPE			
6	1	NN1218-4131	REGION1	—	JAPAN			
7	1	NN1218-4131	REGION1	—	NORTH AMERICA			
8	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
9	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
10	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	10.5857	3.8079	978	2.78	0.0055	0.05	3.1131	18.0583
2	28.7728	3.8203	978	7.53	<.0001	0.05	21.2758	36.2698
3	20.5616	3.8296	978	5.37	<.0001	0.05	13.0464	28.0767
4	5.9702	5.4584	978	1.09	0.2743	0.05	-4.7414	16.6818
5	0.5710	3.8808	978	0.15	0.8831	0.05	-7.0446	8.1865
6	16.1528	4.3227	978	3.74	0.0002	0.05	7.6701	24.6356
7	0
8	-9.6620	3.3711	978	-2.87	0.0042	0.05	-16.2774	-3.0466
9	0
10	0.2796	0.02651	978	10.55	<.0001	0.05	0.2276	0.3316

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The Mixed procedure
Solution for Fixed Effects

Parameter Code=P9PGIEU Parameter=PPG increment main evening meal (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1			BOLAD1
11	1	NN1218-4131	TRTPN	2				
12	1	NN1218-4131	TRTPN	3				
13	1	NN1218-4131	TRTPN	4				
14	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
15	1	NN1218-4131	REGION1	—	EUROPE			
16	1	NN1218-4131	REGION1	—	JAPAN			
17	1	NN1218-4131	REGION1	—	NORTH AMERICA			
18	1	NN1218-4131	BOLAD1	—				BOLUS INSULIN ALGORITHM (SLIDING SCALE)
19	1	NN1218-4131	BOLAD1	—				CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY
20	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
11	12.0045	3.8883	971	3.09	0.0021	0.05	4.3740	19.6350
12	23.6379	3.9566	971	5.97	<.0001	0.05	15.8734	31.4025
13	16.9190	3.9294	971	4.31	<.0001	0.05	9.2079	24.6301
14	-19.7407	5.7977	971	-3.40	0.0007	0.05	-31.1181	-8.3632
15	-2.7801	4.1311	971	-0.67	0.5011	0.05	-10.8869	5.3267
16	-0.03821	4.5938	971	-0.01	0.9934	0.05	-9.0532	8.9767
17	0
18	2.7859	3.5846	971	0.78	0.4372	0.05	-4.2485	9.8203
19	0
20	0.2299	0.02914	971	7.89	<.0001	0.05	0.1727	0.2871

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The Mixed procedure
Solution for Fixed Effects

Parameter Code=P9PGILU Parameter=PPG increment lunch (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
21	1	NN1218-4131	TRTPN	2				
22	1	NN1218-4131	TRTPN	3				
23	1	NN1218-4131	TRTPN	4				
24	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
25	1	NN1218-4131	REGION1	—	EUROPE			
26	1	NN1218-4131	REGION1	—	JAPAN			
27	1	NN1218-4131	REGION1	—	NORTH AMERICA			
28	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
29	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
30	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
21	15.4132	3.6620	974	4.21	<.0001	0.05	8.2269	22.5995
22	24.6608	3.7121	974	6.64	<.0001	0.05	17.3761	31.9454
23	21.0486	3.6796	974	5.72	<.0001	0.05	13.8277	28.2694
24	-3.0775	5.3349	974	-0.58	0.5642	0.05	-13.5468	7.3918
25	-9.8293	3.7998	974	-2.59	0.0098	0.05	-17.2861	-2.3725
26	11.0559	4.3100	974	2.57	0.0105	0.05	2.5979	19.5138
27	0
28	1.1076	3.2965	974	0.34	0.7369	0.05	-5.3615	7.5768
29	0
30	0.2612	0.03022	974	8.64	<.0001	0.05	0.2019	0.3205

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The Mixed procedure
Solution for Fixed Effects

Parameter Code=P9PPGINC Parameter=PPG increment all meals (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1		BOLAD1	
31	1	NN1218-4131	TRTPN	2				
32	1	NN1218-4131	TRTPN	3				
33	1	NN1218-4131	TRTPN	4				
34	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
35	1	NN1218-4131	REGION1	—	EUROPE			
36	1	NN1218-4131	REGION1	—	JAPAN			
37	1	NN1218-4131	REGION1	—	NORTH AMERICA			
38	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
39	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
40	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
31	0.4450	0.1369	966	3.25	0.0012	0.05	0.1764	0.7136
32	1.1960	0.1384	966	8.64	<.0001	0.05	0.9244	1.4676
33	0.9053	0.1363	966	6.64	<.0001	0.05	0.6378	1.1728
34	-0.2194	0.1931	966	-1.14	0.2562	0.05	-0.5983	0.1595
35	-0.1984	0.1379	966	-1.44	0.1507	0.05	-0.4691	0.07228
36	0.4039	0.1554	966	2.60	0.0095	0.05	0.09894	0.7088
37	0
38	-0.09837	0.1201	966	-0.82	0.4130	0.05	-0.3341	0.1373
39	0
40	0.3909	0.02689	966	14.54	<.0001	0.05	0.3381	0.4436

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The Mixed procedure
Solution for Fixed Effects

Parameter Code=P9PGINCB Parameter=PPG increment breakfast (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1			BOLAD1
41	1	NN1218-4131	TRTPN	2				
42	1	NN1218-4131	TRTPN	3				
43	1	NN1218-4131	TRTPN	4				
44	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
45	1	NN1218-4131	REGION1	—	EUROPE			
46	1	NN1218-4131	REGION1	—	JAPAN			
47	1	NN1218-4131	REGION1	—	NORTH AMERICA			
48	1	NN1218-4131	BOLAD1	—				BOLUS INSULIN ALGORITHM (SLIDING SCALE)
49	1	NN1218-4131	BOLAD1	—				CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY
50	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
41	0.5874	0.2113	978	2.78	0.0055	0.05	0.1728	1.0021
42	1.5967	0.2120	978	7.53	<.0001	0.05	1.1807	2.0128
43	1.1410	0.2125	978	5.37	<.0001	0.05	0.7240	1.5581
44	0.3313	0.3029	978	1.09	0.2743	0.05	-0.2631	0.9257
45	0.03169	0.2154	978	0.15	0.8831	0.05	-0.3909	0.4543
46	0.8964	0.2399	978	3.74	0.0002	0.05	0.4256	1.3671
47	0
48	-0.5362	0.1871	978	-2.87	0.0042	0.05	-0.9033	-0.1691
49	0
50	0.2796	0.02651	978	10.55	<.0001	0.05	0.2276	0.3316

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The Mixed procedure
Solution for Fixed Effects

Parameter Code=P9PGINCE Parameter=PPG increment main evening meal (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1			BOLAD1
51	1	NN1218-4131	TRTPN	2				
52	1	NN1218-4131	TRTPN	3				
53	1	NN1218-4131	TRTPN	4				
54	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
55	1	NN1218-4131	REGION1	—	EUROPE			
56	1	NN1218-4131	REGION1	—	JAPAN			
57	1	NN1218-4131	REGION1	—	NORTH AMERICA			
58	1	NN1218-4131	BOLAD1	—				BOLUS INSULIN ALGORITHM (SLIDING SCALE)
59	1	NN1218-4131	BOLAD1	—				CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY
60	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
51	0.6662	0.2158	971	3.09	0.0021	0.05	0.2427	1.0896
52	1.3118	0.2196	971	5.97	<.0001	0.05	0.8809	1.7426
53	0.9389	0.2181	971	4.31	<.0001	0.05	0.5110	1.3668
54	-1.0955	0.3217	971	-3.40	0.0007	0.05	-1.7269	-0.4641
55	-0.1543	0.2292	971	-0.67	0.5011	0.05	-0.6042	0.2956
56	-0.00212	0.2549	971	-0.01	0.9934	0.05	-0.5024	0.4982
57	0
58	0.1546	0.1989	971	0.78	0.4372	0.05	-0.2358	0.5450
59	0
60	0.2299	0.02914	971	7.89	<.0001	0.05	0.1727	0.2871

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The Mixed procedure
Solution for Fixed Effects

Parameter Code=P9PGINCL Parameter=PPG increment lunch (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1			BOLAD1
61	1	NN1218-4131	TRTPN	2				
62	1	NN1218-4131	TRTPN	3				
63	1	NN1218-4131	TRTPN	4				
64	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
65	1	NN1218-4131	REGION1	—	EUROPE			
66	1	NN1218-4131	REGION1	—	JAPAN			
67	1	NN1218-4131	REGION1	—	NORTH AMERICA			
68	1	NN1218-4131	BOLAD1	—				BOLUS INSULIN ALGORITHM (SLIDING SCALE)
69	1	NN1218-4131	BOLAD1	—				CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY
70	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
61	0.8553	0.2032	974	4.21	<.0001	0.05	0.4565	1.2541
62	1.3685	0.2060	974	6.64	<.0001	0.05	0.9643	1.7728
63	1.1681	0.2042	974	5.72	<.0001	0.05	0.7674	1.5688
64	-0.1708	0.2961	974	-0.58	0.5642	0.05	-0.7518	0.4102
65	-0.5455	0.2109	974	-2.59	0.0098	0.05	-0.9593	-0.1317
66	0.6135	0.2392	974	2.57	0.0105	0.05	0.1442	1.0829
67	0
68	0.06147	0.1829	974	0.34	0.7369	0.05	-0.2975	0.4205
69	0
70	0.2612	0.03022	974	8.64	<.0001	0.05	0.2019	0.3205

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The Mixed procedure
Solution for Fixed Effects

Parameter Code=P9PGIU Parameter=PPG increment all meals (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
71	1	NN1218-4131	TRTPN	2				
72	1	NN1218-4131	TRTPN	3				
73	1	NN1218-4131	TRTPN	4				
74	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
75	1	NN1218-4131	REGION1	—	EUROPE			
76	1	NN1218-4131	REGION1	—	JAPAN			
77	1	NN1218-4131	REGION1	—	NORTH AMERICA			
78	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
79	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
80	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
71	8.0192	2.4665	966	3.25	0.0012	0.05	3.1789	12.8594
72	21.5524	2.4939	966	8.64	<.0001	0.05	16.6583	26.4465
73	16.3133	2.4565	966	6.64	<.0001	0.05	11.4926	21.1341
74	-3.9533	3.4794	966	-1.14	0.2562	0.05	-10.7814	2.8748
75	-3.5750	2.4854	966	-1.44	0.1507	0.05	-8.4525	1.3025
76	7.2774	2.7999	966	2.60	0.0095	0.05	1.7829	12.7719
77	0
78	-1.7726	2.1642	966	-0.82	0.4130	0.05	-6.0196	2.4745
79	0
80	0.3909	0.02689	966	14.54	<.0001	0.05	0.3381	0.4436

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Fast-acting insulin aspart
NN1218-4131

Clinical Trial Report
Statistical document

Date: 14 February 2018
Version: 1.0

Status: Final
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Novo Nordisk

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Least Squares Means

Obs	_Imputation_	PARAMCD	PARAM	STUDYID	Effect
1	1	P9PGIBU	PPG increment breakfast (SMPG) (mg/dL)	NN1218-4131	TRTPN
20001	1	P9PGIEU	PPG increment main evening meal (SMPG) (mg/dL)	NN1218-4131	TRTPN
40001	1	P9PGILU	PPG increment lunch (SMPG) (mg/dL)	NN1218-4131	TRTPN
60001	1	P9PGINC	PPG increment all meals (SMPG) (mmol/L)	NN1218-4131	TRTPN
80001	1	P9PGINCB	PPG increment breakfast (SMPG) (mmol/L)	NN1218-4131	TRTPN
100001	1	P9PGINCE	PPG increment main evening meal (SMPG) (mmol/L)	NN1218-4131	TRTPN
120001	1	P9PGINCL	PPG increment lunch (SMPG) (mmol/L)	NN1218-4131	TRTPN
140001	1	P9PGIU	PPG increment all meals (SMPG) (mg/dL)	NN1218-4131	TRTPN
160001	1	P9PGIBU	PPG increment breakfast (SMPG) (mg/dL)	NN1218-4131	TRTPN
180001	1	P9PGIEU	PPG increment main evening meal (SMPG) (mg/dL)	NN1218-4131	TRTPN
200001	1	P9PGILU	PPG increment lunch (SMPG) (mg/dL)	NN1218-4131	TRTPN
220001	1	P9PGINC	PPG increment all meals (SMPG) (mmol/L)	NN1218-4131	TRTPN
240001	1	P9PGINCB	PPG increment breakfast (SMPG) (mmol/L)	NN1218-4131	TRTPN
260001	1	P9PGINCE	PPG increment main evening meal (SMPG) (mmol/L)	NN1218-4131	TRTPN

Obs	TRTPN	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	2	WORK.IMPUTE	-16.8536	2.5918	978	-6.50	<.0001	0.05	-21.9397	-11.7675
20001	2	WORK.IMPUTE	-3.1691	2.7517	971	-1.15	0.2497	0.05	-8.5690	2.2308
40001	2	WORK.IMPUTE	-9.3579	2.5284	974	-3.70	0.0002	0.05	-14.3196	-4.3962
60001	2	WORK.IMPUTE	-0.5965	0.09187	966	-6.49	<.0001	0.05	-0.7768	-0.4162
80001	2	WORK.IMPUTE	-0.9353	0.1438	978	-6.50	<.0001	0.05	-1.2175	-0.6530
100001	2	WORK.IMPUTE	-0.1759	0.1527	971	-1.15	0.2497	0.05	-0.4755	0.1238
120001	2	WORK.IMPUTE	-0.5193	0.1403	974	-3.70	0.0002	0.05	-0.7946	-0.2440
140001	2	WORK.IMPUTE	-10.7492	1.6556	966	-6.49	<.0001	0.05	-13.9982	-7.5003
160001	3	WORK.IMPUTE	1.3335	2.5706	978	0.52	0.6040	0.05	-3.7111	6.3781
180001	3	WORK.IMPUTE	8.4643	2.7459	971	3.08	0.0021	0.05	3.0757	13.8528
200001	3	WORK.IMPUTE	-0.1103	2.5301	974	-0.04	0.9652	0.05	-5.0754	4.8549
220001	3	WORK.IMPUTE	0.1545	0.09179	966	1.68	0.0927	0.05	-0.02563	0.3346
240001	3	WORK.IMPUTE	0.07400	0.1427	978	0.52	0.6040	0.05	-0.2059	0.3539
260001	3	WORK.IMPUTE	0.4697	0.1524	971	3.08	0.0021	0.05	0.1707	0.7687

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Fast-acting insulin aspart
NN1218-4131

Clinical Trial Report
Statistical document

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Novo Nordisk

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Least Squares Means

Obs	_Imputation_	PARAMCD	PARAM	STUDYID	Effect
280001	1	P9PGINCL	PPG increment lunch (SMPG) (mmol/L)	NN1218-4131	TRTPN
300001	1	P9PGIU	PPG increment all meals (SMPG) (mg/dL)	NN1218-4131	TRTPN
320001	1	P9PGIBU	PPG increment breakfast (SMPG) (mg/dL)	NN1218-4131	TRTPN
340001	1	P9PGIEU	PPG increment main evening meal (SMPG) (mg/dL)	NN1218-4131	TRTPN
360001	1	P9PGILU	PPG increment lunch (SMPG) (mg/dL)	NN1218-4131	TRTPN
380001	1	P9PGINC	PPG increment all meals (SMPG) (mmol/L)	NN1218-4131	TRTPN
400001	1	P9PGINCB	PPG increment breakfast (SMPG) (mmol/L)	NN1218-4131	TRTPN
420001	1	P9PGINCE	PPG increment main evening meal (SMPG) (mmol/L)	NN1218-4131	TRTPN
440001	1	P9PGINCL	PPG increment lunch (SMPG) (mmol/L)	NN1218-4131	TRTPN
460001	1	P9PGIU	PPG increment all meals (SMPG) (mg/dL)	NN1218-4131	TRTPN

Obs	TRTPN	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
280001	3	WORK.IMPUTE	-0.00612	0.1404	974	-0.04	0.9652	0.05	-0.2817	0.2694
300001	3	WORK.IMPUTE	2.7840	1.6540	966	1.68	0.0927	0.05	-0.4619	6.0299
320001	4	WORK.IMPUTE	-6.8777	2.5780	978	-2.67	0.0078	0.05	-11.9368	-1.8187
340001	4	WORK.IMPUTE	1.7453	2.7381	971	0.64	0.5240	0.05	-3.6280	7.1186
360001	4	WORK.IMPUTE	-3.7225	2.5196	974	-1.48	0.1399	0.05	-8.6669	1.2219
380001	4	WORK.IMPUTE	-0.1362	0.09114	966	-1.49	0.1353	0.05	-0.3151	0.04261
400001	4	WORK.IMPUTE	-0.3817	0.1431	978	-2.67	0.0078	0.05	-0.6624	-0.1009
420001	4	WORK.IMPUTE	0.09685	0.1519	971	0.64	0.5240	0.05	-0.2013	0.3950
440001	4	WORK.IMPUTE	-0.2066	0.1398	974	-1.48	0.1399	0.05	-0.4810	0.06781
460001	4	WORK.IMPUTE	-2.4551	1.6423	966	-1.49	0.1353	0.05	-5.6779	0.7678

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Least Squares Means Estimate

Parameter Code=P9PGIBU Parameter=PPG increment breakfast (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
1	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
20001	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	WORK.IMPUTE	-9.9759	3.6581	978	-2.73	0.0065	0.05	-17.1546	-2.7972
20001	WORK.IMPUTE	8.2113	3.6411	978	2.26	0.0243	0.05	1.0660	15.3565

Parameter Code=P9PGIEU Parameter=PPG increment main evening meal (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
40001	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
60001	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
40001	WORK.IMPUTE	-4.9144	3.8855	971	-1.26	0.2062	0.05	-12.5393	2.7105
60001	WORK.IMPUTE	6.7190	3.8792	971	1.73	0.0836	0.05	-0.8936	14.3315

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Least Squares Means Estimate

Parameter Code=P9PGILU Parameter=PPG increment lunch (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label				
80001	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)				
100001	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)				

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
80001	WORK.IMPUTE	-5.6354	3.5733	974	-1.58	0.1151	0.05	-12.6475	1.3768
100001	WORK.IMPUTE	3.6122	3.5715	974	1.01	0.3121	0.05	-3.3966	10.6210

Parameter Code=P9PGINC Parameter=PPG increment all meals (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label				
120001	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)				
140001	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)				

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
120001	WORK.IMPUTE	-0.4603	0.1296	966	-3.55	0.0004	0.05	-0.7145	-0.2060
140001	WORK.IMPUTE	0.2907	0.1294	966	2.25	0.0249	0.05	0.03684	0.5446

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Least Squares Means Estimate

Parameter Code=P9PGINCB Parameter=PPG increment breakfast (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label				
160001	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)				
180001	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)				

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
160001	WORK.IMPUTE	-0.5536	0.2030	978	-2.73	0.0065	0.05	-0.9520	-0.1552
180001	WORK.IMPUTE	0.4557	0.2021	978	2.26	0.0243	0.05	0.05916	0.8522

Parameter Code=P9PGINCE Parameter=PPG increment main evening meal (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label				
200001	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)				
220001	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)				

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
200001	WORK.IMPUTE	-0.2727	0.2156	971	-1.26	0.2062	0.05	-0.6959	0.1504
220001	WORK.IMPUTE	0.3729	0.2153	971	1.73	0.0836	0.05	-0.04959	0.7953

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Least Squares Means Estimate

Parameter Code=P9PGINCL Parameter=PPG increment lunch (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label				
240001	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)				
260001	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)				

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
240001	WORK.IMPUTE	-0.3127	0.1983	974	-1.58	0.1151	0.05	-0.7019	0.07640
260001	WORK.IMPUTE	0.2005	0.1982	974	1.01	0.3121	0.05	-0.1885	0.5894

Parameter Code=P9PGIU Parameter=PPG increment all meals (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label				
280001	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)				
300001	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)				

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
280001	WORK.IMPUTE	-8.2942	2.3347	966	-3.55	0.0004	0.05	-12.8759	-3.7125
300001	WORK.IMPUTE	5.2390	2.3314	966	2.25	0.0249	0.05	0.6638	9.8143

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9PGIBU Parameter=PPG increment breakfast (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.551593	6.677561	7.229182	3.43E6	0.082608	0.076305	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	20.421008	2.688714	15.15122	25.69079	3.43E6	17.364782	23.232456

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	7.60	<.0001

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9PGIEU Parameter=PPG increment main evening meal (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.544136	7.616168	8.160331	4.5E6	0.071448	0.066684	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	13.157658	2.856629	7.558766	18.75655	4.5E6	10.080854	16.449726

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	4.61	<.0001

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9PGILU Parameter=PPG increment lunch (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.494120	6.375845	6.869989	3.87E6	0.077503	0.071928	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	23.239221	2.621066	18.10202	28.37642	3.87E6	20.199265	25.957550

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	8.87	<.0001

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9PGINC Parameter=PPG increment all meals (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000725	0.008463	0.009188	3.21E6	0.085704	0.078939	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	1.025872	0.095856	0.837999	1.213746	3.21E6	0.912484	1.135881

Parameter Estimates

Parameter	Theta0	t for H0: Parameter=Theta0	Pr > t
Estimate	0	10.70	<.0001

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9PGINCB Parameter=PPG increment breakfast (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.001699	0.020564	0.022263	3.43E6	0.082608	0.076305	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	1.133241	0.149207	0.840800	1.425682	3.43E6	0.963639	1.289259

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	7.60	<.0001

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9PGINCE Parameter=PPG increment main evening meal (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.001676	0.023455	0.025130	4.5E6	0.071448	0.066684	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits	DF	Minimum	Maximum
Estimate	0.730170	0.158525	0.419465 1.040874	4.5E6	0.559426	0.912859

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	4.61	<.0001

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9PGINCL Parameter=PPG increment lunch (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.001522	0.019635	0.021157	3.87E6	0.077503	0.071928	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	1.289635	0.145453	1.004552	1.574718	3.87E6	1.120936	1.440486

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	8.87	<.0001

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9PGIU Parameter=PPG increment all meals (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.235511	2.748099	2.983621	3.21E6	0.085704	0.078939	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	18.486221	1.727316	15.10074	21.87170	3.21E6	16.442954	20.468573

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	10.70	<.0001

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9PGIBU Parameter=PPG increment breakfast (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.303049	6.568968	6.872033	1.03E7	0.046136	0.044101	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	38.023705	2.621456	32.88574	43.16167	1.03E7	35.653182	40.302144

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	14.50	<.0001

nn1218/nn1218-4131/ctr_20180214_er
09FEB2018:20:27:18 - a_797pp_stat_diff.sas/a_9pp_ppginc_stat_in_fas_app.txt

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9PGIEU Parameter=PPG increment main evening meal (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.334930	7.584158	7.919105	1.12E7	0.044164	0.042296	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	25.319613	2.814090	19.80410	30.83513	1.12E7	23.133989	27.732524

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	9.00	<.0001

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9PGILU Parameter=PPG increment lunch (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.332660	6.384763	6.717440	8.15E6	0.052105	0.049525	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	32.660863	2.591802	27.58102	37.74070	8.15E6	30.090435	35.310417

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	12.60	<.0001

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Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2424 of 4425	Novo Nordisk
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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9PGINC Parameter=PPG increment all meals (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000386	0.008447	0.008833	1.05E7	0.045737	0.043737	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	1.755597	0.093986	1.571388	1.939807	1.05E7	1.677150	1.840931

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	18.68	<.0001

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9PGINCB Parameter=PPG increment breakfast (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000933	0.020230	0.021163	1.03E7	0.046136	0.044101	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	2.110084	0.145475	1.824958	2.395209	1.03E7	1.978534	2.236523

Parameter Estimates

Parameter	Theta0	t for H0: Parameter=Theta0	Pr > t
Estimate	0	14.50	<.0001

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9PGINCE Parameter=PPG increment main evening meal (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.001031	0.023356	0.024387	1.12E7	0.044164	0.042296	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	1.405084	0.156165	1.099006	1.711161	1.12E7	1.283795	1.538986

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	9.00	<.0001

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9PGINCL Parameter=PPG increment lunch (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.001024	0.019662	0.020687	8.15E6	0.052105	0.049525	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	1.812479	0.143829	1.530578	2.094379	8.15E6	1.669835	1.959513

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	12.60	<.0001

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9PGIU Parameter=PPG increment all meals (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.125447	2.742919	2.868373	1.05E7	0.045737	0.043737	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	31.635865	1.693627	28.31642	34.95531	1.05E7	30.222243	33.173573

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	18.68	<.0001

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9PGIBU Parameter=PPG increment breakfast (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.451549	6.606725	7.058297	4.89E6	0.068350	0.063978	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	30.852779	2.656746	25.64565	36.05991	4.89E6	27.674881	33.620210

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	11.61	<.0001

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9PGIEU Parameter=PPG increment main evening meal (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.513762	7.541242	8.055029	4.92E6	0.068130	0.063785	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	19.403662	2.838138	13.84101	24.96631	4.92E6	16.756601	22.735764

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	6.84	<.0001

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9PGILU Parameter=PPG increment lunch (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.450622	6.331596	6.782240	4.53E6	0.071174	0.066445	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	30.420379	2.604273	25.31610	35.52466	4.53E6	27.921268	33.132514

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	11.68	<.0001

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9PGINC Parameter=PPG increment all meals (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000644	0.008328	0.008972	3.88E6	0.077369	0.071813	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	1.502027	0.094721	1.316378	1.687676	3.88E6	1.400022	1.605931

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	15.86	<.0001

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Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2433 of 4425	Novo Nordisk
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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9PGINCB Parameter=PPG increment breakfast (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.001391	0.020346	0.021737	4.89E6	0.068350	0.063978	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits	DF	Minimum	Maximum
Estimate	1.712141	0.147433	1.423177 2.001105	4.89E6	1.535787	1.865716

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	11.61	<.0001

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9PGINCE Parameter=PPG increment main evening meal (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.001582	0.023224	0.024806	4.92E6	0.068130	0.063785	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	1.076785	0.157499	0.768092	1.385478	4.92E6	0.929889	1.261696

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	6.84	<.0001

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9PGINCL Parameter=PPG increment lunch (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.001388	0.019499	0.020886	4.53E6	0.071174	0.066445	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	1.688145	0.144521	1.404889	1.971402	4.53E6	1.549460	1.838652

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	11.68	<.0001

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9PGIU Parameter=PPG increment all meals (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.209208	2.704178	2.913397	3.88E6	0.077369	0.071813	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	27.066523	1.706868	23.72112	30.41192	3.88E6	25.228400	28.938875

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	15.86	<.0001

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25: Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=P9PGIU Planned Treatment for Period 30 (N)=2

Obs	PARAM					Description	Value
1	PPG increment	all	meals	(SMPG)	(mg/dL)	Data Set	WORK.ENDPOINT_PARAM
2	PPG increment	all	meals	(SMPG)	(mg/dL)	Method	Monotone-data_MCMC
3	PPG increment	all	meals	(SMPG)	(mg/dL)	Multiple Imputation Chain	Multiple Chains
4	PPG increment	all	meals	(SMPG)	(mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
5	PPG increment	all	meals	(SMPG)	(mg/dL)	Start	Starting Value
6	PPG increment	all	meals	(SMPG)	(mg/dL)	Prior	Jeffreys
7	PPG increment	all	meals	(SMPG)	(mg/dL)	Number of Imputations	20000
8	PPG increment	all	meals	(SMPG)	(mg/dL)	Number of Burn-in Iterations	200
9	PPG increment	all	meals	(SMPG)	(mg/dL)	Seed for random number generator	1234

Parameter Code=P9PGIU Planned Treatment for Period 30 (N)=3

Obs	PARAM					Description	Value
10	PPG increment	all	meals	(SMPG)	(mg/dL)	Data Set	WORK.ENDPOINT_PARAM
11	PPG increment	all	meals	(SMPG)	(mg/dL)	Method	Monotone-data_MCMC
12	PPG increment	all	meals	(SMPG)	(mg/dL)	Multiple Imputation Chain	Multiple Chains
13	PPG increment	all	meals	(SMPG)	(mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
14	PPG increment	all	meals	(SMPG)	(mg/dL)	Start	Starting Value
15	PPG increment	all	meals	(SMPG)	(mg/dL)	Prior	Jeffreys
16	PPG increment	all	meals	(SMPG)	(mg/dL)	Number of Imputations	20000
17	PPG increment	all	meals	(SMPG)	(mg/dL)	Number of Burn-in Iterations	200
18	PPG increment	all	meals	(SMPG)	(mg/dL)	Seed for random number generator	280880820

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=P9PGIU Planned Treatment for Period 30 (N)=4

Obs	PARAM				Description	Value
19	PPG increment	all meals	(SMPG)	(mg/dL)	Data Set	WORK.ENDPOINT_PARAM
20	PPG increment	all meals	(SMPG)	(mg/dL)	Method	Monotone-data_MCMC
21	PPG increment	all meals	(SMPG)	(mg/dL)	Multiple Imputation Chain	Multiple Chains
22	PPG increment	all meals	(SMPG)	(mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
23	PPG increment	all meals	(SMPG)	(mg/dL)	Start	Starting Value
24	PPG increment	all meals	(SMPG)	(mg/dL)	Prior	Jeffreys
25	PPG increment	all meals	(SMPG)	(mg/dL)	Number of Imputations	20000
26	PPG increment	all meals	(SMPG)	(mg/dL)	Number of Burn-in Iterations	200
27	PPG increment	all meals	(SMPG)	(mg/dL)	Seed for random number generator	2098581780

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC

Missing data pattern

Parameter Code=P9PGIU Planned Treatment for Period 30 (N)=2

				P A R A M	G r o u p	B S E	v i s i t B A S E \bar{M} i s s	v i s i t 3 6 0 0 \bar{M} i s s	F r e q	P e r c e n t	B A S E	v i s i t 2 2 0 0	v i s i t 3 6 0 0	
O b j e c t s														
1	PPG increment	all meals	(SMPG)	(mg/dL)	1	X X X	282	87.31	32.577372	-15.964789	-13.648866			
2	PPG increment	all meals	(SMPG)	(mg/dL)	2	X X O	14	4.33	9.335000	14.020651	.			
3	PPG increment	all meals	(SMPG)	(mg/dL)	3	X . X	15	4.64	36.388089	.	-8.228874			
4	PPG increment	all meals	(SMPG)	(mg/dL)	4	X O O	12	3.72	-4.923065	.	.			

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC

Missing data pattern

Parameter Code=P9PGIU Planned Treatment for Period 30 (N)=3

O		b		s		P		A		R		M		G		r		o		u		p		B		A		S		E		v		i		s		i		t		t		v		i		s		i		t		t	
5		6		7		8		PPG		increment		all		meals		(SMPG)		(mg/dL)		1		X		X		X		289		89.47		32.452042		2.920148		1.109417																			
5	PPG	increment	all	meals	(SMPG)	(mg/dL)	1	X	X	X	289	89.47	32.452042	2.920148	1.109417																																								
6	PPG	increment	all	meals	(SMPG)	(mg/dL)	2	X	X	O	11	3.41	9.331495	19.370455	.																																								
7	PPG	increment	all	meals	(SMPG)	(mg/dL)	3	X	.	X	16	4.95	19.089750	.	4.728062																																								
8	PPG	increment	all	meals	(SMPG)	(mg/dL)	4	X	O	O	7	2.17	4.624270	.																																									

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC
Missing data pattern

Parameter Code=P9PGIU Planned Treatment for Period 30 (N)=4

										v		v	
										i		i	
										s		s	
										i		i	
										t		t	
										B		2	
										A		2	
										S		0	
										E		0	
O b s	P A R A M		G r o u p					F r e q	P e r c e n t	B A S E		v i s i t 2 0 0	v i s i t 3 6 0 0
					\bar{M}	\bar{M}	\bar{M}						
					i	i	i						
					s	s	s						
					s	s	s						
9	PPG increment	all meals	(SMPG)	(mg/dL)	1	X	X	X	285	86.89	27.159522	-0.386919	-0.418753
10	PPG increment	all meals	(SMPG)	(mg/dL)	2	X	X	O	13	3.96	36.377778	-4.353974	.
11	PPG increment	all meals	(SMPG)	(mg/dL)	3	X	.	X	15	4.57	26.589259	.	-7.537541
12	PPG increment	all meals	(SMPG)	(mg/dL)	4	X	O	O	15	4.57	15.628681	.	.

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PGIU Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG increment all meals (SMPG) (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG increment all meals (SMPG) (mg/dL)	Method	Monotone
3	1	PPG increment all meals (SMPG) (mg/dL)	Number of Imputations	1
4	1	PPG increment all meals (SMPG) (mg/dL)	Seed for random number generator	4321

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression Missing Data Pattern

Parameter Code=P9PGIU Planned Treatment for Period 30 (N)=2

	O b s	I m p u t a t i o n —	P A R A M	G r o u p	R E G I O N D S 1 1 E	B B O L A A D S 0 0 0 0 0	S i i t t 2 2 6 0 0 0 0 0	V v i i s s i i t t 2 3 2 6 0 0 0 0 0	F r e q	P e r c e n t	B A S E	v i s i t 2 2 0 0	v i s i t 3 6 0 0
1	1	PPG increment all meals (SMPG) (mg/dL)		1	X X X X X X				297	91.95	32.76	-16.21	-13.37
2	1	PPG increment all meals (SMPG) (mg/dL)		2	X X X X .				14	4.33	9.33	14.02	.
3	1	PPG increment all meals (SMPG) (mg/dL)		3	X X X . .				12	3.72	-4.92	.	.

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGIU Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG increment all meals (SMPG) (mg/dL)	Intercept	
2	1	PPG increment all meals (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG increment all meals (SMPG) (mg/dL)	REGION1	EUROPE
4	1	PPG increment all meals (SMPG) (mg/dL)	REGION1	JAPAN
5	1	PPG increment all meals (SMPG) (mg/dL)	BOLAD1	
6	1	PPG increment all meals (SMPG) (mg/dL)	BASE	

Obs	BOLAD1	ObsVal	_1
1		0.00356	0.036221
2		-0.06429	-0.034871
3		0.03683	-0.091791
4		0.06828	0.047908
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.05823	0.010359
6		-0.59093	-0.618464

Parameter Code=P9PGIU Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	PPG increment all meals (SMPG) (mg/dL)	Intercept			-0.03029	0.023583
8	1	PPG increment all meals (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)		-0.25508	-0.411835
9	1	PPG increment all meals (SMPG) (mg/dL)	REGION1	EUROPE		0.09274	0.117172

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression Regression Information

Parameter Code=P9PGIU Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

(continued)

	O	b	s	P	E	R	B	O	I		
	n	a	t	A	f	E	O	b			
	s	m	i	R	c	G	L	s			
	-			A	t	N	D	V			
				M		l	l	a	I		
								l			
10	1	PPG	increment	all	meals	(SMPG)	(mg/dL)	REGION1	JAPAN	-0.02073	0.164787
11	1	PPG	increment	all	meals	(SMPG)	(mg/dL)	BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.11880	0.152031
12	1	PPG	increment	all	meals	(SMPG)	(mg/dL)	BASE		-0.40071	-0.442350
13	1	PPG	increment	all	meals	(SMPG)	(mg/dL)	visit2200		0.31225	0.330974

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2446 of 4425	Novo Nordisk
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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PGIU Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG increment all meals (SMPG) (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG increment all meals (SMPG) (mg/dL)	Method	Monotone
3	1	PPG increment all meals (SMPG) (mg/dL)	Number of Imputations	1
4	1	PPG increment all meals (SMPG) (mg/dL)	Seed for random number generator	4322

nn1218/nn1218-4131/ctr_20180214_er
10FEB2018:18:44:27 - a_797pp_stat_diff.sas/a_9pp_ppginc_stat_on_fas_app.txt

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGIU Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG increment all meals (SMPG) (mg/dL)	Intercept	
2	1	PPG increment all meals (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG increment all meals (SMPG) (mg/dL)	REGION1	EUROPE
4	1	PPG increment all meals (SMPG) (mg/dL)	REGION1	JAPAN
5	1	PPG increment all meals (SMPG) (mg/dL)	BOLAD1	
6	1	PPG increment all meals (SMPG) (mg/dL)	BASE	

Obs	BOLAD1	ObsVal	_1
1		0.05083	0.151788
2		0.11769	0.249884
3		-0.17820	-0.173328
4		0.23168	0.135783
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.12761	-0.099101
6		-0.49709	-0.530696

Parameter Code=P9PGIU Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	PPG increment all meals (SMPG) (mg/dL)	Intercept			0.0000946	-0.008456
8	1	PPG increment all meals (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)		-0.25299	-0.300217
9	1	PPG increment all meals (SMPG) (mg/dL)	REGION1	EUROPE		-0.09706	-0.136461

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGIU Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

(continued)

Imputed							Observations	
Observed							Total	
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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PGIU Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG increment all meals (SMPG) (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG increment all meals (SMPG) (mg/dL)	Method	Monotone
3	1	PPG increment all meals (SMPG) (mg/dL)	Number of Imputations	1
4	1	PPG increment all meals (SMPG) (mg/dL)	Seed for random number generator	4323

nn1218/nn1218-4131/ctr_20180214_er
10FEB2018:18:44:27 - a_797pp_stat_diff.sas/a_9pp_ppginc_stat_on_fas_app.txt

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression Missing Data Pattern

Parameter Code=P9PGIU Planned Treatment for Period 30 (N)=4

O b s	I m p u t a t i o n —	P A R A M	G r o u p	R E G I O N 1	B E T W E E N 1	B E T W E E N 2	B E T W E E N 3	B E T W E E N 4	B E T W E E N 5	F r e q	P e r c e n t	B A S E	v i s i t 2 0 0	v i s i t 3 6 0 0	
1	1	PPG increment	all meals (SMPG)	(mg/dL)	1	X	X	X	X	X	300	91.46	27.131009	-0.145543	-0.774693
2	1	PPG increment	all meals (SMPG)	(mg/dL)	2	X	X	X	X	.	13	3.96	36.377778	-4.353974	.
3	1	PPG increment	all meals (SMPG)	(mg/dL)	3	X	X	X	.	.	15	4.57	15.628681	.	.

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGIU Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG increment all meals (SMPG) (mg/dL)	Intercept	
2	1	PPG increment all meals (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG increment all meals (SMPG) (mg/dL)	REGION1	EUROPE
4	1	PPG increment all meals (SMPG) (mg/dL)	REGION1	JAPAN
5	1	PPG increment all meals (SMPG) (mg/dL)	BOLAD1	
6	1	PPG increment all meals (SMPG) (mg/dL)	BASE	

Obs	BOLAD1	ObsVal	_1
1		-0.00265	-0.049597
2		-0.13033	-0.075776
3		0.00953	-0.108502
4		0.23227	0.273530
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.00412	-0.001827
6		-0.57428	-0.651008

Parameter Code=P9PGIU Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	PPG increment all meals (SMPG) (mg/dL)	Intercept			0.03552	0.082135
8	1	PPG increment all meals (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)		0.18098	0.205817
9	1	PPG increment all meals (SMPG) (mg/dL)	REGION1	EUROPE		-0.14721	-0.070966

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression Regression Information

Parameter Code=P9PGIU Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

(continued)

										Input	Obs				
										P	E	R	B	O	
										A	f	E	O	b	
										R	e	G	L	s	
										A	c	I	A	V	
										M	t	N	D	a	I
												1	1	1	
10	1	PPG	increment	all	meals	(SMPG)	(mg/dL)	REGION1	JAPAN					0.02156	-0.162745
11	1	PPG	increment	all	meals	(SMPG)	(mg/dL)	BOLAD1		BOLUS	INSULIN	ALGORITHM	(SLIDING SCALE)	-0.07198	-0.079422
12	1	PPG	increment	all	meals	(SMPG)	(mg/dL)	BASE						-0.33158	-0.423514
13	1	PPG	increment	all	meals	(SMPG)	(mg/dL)	visit2200						0.47642	0.378546

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=P9PGINC Planned Treatment for Period 30 (N)=2

Obs	PARAM					Description	Value
1	PPG increment	all meals	(SMPG)	(mmol/L)		Data Set	WORK.ENDPOINT_PARAM
2	PPG increment	all meals	(SMPG)	(mmol/L)		Method	Monotone-data_MCMC
3	PPG increment	all meals	(SMPG)	(mmol/L)		Multiple Imputation Chain	Multiple Chains
4	PPG increment	all meals	(SMPG)	(mmol/L)		Initial Estimates for MCMC	EM Posterior Mode
5	PPG increment	all meals	(SMPG)	(mmol/L)		Start	Starting Value
6	PPG increment	all meals	(SMPG)	(mmol/L)		Prior	Jeffreys
7	PPG increment	all meals	(SMPG)	(mmol/L)		Number of Imputations	20000
8	PPG increment	all meals	(SMPG)	(mmol/L)		Number of Burn-in Iterations	200
9	PPG increment	all meals	(SMPG)	(mmol/L)		Seed for random number generator	1234

Parameter Code=P9PGINC Planned Treatment for Period 30 (N)=3

Obs	PARAM					Description	Value
10	PPG increment	all meals	(SMPG)	(mmol/L)		Data Set	WORK.ENDPOINT_PARAM
11	PPG increment	all meals	(SMPG)	(mmol/L)		Method	Monotone-data_MCMC
12	PPG increment	all meals	(SMPG)	(mmol/L)		Multiple Imputation Chain	Multiple Chains
13	PPG increment	all meals	(SMPG)	(mmol/L)		Initial Estimates for MCMC	EM Posterior Mode
14	PPG increment	all meals	(SMPG)	(mmol/L)		Start	Starting Value
15	PPG increment	all meals	(SMPG)	(mmol/L)		Prior	Jeffreys
16	PPG increment	all meals	(SMPG)	(mmol/L)		Number of Imputations	20000
17	PPG increment	all meals	(SMPG)	(mmol/L)		Number of Burn-in Iterations	200
18	PPG increment	all meals	(SMPG)	(mmol/L)		Seed for random number generator	280880820

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=P9PGINC Planned Treatment for Period 30 (N)=4

Obs	PARAM				Description	Value
19	PPG increment	all meals	(SMPG)	(mmol/L)	Data Set	WORK.ENDPOINT_PARAM
20	PPG increment	all meals	(SMPG)	(mmol/L)	Method	Monotone-data_MCMC
21	PPG increment	all meals	(SMPG)	(mmol/L)	Multiple Imputation Chain	Multiple Chains
22	PPG increment	all meals	(SMPG)	(mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
23	PPG increment	all meals	(SMPG)	(mmol/L)	Start	Starting Value
24	PPG increment	all meals	(SMPG)	(mmol/L)	Prior	Jeffreys
25	PPG increment	all meals	(SMPG)	(mmol/L)	Number of Imputations	20000
26	PPG increment	all meals	(SMPG)	(mmol/L)	Number of Burn-in Iterations	200
27	PPG increment	all meals	(SMPG)	(mmol/L)	Seed for random number generator	2098581780

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC
Missing data pattern

Parameter Code=P9PPGINC Planned Treatment for Period 30 (N)=2

							v i s i t t						v i s i t t		
							B A S E						v i s i t t		
							M̄ i s s						2 6 0 0		
							P A R A M						P e r c e n t		
							G r o u p						B A S E		
							s s s						2 3 6 0 0		
							F r e q						2 3 6 0 0		
1	PPG	increment	all	meals	(SMPG)	(mmol/L)	1	X	X	X	282	87.31	1.807845	-0.885948	-0.757429
2	PPG	increment	all	meals	(SMPG)	(mmol/L)	2	X	X	O	14	4.33	0.518036	0.778061	.
3	PPG	increment	all	meals	(SMPG)	(mmol/L)	3	X	.	X	15	4.64	2.019317	.	-0.456652
4	PPG	increment	all	meals	(SMPG)	(mmol/L)	4	X	O	O	12	3.72	-0.273200	.	.

Fast-acting insulin aspart
NN1218-4131

Clinical Trial Report
Statistical document

Date:
Version:

14 February 2018
1.0

Status:
Page:

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Novo Nordisk

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC
Missing data pattern

Parameter Code=P9PPGINC Planned Treatment for Period 30 (N)=3

O b s														
	P	G												
	A	r	\bar{M}	\bar{M}	\bar{M}	F	P	B	v	v				
	R	o	i	i	i	r	e	A	i	i				
	A	u	s	s	s	e	n	S	s	s				
	M	p	s	s	s	q	t	E	t	t				
5	PPG increment	all meals	(SMPG)	(mmol/L)	1	X	X	X	289	89.47	1.800890	0.162050	0.061566	
6	PPG increment	all meals	(SMPG)	(mmol/L)	2	X	X	O	11	3.41	0.517841	1.074942	.	
7	PPG increment	all meals	(SMPG)	(mmol/L)	3	X	.	X	16	4.95	1.059365	.	0.262379	
8	PPG increment	all meals	(SMPG)	(mmol/L)	4	X	O	O	7	2.17	0.256619	.	.	

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC
Missing data pattern

Parameter Code=P9PPGINC Planned Treatment for Period 30 (N)=4

O b s						P A R A M	G r o u p	v i s i t			F r e q	P e r c e n t	B A S E	v i s i t		
								B A S E						v i s i t		
								2 2 0 0						3 6 0 0		
								0 0 0						0 0 0		
								M	M	M						
9	PPG	increment	all	meals	(SMPG)	(mmol/L)	1	X	X	X	285	86.89	1.507188	-0.021472	-0.023238	
10	PPG	increment	all	meals	(SMPG)	(mmol/L)	2	X	X	O	13	3.96	2.018745	-0.241619	.	
11	PPG	increment	all	meals	(SMPG)	(mmol/L)	3	X	.	X	15	4.57	1.475542	.	-0.418287	
12	PPG	increment	all	meals	(SMPG)	(mmol/L)	4	X	O	O	15	4.57	0.867296	.	.	

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PGINC Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG increment all meals (SMPG) (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG increment all meals (SMPG) (mmol/L)	Method	Monotone
3	1	PPG increment all meals (SMPG) (mmol/L)	Number of Imputations	1
4	1	PPG increment all meals (SMPG) (mmol/L)	Seed for random number generator	4321

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nn1218/nn1218-4131/ctr_20180214_er
10FEB2018:18:44:27 - a 797pp stat diff.sas/a 9pp ppginc stat on_fas app.txt
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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGINC Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG increment all meals (SMPG) (mmol/L)	Intercept	
2	1	PPG increment all meals (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG increment all meals (SMPG) (mmol/L)	REGION1	EUROPE
4	1	PPG increment all meals (SMPG) (mmol/L)	REGION1	JAPAN
5	1	PPG increment all meals (SMPG) (mmol/L)	BOLAD1	
6	1	PPG increment all meals (SMPG) (mmol/L)	BASE	

Obs	BOLAD1	ObsVal	_1
1		0.00356	0.036221
2		-0.06429	-0.034871
3		0.03683	-0.091791
4		0.06828	0.047908
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.05823	0.010359
6		-0.59093	-0.618464

Parameter Code=P9PGINC Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	PPG increment all meals (SMPG) (mmol/L)	Intercept			-0.03029	0.023583
8	1	PPG increment all meals (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)		-0.25508	-0.411835
9	1	PPG increment all meals (SMPG) (mmol/L)	REGION1	EUROPE		0.09274	0.117172

										Output					
										Obs					
										PAAM	Effect	Region	BOLD	Obs	Mean
10	1	PPG	increment	all	meals	(SMPG)	(mmol/L)	REGION1	JAPAN					-0.02073	0.164787
11	1	PPG	increment	all	meals	(SMPG)	(mmol/L)	BOLAD1		BOLUS	INSULIN	ALGORITHM (SLIDING SCALE)		0.11880	0.152031
12	1	PPG	increment	all	meals	(SMPG)	(mmol/L)	BASE						-0.40071	-0.442350
13	1	PPG	increment	all	meals	(SMPG)	(mmol/L)	visit2200						0.31225	0.330974

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PGINC Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG increment all meals (SMPG) (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG increment all meals (SMPG) (mmol/L)	Method	Monotone
3	1	PPG increment all meals (SMPG) (mmol/L)	Number of Imputations	1
4	1	PPG increment all meals (SMPG) (mmol/L)	Seed for random number generator	4322

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGINC Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG increment all meals (SMPG) (mmol/L)	Intercept	
2	1	PPG increment all meals (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG increment all meals (SMPG) (mmol/L)	REGION1	EUROPE
4	1	PPG increment all meals (SMPG) (mmol/L)	REGION1	JAPAN
5	1	PPG increment all meals (SMPG) (mmol/L)	BOLAD1	
6	1	PPG increment all meals (SMPG) (mmol/L)	BASE	

Obs	BOLAD1	ObsVal	_1
1		0.05083	0.151788
2		0.11769	0.249884
3		-0.17820	-0.173328
4		0.23168	0.135783
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.12761	-0.099101
6		-0.49709	-0.530696

Parameter Code=P9PGINC Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	PPG increment all meals (SMPG) (mmol/L)	Intercept			0.0000946	-0.008456
8	1	PPG increment all meals (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)		-0.25299	-0.300217
9	1	PPG increment all meals (SMPG) (mmol/L)	REGION1	EUROPE		-0.09706	-0.136461

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PPGINC Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

(continued)

Imputed									
Observations									
		P		E	R		B	O	
		A		f	E		O	b	
		R		f	I		L	s	
		A		e	O		A	V	
		M		c	N		D	a	
				t	1		1	1	\bar{I}
10	1	PPG increment	all meals (SMPG)	(mmol/L)	REGION1	JAPAN		0.40440	0.511739
11	1	PPG increment	all meals (SMPG)	(mmol/L)	BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.10115	-0.125359
12	1	PPG increment	all meals (SMPG)	(mmol/L)	BASE			-0.44234	-0.435350
13	1	PPG increment	all meals (SMPG)	(mmol/L)	visit2200			0.37009	0.314184

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PGINC Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG increment all meals (SMPG) (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG increment all meals (SMPG) (mmol/L)	Method	Monotone
3	1	PPG increment all meals (SMPG) (mmol/L)	Number of Imputations	1
4	1	PPG increment all meals (SMPG) (mmol/L)	Seed for random number generator	4323

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGINC Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG increment all meals (SMPG) (mmol/L)	Intercept	
2	1	PPG increment all meals (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG increment all meals (SMPG) (mmol/L)	REGION1	EUROPE
4	1	PPG increment all meals (SMPG) (mmol/L)	REGION1	JAPAN
5	1	PPG increment all meals (SMPG) (mmol/L)	BOLAD1	
6	1	PPG increment all meals (SMPG) (mmol/L)	BASE	

Obs	BOLAD1	ObsVal	_1
1		-0.00265	-0.049597
2		-0.13033	-0.075776
3		0.00953	-0.108502
4		0.23227	0.273530
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.00412	-0.001827
6		-0.57428	-0.651008

Parameter Code=P9PGINC Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	PPG increment all meals (SMPG) (mmol/L)	Intercept			0.03552	0.082135
8	1	PPG increment all meals (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)		0.18098	0.205817
9	1	PPG increment all meals (SMPG) (mmol/L)	REGION1	EUROPE		-0.14721	-0.070966

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PPGINC Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

(continued)

Imputed									
Observations									
		P		E	R		B	O	
		A		f	E		O	b	
		R		f	I		L	s	
		A		e	O		A	V	
		M		c	N		D	a	
				t	1		1	1	\bar{I}
10	1	PPG increment	all meals (SMPG)	(mmol/L)	REGION1	JAPAN		0.02156	-0.162745
11	1	PPG increment	all meals (SMPG)	(mmol/L)	BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.07198	-0.079422
12	1	PPG increment	all meals (SMPG)	(mmol/L)	BASE			-0.33158	-0.423514
13	1	PPG increment	all meals (SMPG)	(mmol/L)	visit2200			0.47642	0.378546

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=P9PGIBU Planned Treatment for Period 30 (N)=2

Obs	PARAM				Description	Value
1	PPG	increment	breakfast	(SMPG) (mg/dL)	Data Set	WORK.ENDPOINT_PARAM
2	PPG	increment	breakfast	(SMPG) (mg/dL)	Method	Monotone-data_MCMC
3	PPG	increment	breakfast	(SMPG) (mg/dL)	Multiple Imputation Chain	Multiple Chains
4	PPG	increment	breakfast	(SMPG) (mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
5	PPG	increment	breakfast	(SMPG) (mg/dL)	Start	Starting Value
6	PPG	increment	breakfast	(SMPG) (mg/dL)	Prior	Jeffreys
7	PPG	increment	breakfast	(SMPG) (mg/dL)	Number of Imputations	20000
8	PPG	increment	breakfast	(SMPG) (mg/dL)	Number of Burn-in Iterations	200
9	PPG	increment	breakfast	(SMPG) (mg/dL)	Seed for random number generator	1234

Parameter Code=P9PGIBU Planned Treatment for Period 30 (N)=3

Obs	PARAM				Description	Value
10	PPG	increment	breakfast	(SMPG) (mg/dL)	Data Set	WORK.ENDPOINT_PARAM
11	PPG	increment	breakfast	(SMPG) (mg/dL)	Method	Monotone-data_MCMC
12	PPG	increment	breakfast	(SMPG) (mg/dL)	Multiple Imputation Chain	Multiple Chains
13	PPG	increment	breakfast	(SMPG) (mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
14	PPG	increment	breakfast	(SMPG) (mg/dL)	Start	Starting Value
15	PPG	increment	breakfast	(SMPG) (mg/dL)	Prior	Jeffreys
16	PPG	increment	breakfast	(SMPG) (mg/dL)	Number of Imputations	20000
17	PPG	increment	breakfast	(SMPG) (mg/dL)	Number of Burn-in Iterations	200
18	PPG	increment	breakfast	(SMPG) (mg/dL)	Seed for random number generator	15348205

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=P9PGIBU Planned Treatment for Period 30 (N)=4

Obs	PARAM			Description	Value
19	PPG increment breakfast	(SMPG)	(mg/dL)	Data Set	WORK.ENDPOINT_PARAM
20	PPG increment breakfast	(SMPG)	(mg/dL)	Method	Monotone-data_MCMC
21	PPG increment breakfast	(SMPG)	(mg/dL)	Multiple Imputation Chain	Multiple Chains
22	PPG increment breakfast	(SMPG)	(mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
23	PPG increment breakfast	(SMPG)	(mg/dL)	Start	Starting Value
24	PPG increment breakfast	(SMPG)	(mg/dL)	Prior	Jeffreys
25	PPG increment breakfast	(SMPG)	(mg/dL)	Number of Imputations	20000
26	PPG increment breakfast	(SMPG)	(mg/dL)	Number of Burn-in Iterations	200
27	PPG increment breakfast	(SMPG)	(mg/dL)	Seed for random number generator	1716003805

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC

Missing data pattern

Parameter Code=P9PGIBU Planned Treatment for Period 30 (N)=2

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation -
statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC
Missing data pattern

Parameter Code=P9PGIBU Planned Treatment for Period 30 (N)=3

O b s	P A R A M	G r o u p	v i s i t t			F r e q	P e r c e n t	B A S E	v i s i t t	v i s i t t	
			B	2	3						
			A	2	6						
			S	0	0						
			\bar{M}	\bar{M}	\bar{M}				2	3	
			i	i	i				2	6	
			s	s	s				0	0	
5	PPG increment breakfast (SMPG)	(mg/dL)	1	X	X	X	298	90.03	38.745235	0.464874	1.014346
6	PPG increment breakfast (SMPG)	(mg/dL)	2	X	X	O	13	3.93	4.180205	1.680538	.
7	PPG increment breakfast (SMPG)	(mg/dL)	3	X	.	X	15	4.53	18.929511	.	4.539422
8	PPG increment breakfast (SMPG)	(mg/dL)	4	X	O	O	5	1.51	28.314267	.	.

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The MI Procedure with MCMC
Missing data pattern

Parameter Code=P9PGIBU Planned Treatment for Period 30 (N)=4

O b s	P A R A M	G r o u p	v i s i t t			F r e q	P e r c e n t	B A S E	v i s i t t	v i s i t t
			B	2	3					
			A	2	6					
			S	0	0					
			E	0	0					
			\bar{M}	\bar{M}	\bar{M}					
			i	i	i					
			s	s	s					
			s	s	s					
			1	X	X					
			2	X	X					
			3	X	.					
9	PPG increment breakfast (SMPG) (mg/dL)	1	X	X	X	291	88.45	38.827229	-4.305868	-6.940796
10	PPG increment breakfast (SMPG) (mg/dL)	2	X	X	O	11	3.34	37.218000	-21.836939	.
11	PPG increment breakfast (SMPG) (mg/dL)	3	X	.	X	12	3.65	10.059944	.	13.620278
12	PPG increment breakfast (SMPG) (mg/dL)	4	X	O	O	15	4.56	14.921600	.	.

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PGIBU Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG increment breakfast (SMPG) (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG increment breakfast (SMPG) (mg/dL)	Method	Monotone
3	1	PPG increment breakfast (SMPG) (mg/dL)	Number of Imputations	1
4	1	PPG increment breakfast (SMPG) (mg/dL)	Seed for random number generator	4321

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression Missing Data Pattern

Parameter Code=P9PGIBU Planned Treatment for Period 30 (N)=2

O b s	I m p u t a t i o n s	P A R A M	G r o u p	R E G I O N A L	E B O L D S	B E T W E E N	F r e q	P e r c e n t	B A S E	v i s i t 2 0 0	v i s i t 3 6 0 0																			
												M	M	M	M	M	M	M	M	M	M									
																						M	M	M	M	M	M	M	M	M
1	2	3	4	5	6	7	8	9	10	11	12																			
1	1	PPG	increment	breakfast	(SMPG)	(mg/dL)	1	X	X	X	X	X	303	92.94	42.036563	-19.660324	-20.918230													
2	1	PPG	increment	breakfast	(SMPG)	(mg/dL)	2	X	X	X	X	.	11	3.37	9.093697	14.312000	.													
3	1	PPG	increment	breakfast	(SMPG)	(mg/dL)	3	X	X	X	.	.	12	3.68	-15.769722	.	.													

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGIBU Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG increment breakfast (SMPG) (mg/dL)	Intercept	
2	1	PPG increment breakfast (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG increment breakfast (SMPG) (mg/dL)	REGION1	EUROPE
4	1	PPG increment breakfast (SMPG) (mg/dL)	REGION1	JAPAN
5	1	PPG increment breakfast (SMPG) (mg/dL)	BOLAD1	
6	1	PPG increment breakfast (SMPG) (mg/dL)	BASE	

Obs	BOLAD1	ObsVal	_1
1		0.02164	0.051168
2		0.00386	0.031076
3		0.03292	-0.083193
4		-0.02273	-0.042912
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.00270	-0.046234
6		-0.68397	-0.712967

Parameter Code=P9PGIBU Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	PPG increment breakfast (SMPG) (mg/dL)	Intercept			0.02061	0.071616
8	1	PPG increment breakfast (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)		-0.10581	-0.251494
9	1	PPG increment breakfast (SMPG) (mg/dL)	REGION1	EUROPE		-0.05306	-0.027125

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression Regression Information

Parameter Code=P9PGIBU Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

(continued)

	O b s _	P A R A M	E f f e c t	R E G I O N	B O L U S	O b s V a l	I
10	1	PPG increment breakfast (SMPG) (mg/dL)	REGION1	JAPAN		0.08040	0.248525
11	1	PPG increment breakfast (SMPG) (mg/dL)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.0007805	0.033747
12	1	PPG increment breakfast (SMPG) (mg/dL)	BASE			-0.48435	-0.503903
13	1	PPG increment breakfast (SMPG) (mg/dL)	visit2200			0.27794	0.302099

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The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PGIBU Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG increment breakfast (SMPG) (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG increment breakfast (SMPG) (mg/dL)	Method	Monotone
3	1	PPG increment breakfast (SMPG) (mg/dL)	Number of Imputations	1
4	1	PPG increment breakfast (SMPG) (mg/dL)	Seed for random number generator	4322

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression Missing Data Pattern

Parameter Code=P9PGIBU Planned Treatment for Period 30 (N)=3

O b s	I m p u t a t i o n s	P A R M	G r o u p	R E G I O N A L	B E H A V I O R	S O C I O E C O N O M I C	F r e q	P e r c e n t	B A S E	v i s i t 2 0 0	v i s i t 3 6 0 0		
1	1	PPG increment breakfast (SMPG) (mg/dL)	1	X	X	X	X	X	313	94.56	37.795600	1.044892	1.183279
2	1	PPG increment breakfast (SMPG) (mg/dL)	2	X	X	X	X	.	13	3.93	4.180205	1.680538	.
3	1	PPG increment breakfast (SMPG) (mg/dL)	3	X	X	X	.	.	5	1.51	28.314267	.	.

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGIBU Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG increment breakfast (SMPG) (mg/dL)	Intercept	
2	1	PPG increment breakfast (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG increment breakfast (SMPG) (mg/dL)	REGION1	EUROPE
4	1	PPG increment breakfast (SMPG) (mg/dL)	REGION1	JAPAN
5	1	PPG increment breakfast (SMPG) (mg/dL)	BOLAD1	
6	1	PPG increment breakfast (SMPG) (mg/dL)	BASE	

Obs	BOLAD1	ObsVal	_1
1		0.05546	0.147811
2		0.17088	0.293816
3		-0.14138	-0.139677
4		0.20234	0.116511
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.16115	-0.135375
6		-0.58818	-0.625250

Parameter Code=P9PGIBU Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	PPG increment breakfast (SMPG) (mg/dL)	Intercept			0.02758	-0.027290
8	1	PPG increment breakfast (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)		-0.03684	-0.122611
9	1	PPG increment breakfast (SMPG) (mg/dL)	REGION1	EUROPE		-0.01503	0.004836

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
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Parameter Code=P9PGIBU Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

(continued)

Imputed				Region		BOLUS		INSULIN		ALGORITHM		SLIDING SCALE		T	
O	b	n	s	P	E	R	B	O	L	A	D	1	1	1	1
10	1	PPG	increment	breakfast	(SMPG)	(mg/dL)	REGION1	JAPAN						0.20553	0.202578
11	1	PPG	increment	breakfast	(SMPG)	(mg/dL)	BOLAD1							-0.15673	-0.167396
12	1	PPG	increment	breakfast	(SMPG)	(mg/dL)	BASE							-0.51070	-0.450158
13	1	PPG	increment	breakfast	(SMPG)	(mg/dL)	visit2200							0.32969	0.348785

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PGIBU Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG increment breakfast (SMPG) (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG increment breakfast (SMPG) (mg/dL)	Method	Monotone
3	1	PPG increment breakfast (SMPG) (mg/dL)	Number of Imputations	1
4	1	PPG increment breakfast (SMPG) (mg/dL)	Seed for random number generator	4323

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression Missing Data Pattern

Parameter Code=P9PGIBU Planned Treatment for Period 30 (N)=4

O b s	I m p u t a t i o n —	P A R A M	G r o u p	R E G I O N A L D I S T R I B U T I O N					F r e q	P e r c e n t	B A S E	v i s i t 2 0 0	v i s i t 3 6 0 0
				M	M	M	M	M					
1	1	PPG increment breakfast (SMPG) (mg/dL)	1	X	X	X	X	X	303	92.10	37.687931	-4.597000	-6.126496
2	1	PPG increment breakfast (SMPG) (mg/dL)	2	X	X	X	X	.	11	3.34	37.218000	-21.836939	.
3	1	PPG increment breakfast (SMPG) (mg/dL)	3	X	X	X	.	.	15	4.56	14.921600	.	.

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGIBU Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG increment breakfast (SMPG) (mg/dL)	Intercept	
2	1	PPG increment breakfast (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG increment breakfast (SMPG) (mg/dL)	REGION1	EUROPE
4	1	PPG increment breakfast (SMPG) (mg/dL)	REGION1	JAPAN
5	1	PPG increment breakfast (SMPG) (mg/dL)	BOLAD1	
6	1	PPG increment breakfast (SMPG) (mg/dL)	BASE	

Obs	BOLAD1	ObsVal	_1
1		0.03679	-0.010013
2		0.06078	0.114559
3		-0.06184	-0.178627
4		0.21343	0.254603
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.07818	-0.083838
6		-0.56602	-0.644759

Parameter Code=P9PGIBU Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	PPG increment breakfast (SMPG) (mg/dL)	Intercept			0.01829	0.066800
8	1	PPG increment breakfast (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)		0.07125	0.097652
9	1	PPG increment breakfast (SMPG) (mg/dL)	REGION1	EUROPE		-0.07246	0.005524

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=P9PGINCB Planned Treatment for Period 30 (N)=2

Obs	PARAM				Description	Value
1	PPG	increment	breakfast	(SMPG) (mmol/L)	Data Set	WORK.ENDPOINT_PARAM
2	PPG	increment	breakfast	(SMPG) (mmol/L)	Method	Monotone-data_MCMC
3	PPG	increment	breakfast	(SMPG) (mmol/L)	Multiple Imputation Chain	Multiple Chains
4	PPG	increment	breakfast	(SMPG) (mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
5	PPG	increment	breakfast	(SMPG) (mmol/L)	Start	Starting Value
6	PPG	increment	breakfast	(SMPG) (mmol/L)	Prior	Jeffreys
7	PPG	increment	breakfast	(SMPG) (mmol/L)	Number of Imputations	20000
8	PPG	increment	breakfast	(SMPG) (mmol/L)	Number of Burn-in Iterations	200
9	PPG	increment	breakfast	(SMPG) (mmol/L)	Seed for random number generator	1234

Parameter Code=P9PGINCB Planned Treatment for Period 30 (N)=3

Obs	PARAM				Description	Value
10	PPG	increment	breakfast	(SMPG) (mmol/L)	Data Set	WORK.ENDPOINT_PARAM
11	PPG	increment	breakfast	(SMPG) (mmol/L)	Method	Monotone-data_MCMC
12	PPG	increment	breakfast	(SMPG) (mmol/L)	Multiple Imputation Chain	Multiple Chains
13	PPG	increment	breakfast	(SMPG) (mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
14	PPG	increment	breakfast	(SMPG) (mmol/L)	Start	Starting Value
15	PPG	increment	breakfast	(SMPG) (mmol/L)	Prior	Jeffreys
16	PPG	increment	breakfast	(SMPG) (mmol/L)	Number of Imputations	20000
17	PPG	increment	breakfast	(SMPG) (mmol/L)	Number of Burn-in Iterations	200
18	PPG	increment	breakfast	(SMPG) (mmol/L)	Seed for random number generator	15348205

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=P9PGINCB Planned Treatment for Period 30 (N)=4

Obs	PARAM				Description	Value
19	PPG increment breakfast	(SMPG)	(mmol/L)		Data Set	WORK.ENDPOINT_PARAM
20	PPG increment breakfast	(SMPG)	(mmol/L)		Method	Monotone-data_MCMC
21	PPG increment breakfast	(SMPG)	(mmol/L)		Multiple Imputation Chain	Multiple Chains
22	PPG increment breakfast	(SMPG)	(mmol/L)		Initial Estimates for MCMC	EM Posterior Mode
23	PPG increment breakfast	(SMPG)	(mmol/L)		Start	Starting Value
24	PPG increment breakfast	(SMPG)	(mmol/L)		Prior	Jeffreys
25	PPG increment breakfast	(SMPG)	(mmol/L)		Number of Imputations	20000
26	PPG increment breakfast	(SMPG)	(mmol/L)		Number of Burn-in Iterations	200
27	PPG increment breakfast	(SMPG)	(mmol/L)		Seed for random number generator	1716003805

Fast-acting insulin aspart
NN1218-4131

Clinical Trial Report
Statistical document

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Novo Nordisk

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation -
statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC
Missing data pattern

Parameter Code=P9PPGINCB Planned Treatment for Period 30 (N)=2

O b s						G r o u p	v i s i t t			F r e q	P e r c e n t	B A S E	v i s i t t		v i s i t t	
							B	A	S				E			
							2	2	0				0			
							0	0	0				0			
	P	A	R	A	M		\bar{M}	\bar{M}	\bar{M}							
							i	i	i							
							s	s	s							
1	PPG	increment	breakfast	(SMPG)	(mmol/L)	1	X	X	X	289	88.65	2.345405	-1.158103	-1.149584		
2	PPG	increment	breakfast	(SMPG)	(mmol/L)	2	X	X	O	11	3.37	0.504645	0.794229	.		
3	PPG	increment	breakfast	(SMPG)	(mmol/L)	3	X	.	X	14	4.29	2.071997	.	-1.393059		
4	PPG	increment	breakfast	(SMPG)	(mmol/L)	4	X	O	O	12	3.68	-0.875123	.	.		

Fast-acting insulin aspart
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Novo Nordisk

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC
Missing data pattern

Parameter Code=P9PPGINCB Planned Treatment for Period 30 (N)=3

Obs						Group	Visit			Frequency	Base	Visit																												
							B	A	S			E	v	v																										
															2	2	3	6	0	0																				
																					0	0	0	0	0															
																										0	0	0	0	0										
																															0	0	0	0	0					
																																				0	0	0	0	0
5	PPG	increment	breakfast	(SMPG)	(mmol/L)	1	X	X	X	298	90.03	2.150124	0.025798	0.056290																										
6	PPG	increment	breakfast	(SMPG)	(mmol/L)	2	X	X	O	13	3.93	0.231976	0.093260	.																										
7	PPG	increment	breakfast	(SMPG)	(mmol/L)	3	X	.	X	15	4.53	1.050472	.	0.251910																										
8	PPG	increment	breakfast	(SMPG)	(mmol/L)	4	X	O	O	5	1.51	1.571269	.	.																										

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC

Missing data pattern

Parameter Code=P9PGINCB Planned Treatment for Period 30 (N)=4

O b s	P A R A M	G r o u p	B A S E			P e r c e n t			F r e q	B A S E	v i s i t 2 2 0 0	v i s i t 3 6 0 0	v i s i t 2 3 0 0	v i s i t 3 6 0 0
			M i s s	M i s s	M i s s	M i s s	M i s s							
9	PPG increment breakfast (SMPG) (mmol/L)	1	X	X	X	291	88.45	2.154674	-0.238949	-0.385172				
10	PPG increment breakfast (SMPG) (mmol/L)	2	X	X	O	11	3.34	2.065372	-1.211817	.				
11	PPG increment breakfast (SMPG) (mmol/L)	3	X	.	X	12	3.65	0.558266	.	0.755842				
12	PPG increment breakfast (SMPG) (mmol/L)	4	X	O	O	15	4.56	0.828058	.	.				

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PGINCB Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG increment breakfast (SMPG) (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG increment breakfast (SMPG) (mmol/L)	Method	Monotone
3	1	PPG increment breakfast (SMPG) (mmol/L)	Number of Imputations	1
4	1	PPG increment breakfast (SMPG) (mmol/L)	Seed for random number generator	4321

nn1218/nn1218-4131/ctr_20180214_er
10FEB2018:18:44:27 - a_797pp_stat_diff.sas/a_9pp_ppginc_stat_on_fas_app.txt

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=P9PGINCB Planned Treatment for Period 30 (N)=2

O b s	I m p u t a t i o n s	P A R A M	G r o u p	R E G I O N O A A N D S 1 1 E 0 0	F r e q	P e r c e n t	B A S E	v i s i t 2 0 0	v i s i t 3 6 0 0	
1	1	PPG increment breakfast (SMPG)	(mmol/L)	1	X X X X X	303	92.94	2.332773	-1.091028	-1.160834
2	1	PPG increment breakfast (SMPG)	(mmol/L)	2	X X X X .	11	3.37	0.504645	0.794229	.
3	1	PPG increment breakfast (SMPG)	(mmol/L)	3	X X X . .	12	3.68	-0.875123	.	.

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGINCB Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG increment breakfast (SMPG) (mmol/L)	Intercept	
2	1	PPG increment breakfast (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG increment breakfast (SMPG) (mmol/L)	REGION1	EUROPE
4	1	PPG increment breakfast (SMPG) (mmol/L)	REGION1	JAPAN
5	1	PPG increment breakfast (SMPG) (mmol/L)	BOLAD1	
6	1	PPG increment breakfast (SMPG) (mmol/L)	BASE	

Obs	BOLAD1	ObsVal	_1
1		0.02164	0.051168
2		0.00386	0.031076
3		0.03292	-0.083193
4		-0.02273	-0.042912
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.00270	-0.046234
6		-0.68397	-0.712967

Parameter Code=P9PGINCB Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	PPG increment breakfast (SMPG) (mmol/L)	Intercept			0.02061	0.071616
8	1	PPG increment breakfast (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)		-0.10581	-0.251494
9	1	PPG increment breakfast (SMPG) (mmol/L)	REGION1	EUROPE		-0.05306	-0.027125

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGINCB Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

(continued)

Imputed				Region		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		Observations	
Treatment				Effect	Estimate	Base	Delta	Count	Mean
Observation				Parameter	Estimate	Base	Delta	Count	Mean
S				M	1	1	1	1	1
10	1	PPG increment breakfast (SMPG)	(mmol/L)	REGION1	JAPAN			0.08040	0.248525
11	1	PPG increment breakfast (SMPG)	(mmol/L)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.0007805	0.033747
12	1	PPG increment breakfast (SMPG)	(mmol/L)	BASE				-0.48435	-0.503903
13	1	PPG increment breakfast (SMPG)	(mmol/L)	visit2200				0.27794	0.302099

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PGINCB Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG increment breakfast (SMPG) (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG increment breakfast (SMPG) (mmol/L)	Method	Monotone
3	1	PPG increment breakfast (SMPG) (mmol/L)	Number of Imputations	1
4	1	PPG increment breakfast (SMPG) (mmol/L)	Seed for random number generator	4322

nn1218/nn1218-4131/ctr_20180214_er
10FEB2018:18:44:27 - a_797pp_stat_diff.sas/a_9pp_ppginc_stat_on_fas_app.txt

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nn1218/nn1218-4131/ctr_20180214_er
10FEB2018:18:44:27 - a 797pp stat diff.sas/a 9pp ppginc stat on_fas app.txt
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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGINCB Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG increment breakfast (SMPG) (mmol/L)	Intercept	
2	1	PPG increment breakfast (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG increment breakfast (SMPG) (mmol/L)	REGION1	EUROPE
4	1	PPG increment breakfast (SMPG) (mmol/L)	REGION1	JAPAN
5	1	PPG increment breakfast (SMPG) (mmol/L)	BOLAD1	
6	1	PPG increment breakfast (SMPG) (mmol/L)	BASE	

Obs	BOLAD1	ObsVal	_1
1		0.05546	0.147811
2		0.17088	0.293816
3		-0.14138	-0.139677
4		0.20234	0.116511
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.16115	-0.135375
6		-0.58818	-0.625250

Parameter Code=P9PGINCB Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	PPG increment breakfast (SMPG) (mmol/L)	Intercept			0.02758	-0.027290
8	1	PPG increment breakfast (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)		-0.03684	-0.122611
9	1	PPG increment breakfast (SMPG) (mmol/L)	REGION1	EUROPE		-0.01503	0.004836

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGINCB Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

(continued)

Imputed				Region		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		Observations	
Treatment				Effect	Estimate	Baseline	Offset	Standard Error	95% Confidence Interval
Observation				Parameter	Estimate	Baseline	Offset	Standard Error	95% Confidence Interval
Sum of Squares				Model	Estimate	Baseline	Offset	Standard Error	95% Confidence Interval
10	1	PPG increment breakfast (SMPG)	(mmol/L)	REGION1	JAPAN			0.20553	0.202578
11	1	PPG increment breakfast (SMPG)	(mmol/L)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.15673	-0.167396
12	1	PPG increment breakfast (SMPG)	(mmol/L)	BASE				-0.51070	-0.450158
13	1	PPG increment breakfast (SMPG)	(mmol/L)	visit2200				0.32969	0.348785

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PGINCB Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG increment breakfast (SMPG) (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG increment breakfast (SMPG) (mmol/L)	Method	Monotone
3	1	PPG increment breakfast (SMPG) (mmol/L)	Number of Imputations	1
4	1	PPG increment breakfast (SMPG) (mmol/L)	Seed for random number generator	4323

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nn1218/nn1218-4131/ctr_20180214_er
10FEB2018:18:44:27 - a 797pp stat diff.sas/a 9pp ppginc stat on_fas app.txt
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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGINCB Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG increment breakfast (SMPG) (mmol/L)	Intercept	
2	1	PPG increment breakfast (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG increment breakfast (SMPG) (mmol/L)	REGION1	EUROPE
4	1	PPG increment breakfast (SMPG) (mmol/L)	REGION1	JAPAN
5	1	PPG increment breakfast (SMPG) (mmol/L)	BOLAD1	
6	1	PPG increment breakfast (SMPG) (mmol/L)	BASE	

Obs	BOLAD1	ObsVal	_1
1		0.03679	-0.010013
2		0.06078	0.114559
3		-0.06184	-0.178627
4		0.21343	0.254603
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.07818	-0.083838
6		-0.56602	-0.644759

Parameter Code=P9PGINCB Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	PPG increment breakfast (SMPG) (mmol/L)	Intercept			0.01829	0.066800
8	1	PPG increment breakfast (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)		0.07125	0.097652
9	1	PPG increment breakfast (SMPG) (mmol/L)	REGION1	EUROPE		-0.07246	0.005524

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGINCB Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

(continued)

Imputed				Region		BOLUS		INSULIN		ALGORITHM		(SLIDING SCALE)		Statistics	
Obs	P	A	M	E	R	B	O	A	D	1	1	1	1	T	T
10	1	PPG	increment	breakfast	(SMPG)	(mmol/L)	REGION1	JAPAN						0.12455	-0.064166
11	1	PPG	increment	breakfast	(SMPG)	(mmol/L)	BOLAD1		BOLUS	INSULIN	ALGORITHM	(SLIDING	SCALE)	-0.00162	-0.010791
12	1	PPG	increment	breakfast	(SMPG)	(mmol/L)	BASE							-0.47027	-0.577253
13	1	PPG	increment	breakfast	(SMPG)	(mmol/L)	visit2200							0.30831	0.202955

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=P9PGILU Planned Treatment for Period 30 (N)=2

Obs	PARAM				Description	Value
1	PPG increment	lunch	(SMPG)	(mg/dL)	Data Set	WORK.ENDPOINT_PARAM
2	PPG increment	lunch	(SMPG)	(mg/dL)	Method	Monotone-data_MCMC
3	PPG increment	lunch	(SMPG)	(mg/dL)	Multiple Imputation Chain	Multiple Chains
4	PPG increment	lunch	(SMPG)	(mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
5	PPG increment	lunch	(SMPG)	(mg/dL)	Start	Starting Value
6	PPG increment	lunch	(SMPG)	(mg/dL)	Prior	Jeffreys
7	PPG increment	lunch	(SMPG)	(mg/dL)	Number of Imputations	20000
8	PPG increment	lunch	(SMPG)	(mg/dL)	Number of Burn-in Iterations	200
9	PPG increment	lunch	(SMPG)	(mg/dL)	Seed for random number generator	1234

Parameter Code=P9PGILU Planned Treatment for Period 30 (N)=3

Obs	PARAM				Description	Value
10	PPG increment	lunch	(SMPG)	(mg/dL)	Data Set	WORK.ENDPOINT_PARAM
11	PPG increment	lunch	(SMPG)	(mg/dL)	Method	Monotone-data_MCMC
12	PPG increment	lunch	(SMPG)	(mg/dL)	Multiple Imputation Chain	Multiple Chains
13	PPG increment	lunch	(SMPG)	(mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
14	PPG increment	lunch	(SMPG)	(mg/dL)	Start	Starting Value
15	PPG increment	lunch	(SMPG)	(mg/dL)	Prior	Jeffreys
16	PPG increment	lunch	(SMPG)	(mg/dL)	Number of Imputations	20000
17	PPG increment	lunch	(SMPG)	(mg/dL)	Number of Burn-in Iterations	200
18	PPG increment	lunch	(SMPG)	(mg/dL)	Seed for random number generator	1688005726

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=P9PGILU Planned Treatment for Period 30 (N)=4

Obs	PARAM			Description	Value
19	PPG increment	lunch	(SMPG) (mg/dL)	Data Set	WORK.ENDPOINT_PARAM
20	PPG increment	lunch	(SMPG) (mg/dL)	Method	Monotone-data_MCMC
21	PPG increment	lunch	(SMPG) (mg/dL)	Multiple Imputation Chain	Multiple Chains
22	PPG increment	lunch	(SMPG) (mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
23	PPG increment	lunch	(SMPG) (mg/dL)	Start	Starting Value
24	PPG increment	lunch	(SMPG) (mg/dL)	Prior	Jeffreys
25	PPG increment	lunch	(SMPG) (mg/dL)	Number of Imputations	20000
26	PPG increment	lunch	(SMPG) (mg/dL)	Number of Burn-in Iterations	200
27	PPG increment	lunch	(SMPG) (mg/dL)	Seed for random number generator	1245877461

Parameter Code=P9PGILU Planned Treatment for Period 30 (N)=2

O b s						v i s i t 2 3 6 0 0						v i s i t 2 3 6 0 0		v i s i t 2 3 6 0 0				
						B A S E						P e r c e n t		B A S E		v i s i t 2 3 6 0 0		
						G r o u p												
						M̄ i s s						F r e q						
		P A R A M																
1	PPG increment	lunch (SMPG)	(mg/dL)		1	X	X	X	288	88.07	35.049113	-11.737397	-12.037829					
2	PPG increment	lunch (SMPG)	(mg/dL)		2	X	X	O	13	3.98	45.726667	-17.801795	.					
3	PPG increment	lunch (SMPG)	(mg/dL)		3	X	.	X	15	4.59	32.477244	.	-0.886533					
4	PPG increment	lunch (SMPG)	(mg/dL)		4	X	O	O	11	3.36	-3.387606	.						

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nn1218/nn1218-4131/ctr_20180214_er
10FEB2018:18:44:27 - a 797pp stat diff.sas/a 9pp ppginc stat on_fas app.txt
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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC

Missing data pattern

Parameter Code=P9PGILU Planned Treatment for Period 30 (N)=4

O b s	P A R A M					G r o u p	v i s i t 2 3 6 0 0			F r e q	P e r c e n t	B A S E		v i s i t 2 2 0 0	v i s i t 3 6 0 0
							\bar{M}	\bar{M}	\bar{M}						
9	PPG	increment	lunch	(SMPG)	(mg/dL)	1	X	X	X	292	88.75	31.205439	-2.082377	0.122959	
10	PPG	increment	lunch	(SMPG)	(mg/dL)	2	X	X	O	12	3.65	22.342833	-3.657167	.	
11	PPG	increment	lunch	(SMPG)	(mg/dL)	3	X	.	X	12	3.65	23.394972	.	-23.958639	
12	PPG	increment	lunch	(SMPG)	(mg/dL)	4	X	O	O	13	3.95	24.246000	.		

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PGILU Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG increment lunch (SMPG) (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG increment lunch (SMPG) (mg/dL)	Method	Monotone
3	1	PPG increment lunch (SMPG) (mg/dL)	Number of Imputations	1
4	1	PPG increment lunch (SMPG) (mg/dL)	Seed for random number generator	4321

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression Missing Data Pattern

Parameter Code=P9PGILU Planned Treatment for Period 30 (N)=2

O b s	I m p u t a t i o n —	P A R A M	G r o u p	R E G I O N A L E S					F r e q	P e r c e n t	B A S E	v i s i t 2 0 0	v i s i t 3 6 0 0			
				M	M	M	M	M								
1	1	PPG increment	lunch	(SMPG)	(mg/dL)	1	X	X	X	X	X	303	92.66	34.921793	-12.099292	-11.485784
2	1	PPG increment	lunch	(SMPG)	(mg/dL)	2	X	X	X	X	.	13	3.98	45.726667	-17.801795	.
3	1	PPG increment	lunch	(SMPG)	(mg/dL)	3	X	X	X	.	.	11	3.36	-3.387606	.	.

Fast-acting insulin aspart
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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGILU Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG increment lunch (SMPG) (mg/dL)	Intercept	
2	1	PPG increment lunch (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG increment lunch (SMPG) (mg/dL)	REGION1	EUROPE
4	1	PPG increment lunch (SMPG) (mg/dL)	REGION1	JAPAN
5	1	PPG increment lunch (SMPG) (mg/dL)	BOLAD1	
6	1	PPG increment lunch (SMPG) (mg/dL)	BASE	

Obs	BOLAD1	ObsVal	_1
1		0.03587	0.069022
2		-0.11143	-0.080932
3		-0.05048	-0.180181
4		0.34759	0.326501
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.06388	-0.110558
6		-0.59002	-0.608363

Parameter Code=P9PGILU Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	PPG increment lunch (SMPG) (mg/dL)	Intercept			-0.03858	-0.069603
8	1	PPG increment lunch (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)		-0.16737	-0.093347
9	1	PPG increment lunch (SMPG) (mg/dL)	REGION1	EUROPE		0.02725	-0.114208

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGILU Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

(continued)

Imputed									
Observed		P	Eff		R	B		O	
		A	f		E	O		b	
		R	e		I	L		s	
		A	c		O	A		V	
s _		M	t		N	D		a	
					1	1		l	\bar{I}
10	1	PPG increment lunch (SMPG) (mg/dL)	REGION1	JAPAN				0.04074	0.072532
11	1	PPG increment lunch (SMPG) (mg/dL)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)			0.11639	0.181360
12	1	PPG increment lunch (SMPG) (mg/dL)	BASE					-0.45502	-0.399042
13	1	PPG increment lunch (SMPG) (mg/dL)	visit2200					0.25929	0.275010

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PGILU Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG increment lunch (SMPG) (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG increment lunch (SMPG) (mg/dL)	Method	Monotone
3	1	PPG increment lunch (SMPG) (mg/dL)	Number of Imputations	1
4	1	PPG increment lunch (SMPG) (mg/dL)	Seed for random number generator	4322

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression Missing Data Pattern

Parameter Code=P9PGILU Planned Treatment for Period 30 (N)=3

O b s	I m p u t a t i o n —	P A R A M	G r o u p	R E G I O N A L E S					F r e q	P e r c e n t	B A S E	v i s i t 2 0 0	v i s i t 3 6 0 0			
				M	M	M	M	M								
1	1	PPG increment	lunch	(SMPG)	(mg/dL)	1	X	X	X	X	X	308	94.48	36.317972	0.061026	-2.200157
2	1	PPG increment	lunch	(SMPG)	(mg/dL)	2	X	X	X	X	.	12	3.68	1.961000	22.065417	.
3	1	PPG increment	lunch	(SMPG)	(mg/dL)	3	X	X	X	.	.	6	1.84	20.100444	.	.

Fast-acting insulin aspart
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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGILU Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG increment lunch (SMPG) (mg/dL)	Intercept	
2	1	PPG increment lunch (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG increment lunch (SMPG) (mg/dL)	REGION1	EUROPE
4	1	PPG increment lunch (SMPG) (mg/dL)	REGION1	JAPAN
5	1	PPG increment lunch (SMPG) (mg/dL)	BOLAD1	
6	1	PPG increment lunch (SMPG) (mg/dL)	BASE	

Obs	BOLAD1	ObsVal	_1
1		0.03681	0.129986
2		0.11619	0.239815
3		-0.14867	-0.145145
4		0.17087	0.081979
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.06085	-0.034286
6		-0.60491	-0.636180

Parameter Code=P9PGILU Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	PPG increment lunch (SMPG) (mg/dL)	Intercept			0.01095	-0.008815
8	1	PPG increment lunch (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)		-0.13610	-0.174176
9	1	PPG increment lunch (SMPG) (mg/dL)	REGION1	EUROPE		-0.16460	-0.182062

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression Regression Information

Parameter Code=P9PGILU Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

(continued)

							Input				Obs		
							Effect	Region				Bolus	Obs
							Parameter	Unit				Value	Interval
Study	Visit	Time	Event	Meal	Medication	Concentration	Region				Bolus	Obs	
10	1	PPG	increment	lunch	(SMPG)	(mg/dL)	REGION1	JAPAN				0.28822	0.250615
11	1	PPG	increment	lunch	(SMPG)	(mg/dL)	BOLAD1		BOLUS	INSULIN	ALGORITHM (SLIDING SCALE)	-0.02376	0.052286
12	1	PPG	increment	lunch	(SMPG)	(mg/dL)	BASE				-0.50528	-0.519739	
13	1	PPG	increment	lunch	(SMPG)	(mg/dL)	visit2200				0.21979	0.244213	

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PGILU Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG increment lunch (SMPG) (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG increment lunch (SMPG) (mg/dL)	Method	Monotone
3	1	PPG increment lunch (SMPG) (mg/dL)	Number of Imputations	1
4	1	PPG increment lunch (SMPG) (mg/dL)	Seed for random number generator	4323

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression Missing Data Pattern

Parameter Code=P9PGILU Planned Treatment for Period 30 (N)=4

O b s	I m p u t a t i o n —	P A R A M	G r o u p	R E G I O N A L E S					F r e q	P e r c e n t	B A S E	v i s i t 2 0 0	v i s i t 3 6 0 0			
				M	M	M	M	M								
1	1	PPG increment	lunch	(SMPG)	(mg/dL)	1	X	X	X	X	X	304	92.40	30.897132	-1.221349	-0.827630
2	1	PPG increment	lunch	(SMPG)	(mg/dL)	2	X	X	X	X	.	12	3.65	22.342833	-3.657167	.
3	1	PPG increment	lunch	(SMPG)	(mg/dL)	3	X	X	X	.	.	13	3.95	24.246000	.	.

Fast-acting insulin aspart
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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGILU Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG increment lunch (SMPG) (mg/dL)	Intercept	
2	1	PPG increment lunch (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG increment lunch (SMPG) (mg/dL)	REGION1	EUROPE
4	1	PPG increment lunch (SMPG) (mg/dL)	REGION1	JAPAN
5	1	PPG increment lunch (SMPG) (mg/dL)	BOLAD1	
6	1	PPG increment lunch (SMPG) (mg/dL)	BASE	

Obs	BOLAD1	ObsVal	_1
1		-0.00982	-0.052888
2		-0.08722	-0.036886
3		-0.04020	-0.147627
4		0.10440	0.141587
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.04960	0.045010
6		-0.64988	-0.719479

Parameter Code=P9PGILU Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	PPG increment lunch (SMPG) (mg/dL)	Intercept			0.04686	0.011135
8	1	PPG increment lunch (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)		0.17357	0.189406
9	1	PPG increment lunch (SMPG) (mg/dL)	REGION1	EUROPE		-0.20525	-0.141228

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression Regression Information

Parameter Code=P9PGILU Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

(continued)

							Input	Observations	Effect	Region	Bolus	Observed		
10	1	PPG	increment	lunch	(SMPG)	(mg/dL)	REGION1	JAPAN					0.13511	0.091169
11	1	PPG	increment	lunch	(SMPG)	(mg/dL)	BOLAD1		BOLUS	INSULIN	ALGORITHM (SLIDING SCALE)		-0.08029	-0.024113
12	1	PPG	increment	lunch	(SMPG)	(mg/dL)	BASE						-0.45685	-0.570064
13	1	PPG	increment	lunch	(SMPG)	(mg/dL)	visit2200						0.30578	0.205281

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=P9PGINCL Planned Treatment for Period 30 (N)=2

Obs	PARAM				Description	Value
1	PPG increment	lunch	(SMPG)	(mmol/L)	Data Set	WORK.ENDPOINT_PARAM
2	PPG increment	lunch	(SMPG)	(mmol/L)	Method	Monotone-data_MCMC
3	PPG increment	lunch	(SMPG)	(mmol/L)	Multiple Imputation Chain	Multiple Chains
4	PPG increment	lunch	(SMPG)	(mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
5	PPG increment	lunch	(SMPG)	(mmol/L)	Start	Starting Value
6	PPG increment	lunch	(SMPG)	(mmol/L)	Prior	Jeffreys
7	PPG increment	lunch	(SMPG)	(mmol/L)	Number of Imputations	20000
8	PPG increment	lunch	(SMPG)	(mmol/L)	Number of Burn-in Iterations	200
9	PPG increment	lunch	(SMPG)	(mmol/L)	Seed for random number generator	1234

Parameter Code=P9PGINCL Planned Treatment for Period 30 (N)=3

Obs	PARAM				Description	Value
10	PPG increment	lunch	(SMPG)	(mmol/L)	Data Set	WORK.ENDPOINT_PARAM
11	PPG increment	lunch	(SMPG)	(mmol/L)	Method	Monotone-data_MCMC
12	PPG increment	lunch	(SMPG)	(mmol/L)	Multiple Imputation Chain	Multiple Chains
13	PPG increment	lunch	(SMPG)	(mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
14	PPG increment	lunch	(SMPG)	(mmol/L)	Start	Starting Value
15	PPG increment	lunch	(SMPG)	(mmol/L)	Prior	Jeffreys
16	PPG increment	lunch	(SMPG)	(mmol/L)	Number of Imputations	20000
17	PPG increment	lunch	(SMPG)	(mmol/L)	Number of Burn-in Iterations	200
18	PPG increment	lunch	(SMPG)	(mmol/L)	Seed for random number generator	1688005726

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=P9PPGINCL Planned Treatment for Period 30 (N)=4

Obs	PARAM				Description	Value
19	PPG increment	lunch	(SMPG)	(mmol/L)	Data Set	WORK.ENDPOINT_PARAM
20	PPG increment	lunch	(SMPG)	(mmol/L)	Method	Monotone-data_MCMC
21	PPG increment	lunch	(SMPG)	(mmol/L)	Multiple Imputation Chain	Multiple Chains
22	PPG increment	lunch	(SMPG)	(mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
23	PPG increment	lunch	(SMPG)	(mmol/L)	Start	Starting Value
24	PPG increment	lunch	(SMPG)	(mmol/L)	Prior	Jeffreys
25	PPG increment	lunch	(SMPG)	(mmol/L)	Number of Imputations	20000
26	PPG increment	lunch	(SMPG)	(mmol/L)	Number of Burn-in Iterations	200
27	PPG increment	lunch	(SMPG)	(mmol/L)	Seed for random number generator	1245877461

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC

Missing data pattern

Parameter Code=P9PGINCL Planned Treatment for Period 30 (N)=2

O b s						v i s i t t						v i s i t t												
						B A S E						v i s i t t												
						M i s s						2 2 0 0												
						G r o u p						P e r c e n t												
P A R A M										B A S E					v i s i t t									
										F r e q					B A S E					2 2 0 0				
																				3 6 0 0				
1	PPG	increment	lunch	(SMPG)	(mmol/L)	1	X	X	X	288	88.07	1.945012	-0.651354	-0.668026										
2	PPG	increment	lunch	(SMPG)	(mmol/L)	2	X	X	O	13	3.98	2.537551	-0.987891	.										
3	PPG	increment	lunch	(SMPG)	(mmol/L)	3	X	.	X	15	4.59	1.802289	.	-0.049197										
4	PPG	increment	lunch	(SMPG)	(mmol/L)	4	X	O	O	11	3.36	-0.187991	.	.										

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC

Missing data pattern

Parameter Code=P9PGINCL Planned Treatment for Period 30 (N)=3

Obs	P A R A M					G r o u p	B A S E M M S S			F r e q	P e r c e n t	B A S E	v i s i t 2 2 0 0	v i s i t 3 6 0 0
	1	2	3	4	5		M	M	M					
5	PPG	increment	lunch	(SMPG)	(mmol/L)	1	X	X	X	295	90.49	2.041126	0.004224	-0.122158
6	PPG	increment	lunch	(SMPG)	(mmol/L)	2	X	X	O	12	3.68	0.108824	1.224496	.
7	PPG	increment	lunch	(SMPG)	(mmol/L)	3	X	.	X	13	3.99	1.432235	.	-0.120676
8	PPG	increment	lunch	(SMPG)	(mmol/L)	4	X	O	O	6	1.84	1.115452	.	.

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC

Missing data pattern

Parameter Code=P9PGINCL Planned Treatment for Period 30 (N)=4

Obs	P A R A M	G r o u p	B A S E	M i s s	M i s s	M i s s	F r e q	P e r c e n t	B A S E	v i s i t 2 2 0 0	v i s i t 3 6 0 0	
9	PPG increment	lunch (SMPG)	(mmol/L)	1	X	X	X	292	88.75	1.731711	-0.115559	0.006823
10	PPG increment	lunch (SMPG)	(mmol/L)	2	X	X	O	12	3.65	1.239891	-0.202950	.
11	PPG increment	lunch (SMPG)	(mmol/L)	3	X	.	X	12	3.65	1.298278	.	-1.329558
12	PPG increment	lunch (SMPG)	(mmol/L)	4	X	O	O	13	3.95	1.345505	.	.

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PPGINCL Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG increment lunch (SMPG) (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG increment lunch (SMPG) (mmol/L)	Method	Monotone
3	1	PPG increment lunch (SMPG) (mmol/L)	Number of Imputations	1
4	1	PPG increment lunch (SMPG) (mmol/L)	Seed for random number generator	4321


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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGINCL Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG increment lunch (SMPG) (mmol/L)	Intercept	
2	1	PPG increment lunch (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG increment lunch (SMPG) (mmol/L)	REGION1	EUROPE
4	1	PPG increment lunch (SMPG) (mmol/L)	REGION1	JAPAN
5	1	PPG increment lunch (SMPG) (mmol/L)	BOLAD1	
6	1	PPG increment lunch (SMPG) (mmol/L)	BASE	

Obs	BOLAD1	ObsVal	_1
1		0.03587	0.069022
2		-0.11143	-0.080932
3		-0.05048	-0.180181
4		0.34759	0.326501
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.06388	-0.110558
6		-0.59002	-0.608363

Parameter Code=P9PGINCL Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	PPG increment lunch (SMPG) (mmol/L)	Intercept			-0.03858	-0.069603
8	1	PPG increment lunch (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)		-0.16737	-0.093347
9	1	PPG increment lunch (SMPG) (mmol/L)	REGION1	EUROPE		0.02725	-0.114208

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression Regression Information

Parameter Code=P9PGINCL Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

(continued)

	O o b s _	P A R A M	E f f e c t	R E G I O N 1	B O L A D 1	O b s V a l	I
10	1	PPG increment lunch (SMPG) (mmol/L)	REGION1	JAPAN		0.04074	0.072532
11	1	PPG increment lunch (SMPG) (mmol/L)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.11639	0.181360
12	1	PPG increment lunch (SMPG) (mmol/L)	BASE			-0.45502	-0.399042
13	1	PPG increment lunch (SMPG) (mmol/L)	visit2200			0.25929	0.275010

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PPGINCL Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG increment lunch (SMPG) (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG increment lunch (SMPG) (mmol/L)	Method	Monotone
3	1	PPG increment lunch (SMPG) (mmol/L)	Number of Imputations	1
4	1	PPG increment lunch (SMPG) (mmol/L)	Seed for random number generator	4322

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=P9PPGINCL Planned Treatment for Period 30 (N)=3

I m p u t a t i o n s	P A R A M E T E R S	G r o u p	R E G I O N A L C O D E	S T A T I S T I C I A N S	F R E Q U E N C Y	P e r c e n t	B A S E	v i s i t e s	v i s i t e s
1	1	PPG increment lunch (SMPG) (mmol/L)	1	X X X X X	308	94.48	2.015426	0.003387	-0.122095
2	1	PPG increment lunch (SMPG) (mmol/L)	2	X X X X .	12	3.68	0.108824	1.224496	.
3	1	PPG increment lunch (SMPG) (mmol/L)	3	X X X . .	6	1.84	1.115452	.	.

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGINCL Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG increment lunch (SMPG) (mmol/L)	Intercept	
2	1	PPG increment lunch (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG increment lunch (SMPG) (mmol/L)	REGION1	EUROPE
4	1	PPG increment lunch (SMPG) (mmol/L)	REGION1	JAPAN
5	1	PPG increment lunch (SMPG) (mmol/L)	BOLAD1	
6	1	PPG increment lunch (SMPG) (mmol/L)	BASE	

Obs	BOLAD1	ObsVal	_1
1		0.03681	0.129986
2		0.11619	0.239815
3		-0.14867	-0.145145
4		0.17087	0.081979
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.06085	-0.034286
6		-0.60491	-0.636180

Parameter Code=P9PGINCL Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	PPG increment lunch (SMPG) (mmol/L)	Intercept			0.01095	-0.008815
8	1	PPG increment lunch (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)		-0.13610	-0.174176
9	1	PPG increment lunch (SMPG) (mmol/L)	REGION1	EUROPE		-0.16460	-0.182062

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression Regression Information

Parameter Code=P9PGINCL Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

(continued)

							Input	Region	Bolus	Observed		
							Rate		Amount			
							mg/min		mmol			
10	1	PPG	increment	lunch	(SMPG)	(mmol/L)	REGION1	JAPAN			0.28822	0.250615
11	1	PPG	increment	lunch	(SMPG)	(mmol/L)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.02376	0.052286
12	1	PPG	increment	lunch	(SMPG)	(mmol/L)	BASE				-0.50528	-0.519739
13	1	PPG	increment	lunch	(SMPG)	(mmol/L)	visit2200				0.21979	0.244213

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PPGINCL Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG increment lunch (SMPG) (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG increment lunch (SMPG) (mmol/L)	Method	Monotone
3	1	PPG increment lunch (SMPG) (mmol/L)	Number of Imputations	1
4	1	PPG increment lunch (SMPG) (mmol/L)	Seed for random number generator	4323

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=P9PPGINCL Planned Treatment for Period 30 (N)=4

I m p u t a t i o n s	P A R A M E T E R S	G r o u p	R E G I O N A L C O D E	E N T R Y C O D E	F r e q	P e r c e n t	B A S E	v i s i t 2 0 0	v i s i t 3 6 0 0
1	1	PPG increment lunch (SMPG) (mmol/L)	1	X X X X X	304	92.40	1.714602	-0.067777	-0.045928
2	1	PPG increment lunch (SMPG) (mmol/L)	2	X X X X .	12	3.65	1.239891	-0.202950	.
3	1	PPG increment lunch (SMPG) (mmol/L)	3	X X X . .	13	3.95	1.345505	.	.

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGINCL Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG increment lunch (SMPG) (mmol/L)	Intercept	
2	1	PPG increment lunch (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG increment lunch (SMPG) (mmol/L)	REGION1	EUROPE
4	1	PPG increment lunch (SMPG) (mmol/L)	REGION1	JAPAN
5	1	PPG increment lunch (SMPG) (mmol/L)	BOLAD1	
6	1	PPG increment lunch (SMPG) (mmol/L)	BASE	

Obs	BOLAD1	ObsVal	_1
1		-0.00982	-0.052888
2		-0.08722	-0.036886
3		-0.04020	-0.147627
4		0.10440	0.141587
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.04960	0.045010
6		-0.64988	-0.719479

Parameter Code=P9PGINCL Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	PPG increment lunch (SMPG) (mmol/L)	Intercept			0.04686	0.011135
8	1	PPG increment lunch (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)		0.17357	0.189406
9	1	PPG increment lunch (SMPG) (mmol/L)	REGION1	EUROPE		-0.20525	-0.141228

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=P9PGIEU Planned Treatment for Period 30 (N)=2

Obs	PARAM	Description	Value
1	PPG increment main evening meal (SMPG) (mg/dL)	Data Set	WORK.ENDPOINT_PARAM
2	PPG increment main evening meal (SMPG) (mg/dL)	Method	Monotone-data_MCMC
3	PPG increment main evening meal (SMPG) (mg/dL)	Multiple Imputation Chain	Multiple Chains
4	PPG increment main evening meal (SMPG) (mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
5	PPG increment main evening meal (SMPG) (mg/dL)	Start	Starting Value
6	PPG increment main evening meal (SMPG) (mg/dL)	Prior	Jeffreys
7	PPG increment main evening meal (SMPG) (mg/dL)	Number of Imputations	20000
8	PPG increment main evening meal (SMPG) (mg/dL)	Number of Burn-in Iterations	200
9	PPG increment main evening meal (SMPG) (mg/dL)	Seed for random number generator	1234

Parameter Code=P9PGIEU Planned Treatment for Period 30 (N)=3

Obs	PARAM	Description	Value
10	PPG increment main evening meal (SMPG) (mg/dL)	Data Set	WORK.ENDPOINT_PARAM
11	PPG increment main evening meal (SMPG) (mg/dL)	Method	Monotone-data_MCMC
12	PPG increment main evening meal (SMPG) (mg/dL)	Multiple Imputation Chain	Multiple Chains
13	PPG increment main evening meal (SMPG) (mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
14	PPG increment main evening meal (SMPG) (mg/dL)	Start	Starting Value
15	PPG increment main evening meal (SMPG) (mg/dL)	Prior	Jeffreys
16	PPG increment main evening meal (SMPG) (mg/dL)	Number of Imputations	20000
17	PPG increment main evening meal (SMPG) (mg/dL)	Number of Burn-in Iterations	200
18	PPG increment main evening meal (SMPG) (mg/dL)	Seed for random number generator	484595065

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=P9PGIEU Planned Treatment for Period 30 (N)=4

Obs	PARAM	Description	Value
19	PPG increment main evening meal (SMPG) (mg/dL)	Data Set	WORK.ENDPOINT_PARAM
20	PPG increment main evening meal (SMPG) (mg/dL)	Method	Monotone-data_MCMC
21	PPG increment main evening meal (SMPG) (mg/dL)	Multiple Imputation Chain	Multiple Chains
22	PPG increment main evening meal (SMPG) (mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
23	PPG increment main evening meal (SMPG) (mg/dL)	Start	Starting Value
24	PPG increment main evening meal (SMPG) (mg/dL)	Prior	Jeffreys
25	PPG increment main evening meal (SMPG) (mg/dL)	Number of Imputations	20000
26	PPG increment main evening meal (SMPG) (mg/dL)	Number of Burn-in Iterations	200
27	PPG increment main evening meal (SMPG) (mg/dL)	Seed for random number generator	1973862693

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC

Missing data pattern

Parameter Code=P9PGIEU Planned Treatment for Period 30 (N)=3

			P	G	v v i i s s i i t t B 2 3 A 2 6 S 0 0 E 0 0	F	P	B	v i s i t	v i s i t
O	A	R	M	o	\bar{M} \bar{M} \bar{M}	r	e	A	2	3
b	s	s	s	p	s s s	q	n	E	0	0
5	PPG increment	main evening meal	(SMPG) (mg/dL)	1	X X X	296	90.80	20.643620	9.738983	6.468768
6	PPG increment	main evening meal	(SMPG) (mg/dL)	2	X X O	10	3.07	-6.221467	37.402967	.
7	PPG increment	main evening meal	(SMPG) (mg/dL)	3	X . X	14	4.29	29.073857	.	-15.157143
8	PPG increment	main evening meal	(SMPG) (mg/dL)	4	X O O	6	1.84	-24.936389	.	

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC

Missing data pattern

Parameter Code=P9PGIEU Planned Treatment for Period 30 (N)=4

O b s							v v i i s s i i t t						B 2 3 A 2 6 S 0 0 E 0 0				v v i i s s i i t t				
							G r o u p			F r e q		P e r c e n t		B A S E				v v i i s s i i t t			
							M M M														
							i i i														
							s s s														
							s s s														
9	PPG	increment	main	evening	meal	(SMPG)	(mg/dL)	1	X	X	X	292	89.02	13.44	8103	4.35	7576	4.58	1622		
10	PPG	increment	main	evening	meal	(SMPG)	(mg/dL)	2	X	X	O	12	3.66	23.01	8444	3.48	2278				
11	PPG	increment	main	evening	meal	(SMPG)	(mg/dL)	3	X	.	X	13	3.96	18.10	7000	.		6.69	5205		
12	PPG	increment	main	evening	meal	(SMPG)	(mg/dL)	4	X	O	O	11	3.35	10.50	9273	.					

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PGIEU Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG increment main evening meal (SMPG) (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG increment main evening meal (SMPG) (mg/dL)	Method	Monotone
3	1	PPG increment main evening meal (SMPG) (mg/dL)	Number of Imputations	1
4	1	PPG increment main evening meal (SMPG) (mg/dL)	Seed for random number generator	4321

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=P9PGIEU Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM				Group	REGION1_ Miss	BOLAD1_ Miss	BASE_ Miss
1	1	PPG increment main evening meal (SMPG) (mg/dL)				1	X	X	X
2	1	PPG increment main evening meal (SMPG) (mg/dL)				2	X	X	X
3	1	PPG increment main evening meal (SMPG) (mg/dL)				3	X	X	X

Obs	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
1	X	X	303	93.23	20.103537	-14.032221	-6.539022
2	X	.	11	3.38	-8.456485	25.231818	.
3	.	.	11	3.38	-9.451758	.	.

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGIEU Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG increment main evening meal (SMPG) (mg/dL)	Intercept	
2	1	PPG increment main evening meal (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG increment main evening meal (SMPG) (mg/dL)	REGION1	EUROPE
4	1	PPG increment main evening meal (SMPG) (mg/dL)	REGION1	JAPAN
5	1	PPG increment main evening meal (SMPG) (mg/dL)	BOLAD1	
6	1	PPG increment main evening meal (SMPG) (mg/dL)	BASE	

Obs	BOLAD1	ObsVal	_1
1		-0.02253	0.006898
2		-0.05987	-0.032759
3		0.00293	-0.112578
4		-0.06037	-0.078965
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.11781	0.076284
6		-0.65596	-0.677541

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGIEU Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

Obs	Imputed			P	E	R		B	O	
				A	f	E	G	O	b	
				R	f	I	I	L	s	
				A	e	O	O	A	V	
				M	c	N	N	D	a	
					t	1	1	1	1	\bar{I}
7	1	PPG increment main evening meal (SMPG)	(mg/dL)	Intercept					-0.04922	-0.078745
8	1	PPG increment main evening meal (SMPG)	(mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)				-0.27422	-0.202020
9	1	PPG increment main evening meal (SMPG)	(mg/dL)	REGION1	EUROPE				0.17489	0.038980

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGIEU Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM	Effect	REGION1
10	1	PPG increment main evening meal (SMPG) (mg/dL)	REGION1	JAPAN
11	1	PPG increment main evening meal (SMPG) (mg/dL)	BOLAD1	
12	1	PPG increment main evening meal (SMPG) (mg/dL)	BASE	
13	1	PPG increment main evening meal (SMPG) (mg/dL)	visit2200	
Obs		BOLAD1	ObsVal	_1
10			-0.03892	-0.010587
11		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.09899	0.162939
12			-0.56388	-0.507459
13			0.11363	0.126510

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PGIEU Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG increment main evening meal (SMPG) (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG increment main evening meal (SMPG) (mg/dL)	Method	Monotone
3	1	PPG increment main evening meal (SMPG) (mg/dL)	Number of Imputations	1
4	1	PPG increment main evening meal (SMPG) (mg/dL)	Seed for random number generator	4322

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=P9PGIEU Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM				Group	REGION1_ Miss	BOLAD1_ Miss	BASE_ Miss
1	1	PPG increment main evening meal (SMPG) (mg/dL)				1	X	X	X
2	1	PPG increment main evening meal (SMPG) (mg/dL)				2	X	X	X
3	1	PPG increment main evening meal (SMPG) (mg/dL)				3	X	X	X

Obs	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
1	X	X	310	95.09	21.024341	9.573689	5.492114
2	X	.	10	3.07	-6.221467	37.402967	.
3	.	.	6	1.84	-24.936389	.	.

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGIEU Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG increment main evening meal (SMPG) (mg/dL)	Intercept	
2	1	PPG increment main evening meal (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG increment main evening meal (SMPG) (mg/dL)	REGION1	EUROPE
4	1	PPG increment main evening meal (SMPG) (mg/dL)	REGION1	JAPAN
5	1	PPG increment main evening meal (SMPG) (mg/dL)	BOLAD1	
6	1	PPG increment main evening meal (SMPG) (mg/dL)	BASE	
Obs		BOLAD1	ObsVal	_1
1			0.00755	0.093824
2			-0.07863	0.035197
3			-0.10878	-0.105547
4			0.21371	0.133218
5		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.02118	0.002748
6			-0.66858	-0.703484

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGIEU Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

Obs	Imputed								Region	Blood	Obs	Mean
		PPG increment	main	evening	meal	(SMPG)	(mg/dL)					
7	1	PPG increment	main	evening	meal	(SMPG)	(mg/dL)	Intercept			-0.02251	-0.040683
8	1	PPG increment	main	evening	meal	(SMPG)	(mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)		-0.29722	-0.332774
9	1	PPG increment	main	evening	meal	(SMPG)	(mg/dL)	REGION1	EUROPE		-0.00546	-0.021459

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGIEU Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM	Effect	REGION1
10	1	PPG increment main evening meal (SMPG) (mg/dL)	REGION1	JAPAN
11	1	PPG increment main evening meal (SMPG) (mg/dL)	BOLAD1	
12	1	PPG increment main evening meal (SMPG) (mg/dL)	BASE	
13	1	PPG increment main evening meal (SMPG) (mg/dL)	visit2200	
Obs		BOLAD1	ObsVal	_1
10			0.31419	0.280862
11		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.03180	0.037560
12			-0.55709	-0.574482
13			0.19297	0.209590

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PGIEU Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG increment main evening meal (SMPG) (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG increment main evening meal (SMPG) (mg/dL)	Method	Monotone
3	1	PPG increment main evening meal (SMPG) (mg/dL)	Number of Imputations	1
4	1	PPG increment main evening meal (SMPG) (mg/dL)	Seed for random number generator	4323

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=P9PGIEU Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM				Group	REGION1_ Miss	BOLAD1_ Miss	BASE_ Miss
1	1	PPG increment main evening meal (SMPG) (mg/dL)				1	X	X	X
2	1	PPG increment main evening meal (SMPG) (mg/dL)				2	X	X	X
3	1	PPG increment main evening meal (SMPG) (mg/dL)				3	X	X	X

Obs	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
1	X	X	305	92.99	13.646679	3.929104	4.671709
2	X	.	12	3.66	23.018444	3.482278	.
3	.	.	11	3.35	10.509273	.	.

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGIEU Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG increment main evening meal (SMPG) (mg/dL)	Intercept	
2	1	PPG increment main evening meal (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG increment main evening meal (SMPG) (mg/dL)	REGION1	EUROPE
4	1	PPG increment main evening meal (SMPG) (mg/dL)	REGION1	JAPAN
5	1	PPG increment main evening meal (SMPG) (mg/dL)	BOLAD1	
6	1	PPG increment main evening meal (SMPG) (mg/dL)	BASE	

Obs	BOLAD1	ObsVal	_1
1		-0.02076	-0.067080
2		-0.21344	-0.159897
3		0.04135	-0.074471
4		0.12584	0.166104
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.01156	-0.016198
6		-0.57187	-0.645412

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGIEU Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

Obs	Imputed											
								P	E	R	B	O
								A	f	E	O	b
								R	e	I	L	s
								A	c	O	A	V
								M	t	N	D	a
										1	1	l
7	1	PPG increment main evening meal	(SMPG)	(mg/dL)	Intercept						-0.00308	-0.032306
8	1	PPG increment main evening meal	(SMPG)	(mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)					-0.00820	-0.016635
9	1	PPG increment main evening meal	(SMPG)	(mg/dL)	REGION1	EUROPE					0.03198	-0.019065

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGIEU Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM	Effect	REGION1
10	1	PPG increment main evening meal (SMPG) (mg/dL)	REGION1	JAPAN
11	1	PPG increment main evening meal (SMPG) (mg/dL)	BOLAD1	
12	1	PPG increment main evening meal (SMPG) (mg/dL)	BASE	
13	1	PPG increment main evening meal (SMPG) (mg/dL)	visit2200	

Obs	BOLAD1	ObsVal	_1
10		-0.09388	-0.038676
11	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.01317	0.037730
12		-0.43644	-0.434898
13		0.30891	0.371775

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=P9PGINCE Planned Treatment for Period 30 (N)=2

Obs	PARAM	Description	Value
1	PPG increment main evening meal (SMPG) (mmol/L)	Data Set	WORK.ENDPOINT_PARAM
2	PPG increment main evening meal (SMPG) (mmol/L)	Method	Monotone-data_MCMC
3	PPG increment main evening meal (SMPG) (mmol/L)	Multiple Imputation Chain	Multiple Chains
4	PPG increment main evening meal (SMPG) (mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
5	PPG increment main evening meal (SMPG) (mmol/L)	Start	Starting Value
6	PPG increment main evening meal (SMPG) (mmol/L)	Prior	Jeffreys
7	PPG increment main evening meal (SMPG) (mmol/L)	Number of Imputations	20000
8	PPG increment main evening meal (SMPG) (mmol/L)	Number of Burn-in Iterations	200
9	PPG increment main evening meal (SMPG) (mmol/L)	Seed for random number generator	1234

Parameter Code=P9PGINCE Planned Treatment for Period 30 (N)=3

Obs	PARAM	Description	Value
10	PPG increment main evening meal (SMPG) (mmol/L)	Data Set	WORK.ENDPOINT_PARAM
11	PPG increment main evening meal (SMPG) (mmol/L)	Method	Monotone-data_MCMC
12	PPG increment main evening meal (SMPG) (mmol/L)	Multiple Imputation Chain	Multiple Chains
13	PPG increment main evening meal (SMPG) (mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
14	PPG increment main evening meal (SMPG) (mmol/L)	Start	Starting Value
15	PPG increment main evening meal (SMPG) (mmol/L)	Prior	Jeffreys
16	PPG increment main evening meal (SMPG) (mmol/L)	Number of Imputations	20000
17	PPG increment main evening meal (SMPG) (mmol/L)	Number of Burn-in Iterations	200
18	PPG increment main evening meal (SMPG) (mmol/L)	Seed for random number generator	484595065

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=P9PGINCE Planned Treatment for Period 30 (N)=4

Obs	PARAM				Description	Value
19	PPG increment	main evening meal	(SMPG)	(mmol/L)	Data Set	WORK.ENDPOINT_PARAM
20	PPG increment	main evening meal	(SMPG)	(mmol/L)	Method	Monotone-data_MCMC
21	PPG increment	main evening meal	(SMPG)	(mmol/L)	Multiple Imputation Chain	Multiple Chains
22	PPG increment	main evening meal	(SMPG)	(mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
23	PPG increment	main evening meal	(SMPG)	(mmol/L)	Start	Starting Value
24	PPG increment	main evening meal	(SMPG)	(mmol/L)	Prior	Jeffreys
25	PPG increment	main evening meal	(SMPG)	(mmol/L)	Number of Imputations	20000
26	PPG increment	main evening meal	(SMPG)	(mmol/L)	Number of Burn-in Iterations	200
27	PPG increment	main evening meal	(SMPG)	(mmol/L)	Seed for random number generator	1973862693

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC

Missing data pattern

Parameter Code=P9PGINCE Planned Treatment for Period 30 (N)=2

O b s							v v i i s s i i t t			B 2 3 A 2 6 S 0 0 E 0 0			P e r c e n t			v i s i t 2 2 0 0			v i s i t 3 6 0 0		
							G r o u p			\bar{M} \bar{M} \bar{M} i i i s s s s s s			F r e q			B A S E					
							P A R A M														
1	PPG	increment	main	evening	meal	(SMPG) (mmol/L)	1	X	X	X	286	88.00	1.063851	-0.791570	-0.361732						
2	PPG	increment	main	evening	meal	(SMPG) (mmol/L)	2	X	X	O	11	3.38	-0.469283	1.400212	.						
3	PPG	increment	main	evening	meal	(SMPG) (mmol/L)	3	X	.	X	17	5.23	1.986623	.	-0.382126						
4	PPG	increment	main	evening	meal	(SMPG) (mmol/L)	4	X	O	O	11	3.38	-0.524515	.							

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC

Missing data pattern

Parameter Code=P9PGINCE Planned Treatment for Period 30 (N)=3

	O	b	s	P A R A M	G r o u p	B A S E	v v i i s i t t B A S E	F r e q	P e r c e n t	B A S E	v i s i t 2 2 0 0	v i s i t 3 6 0 0
5 PPG increment main evening meal (SMPG) (mmol/L)	1	X	X	X	296	90.80	1.145595	0.540454	0.358977	.	.	.
6 PPG increment main evening meal (SMPG) (mmol/L)	2	X	X	O	10	3.07	-0.345253	2.075636
7 PPG increment main evening meal (SMPG) (mmol/L)	3	X	.	X	14	4.29	1.613422	.	-0.841129	.	.	.
8 PPG increment main evening meal (SMPG) (mmol/L)	4	X	O	O	6	1.84	-1.383817

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC

Missing data pattern

Parameter Code=P9PGINCE Planned Treatment for Period 30 (N)=4

	O	b	s	P A R A M	G r o u p	B A S E	V I S I T	F r e q	P e r c e n t	B A S E	v i s i t	v i s i t
				M	p	S S S S	i i i s			E	2 2 0 0	3 6 0 0
9 PPG increment main evening meal (SMPG) (mmol/L)	1 X X X							292	89.02	0.746288	0.241819	0.254252
10 PPG increment main evening meal (SMPG) (mmol/L)	2 X X O							12	3.66	1.277383	0.193245	.
11 PPG increment main evening meal (SMPG) (mmol/L)	3 X . X							13	3.96	1.004828	.	0.371543
12 PPG increment main evening meal (SMPG) (mmol/L)	4 X O O							11	3.35	0.583200	.	

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PGINCE Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG increment main evening meal (SMPG) (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG increment main evening meal (SMPG) (mmol/L)	Method	Monotone
3	1	PPG increment main evening meal (SMPG) (mmol/L)	Number of Imputations	1
4	1	PPG increment main evening meal (SMPG) (mmol/L)	Seed for random number generator	4321

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=P9PGINCE Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM				Group	REGION1_ Miss	BOLAD1_ Miss
1	1	PPG increment main evening meal	(SMPG)	(mmol/L)		1	X	X
2	1	PPG increment main evening meal	(SMPG)	(mmol/L)		2	X	X
3	1	PPG increment main evening meal	(SMPG)	(mmol/L)		3	X	X

Obs	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
1	X	X	X	303	93.23	1.115624	-0.778703	-0.362876
2	X	X	.	11	3.38	-0.469283	1.400212	.
3	X	.	.	11	3.38	-0.524515	.	.

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGINCE Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG increment main evening meal (SMPG) (mmol/L)	Intercept	
2	1	PPG increment main evening meal (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG increment main evening meal (SMPG) (mmol/L)	REGION1	EUROPE
4	1	PPG increment main evening meal (SMPG) (mmol/L)	REGION1	JAPAN
5	1	PPG increment main evening meal (SMPG) (mmol/L)	BOLAD1	
6	1	PPG increment main evening meal (SMPG) (mmol/L)	BASE	

Obs	BOLAD1	ObsVal	_1
1		-0.02253	0.006898
2		-0.05987	-0.032759
3		0.00293	-0.112578
4		-0.06037	-0.078965
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.11781	0.076284
6		-0.65596	-0.677541

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression Regression Information

Parameter Code=P9PGINCE Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

	O b s				P A R A M		E f f e c t	R E G I O N 1	B O L D	O b s V a l	I
7	1	PPG increment main evening meal (SMPG)	(mmol/L)	Intercept						-0.04922	-0.078745
8	1	PPG increment main evening meal (SMPG)	(mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)					-0.27422	-0.202020
9	1	PPG increment main evening meal (SMPG)	(mmol/L)	REGION1	EUROPE					0.17489	0.038980

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PPGINCE Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM						Effect	
10	1	PPG increment main evening meal (SMPG)	(mmol/L)					REGION1	
11	1	PPG increment main evening meal (SMPG)	(mmol/L)					BOLAD1	
12	1	PPG increment main evening meal (SMPG)	(mmol/L)					BASE	
13	1	PPG increment main evening meal (SMPG)	(mmol/L)					visit2200	
Obs	REGION1	BOLAD1						ObsVal	_1
10	JAPAN							-0.03892	-0.010587
11		BOLUS INSULIN ALGORITHM (SLIDING SCALE)						0.09899	0.162939
12								-0.56388	-0.507459
13								0.11363	0.126510

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PGINCE Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG increment main evening meal (SMPG) (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG increment main evening meal (SMPG) (mmol/L)	Method	Monotone
3	1	PPG increment main evening meal (SMPG) (mmol/L)	Number of Imputations	1
4	1	PPG increment main evening meal (SMPG) (mmol/L)	Seed for random number generator	4322

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=P9PGINCE Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM				Group	REGION1_ Miss	BOLAD1_ Miss
1	1	PPG increment main evening meal	(SMPG)	(mmol/L)		1	X	X
2	1	PPG increment main evening meal	(SMPG)	(mmol/L)		2	X	X
3	1	PPG increment main evening meal	(SMPG)	(mmol/L)		3	X	X

Obs	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
1	X	X	X	310	95.09	1.166723	0.531281	0.304779
2	X	X	.	10	3.07	-0.345253	2.075636	.
3	X	.	.	6	1.84	-1.383817	.	.

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGINCE Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG increment main evening meal (SMPG) (mmol/L)	Intercept	
2	1	PPG increment main evening meal (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG increment main evening meal (SMPG) (mmol/L)	REGION1	EUROPE
4	1	PPG increment main evening meal (SMPG) (mmol/L)	REGION1	JAPAN
5	1	PPG increment main evening meal (SMPG) (mmol/L)	BOLAD1	
6	1	PPG increment main evening meal (SMPG) (mmol/L)	BASE	

Obs	BOLAD1	ObsVal	_1
1		0.00755	0.093824
2		-0.07863	0.035197
3		-0.10878	-0.105547
4		0.21371	0.133218
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.02118	0.002748
6		-0.66858	-0.703484

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PPGINCE Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM						Effect	
10	1	PPG increment main evening meal (SMPG)	(mmol/L)					REGION1	
11	1	PPG increment main evening meal (SMPG)	(mmol/L)					BOLAD1	
12	1	PPG increment main evening meal (SMPG)	(mmol/L)					BASE	
13	1	PPG increment main evening meal (SMPG)	(mmol/L)					visit2200	
Obs	REGION1	BOLAD1						ObsVal	_1
10	JAPAN							0.31419	0.280862
11		BOLUS INSULIN ALGORITHM (SLIDING SCALE)						-0.03180	0.037560
12								-0.55709	-0.574482
13								0.19297	0.209590

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PPGINCE Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM	Description	Value
1	1	PPG increment main evening meal (SMPG) (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	PPG increment main evening meal (SMPG) (mmol/L)	Method	Monotone
3	1	PPG increment main evening meal (SMPG) (mmol/L)	Number of Imputations	1
4	1	PPG increment main evening meal (SMPG) (mmol/L)	Seed for random number generator	4323

nn1218/nn1218-4131/ctr_20180214_er
10FEB2018:18:44:27 - a_797pp_stat_diff.sas/a_9pp_ppginc_stat_on_fas_app.txt

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=P9PGINCE Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM				Group	REGION1_ Miss	BOLAD1_ Miss
1	1	PPG increment main evening meal	(SMPG)	(mmol/L)		1	X	X
2	1	PPG increment main evening meal	(SMPG)	(mmol/L)		2	X	X
3	1	PPG increment main evening meal	(SMPG)	(mmol/L)		3	X	X

Obs	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
1	X	X	X	305	92.99	0.757307	0.218041	0.259251
2	X	X	.	12	3.66	1.277383	0.193245	.
3	X	.	.	11	3.35	0.583200	.	.

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGINCE Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	PPG increment main evening meal (SMPG) (mmol/L)	Intercept	
2	1	PPG increment main evening meal (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	PPG increment main evening meal (SMPG) (mmol/L)	REGION1	EUROPE
4	1	PPG increment main evening meal (SMPG) (mmol/L)	REGION1	JAPAN
5	1	PPG increment main evening meal (SMPG) (mmol/L)	BOLAD1	
6	1	PPG increment main evening meal (SMPG) (mmol/L)	BASE	

Obs	BOLAD1	ObsVal	_1
1		-0.02076	-0.067080
2		-0.21344	-0.159897
3		0.04135	-0.074471
4		0.12584	0.166104
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.01156	-0.016198
6		-0.57187	-0.645412

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGINCE Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

Obs	Imputed			P	E	R		B	O	
Obs	Imputed			A	f	E	G	O	b	\bar{I}
				R	f	O	I	L	s	
				A	e	N	O	A	V	
				M	c	1	1	D	a	
7	1	PPG increment main evening meal	(SMPG) (mmol/L)		Intercept				-0.00308	-0.032306
8	1	PPG increment main evening meal	(SMPG) (mmol/L)		REGION1	ASIA (EXCLUDING JAPAN)			-0.00820	-0.016635
9	1	PPG increment main evening meal	(SMPG) (mmol/L)		REGION1	EUROPE			0.03198	-0.019065

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PPGINCE Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM	Effect
10	1	PPG increment main evening meal (SMPG) (mmol/L)	REGION1
11	1	PPG increment main evening meal (SMPG) (mmol/L)	BOLAD1
12	1	PPG increment main evening meal (SMPG) (mmol/L)	BASE
13	1	PPG increment main evening meal (SMPG) (mmol/L)	visit2200

Obs	REGION1	BOLAD1	ObsVal	_1
10	JAPAN		-0.09388	-0.038676
11		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.01317	0.037730
12			-0.43644	-0.434898
13			0.30891	0.371775

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure Model Information

Parameter Code=P9PGIBU Parameter=PPG increment breakfast (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Data Set	WORK.IMPUTE
2	1	NN1218-4131	Dependent Variable	eotVisit
3	1	NN1218-4131	Covariance Structure	Diagonal
4	1	NN1218-4131	Estimation Method	REML
5	1	NN1218-4131	Residual Variance Method	Profile
6	1	NN1218-4131	Fixed Effects SE Method	Model-Based
7	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=P9PGIEU Parameter=PPG increment main evening meal (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
8	1	NN1218-4131	Data Set	WORK.IMPUTE
9	1	NN1218-4131	Dependent Variable	eotVisit
10	1	NN1218-4131	Covariance Structure	Diagonal
11	1	NN1218-4131	Estimation Method	REML
12	1	NN1218-4131	Residual Variance Method	Profile
13	1	NN1218-4131	Fixed Effects SE Method	Model-Based
14	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=P9PGILU Parameter=PPG increment lunch (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
15	1	NN1218-4131	Data Set	WORK.IMPUTE
16	1	NN1218-4131	Dependent Variable	eotVisit
17	1	NN1218-4131	Covariance Structure	Diagonal

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Model Information

Parameter Code=P9PGILU Parameter=PPG increment lunch (SMPG) (mg/dL)

(continued)

Obs	_Imputation_	STUDYID	Descr	Value
18	1	NN1218-4131	Estimation Method	REML
19	1	NN1218-4131	Residual Variance Method	Profile
20	1	NN1218-4131	Fixed Effects SE Method	Model-Based
21	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=P9PGINC Parameter=PPG increment all meals (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
22	1	NN1218-4131	Data Set	WORK.IMPUTE
23	1	NN1218-4131	Dependent Variable	eotVisit
24	1	NN1218-4131	Covariance Structure	Diagonal
25	1	NN1218-4131	Estimation Method	REML
26	1	NN1218-4131	Residual Variance Method	Profile
27	1	NN1218-4131	Fixed Effects SE Method	Model-Based
28	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=P9PGINCB Parameter=PPG increment breakfast (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
29	1	NN1218-4131	Data Set	WORK.IMPUTE
30	1	NN1218-4131	Dependent Variable	eotVisit
31	1	NN1218-4131	Covariance Structure	Diagonal
32	1	NN1218-4131	Estimation Method	REML

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Model Information

Parameter Code=P9PGINCB Parameter=PPG increment breakfast (SMPG) (mmol/L)

(continued)

Obs	_Imputation_	STUDYID	Descr	Value
33	1	NN1218-4131	Residual Variance Method	Profile
34	1	NN1218-4131	Fixed Effects SE Method	Model-Based
35	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=P9PGINCE Parameter=PPG increment main evening meal (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
36	1	NN1218-4131	Data Set	WORK.IMPUTE
37	1	NN1218-4131	Dependent Variable	eotVisit
38	1	NN1218-4131	Covariance Structure	Diagonal
39	1	NN1218-4131	Estimation Method	REML
40	1	NN1218-4131	Residual Variance Method	Profile
41	1	NN1218-4131	Fixed Effects SE Method	Model-Based
42	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=P9PGINCL Parameter=PPG increment lunch (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
43	1	NN1218-4131	Data Set	WORK.IMPUTE
44	1	NN1218-4131	Dependent Variable	eotVisit
45	1	NN1218-4131	Covariance Structure	Diagonal
46	1	NN1218-4131	Estimation Method	REML
47	1	NN1218-4131	Residual Variance Method	Profile

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Model Information

Parameter Code=P9PGINCL Parameter=PPG increment lunch (SMPG) (mmol/L)

(continued)

Obs	_Imputation_	STUDYID	Descr	Value
48	1	NN1218-4131	Fixed Effects SE Method	Model-Based
49	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=P9PGIU Parameter=PPG increment all meals (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
50	1	NN1218-4131	Data Set	WORK.IMPUTE
51	1	NN1218-4131	Dependent Variable	eotVisit
52	1	NN1218-4131	Covariance Structure	Diagonal
53	1	NN1218-4131	Estimation Method	REML
54	1	NN1218-4131	Residual Variance Method	Profile
55	1	NN1218-4131	Fixed Effects SE Method	Model-Based
56	1	NN1218-4131	Degrees of Freedom Method	Residual

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Class Level Information

Parameter Code=P9PGIBU Parameter=PPG increment breakfast (SMPG) (mg/dL)

Obs	Inpution	STUDY ID	Classes	Levels	Values	Unit
1	1	NN1218-4131	TRTPN	3 2 3 4		5
2	1	NN1218-4131	REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA	49
3	1	NN1218-4131	BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULI	85

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Class Level Information

Parameter Code=P9PGIEU Parameter=PPG increment main evening meal (SMPG) (mg/dL)

Ob- s	—	Input ID	STUDY	Class	Level	Values	mi- n
4	1	NN1218-4131	TRTPN		3 2 3 4		5
5	1	NN1218-4131	REGION1		4 ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA		49
6	1	NN1218-4131	BOLAD1		2 BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULI		85

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Class Level Information

Parameter Code=P9PGILU Parameter=PPG increment lunch (SMPG) (mg/dL)

Ob- s	—	Input on D	STUD Y I D	Class s	Lev els	Val ues	mi n — Le g t h
7	1	NN1218-4131	TRTPN		3 2 3 4		5
8	1	NN1218-4131	REGION1		4 ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA		49
9	1	NN1218-4131	BOLAD1		2 BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULI		85

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The Mixed procedure
Class Level Information

Parameter Code=P9PGINC Parameter=PPG increment all meals (SMPG) (mmol/L)

O b s		I n		S t		C l		U s		L e		V a		l e		g t		h	
m		p		u		t		a		t		i		D		Y		I	
s		-																	
10	1	NN1218-4131	TRTPN			3	2	3	4									5	
11	1	NN1218-4131	REGION1			4	ASIA (EXCLUDING JAPAN)	EUROPE	JAPAN	NORTH AMERICA								49	
12	1	NN1218-4131	BOLAD1			2	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	CARBOHYDRATE COUNTING (FLEXIBLE)	BOLUS	INSULI								85	

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Class Level Information

Parameter Code=P9PGINCB Parameter=PPG increment breakfast (SMPG) (mmol/L)

Object	Input	STUDY ID	Classes	Levels	Values	min
13	1	NN1218-4131	TRTPN	3 2 3 4		5
14	1	NN1218-4131	REGION1	4 ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA		49
15	1	NN1218-4131	BOLAD1	2 BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULI		85

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nn1218/nn1218-4131/ctr_20180214_er
10FEB2018:18:44:27 - a 797pp stat diff.sas/a 9pp ppginc stat on_fas app.txt
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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Class Level Information

Parameter Code=P9PGINCL Parameter=PPG increment lunch (SMPG) (mmol/L)

O b s		I n		S t a t i s		C l a s s		L e v e l s		V a r i a b l e s		m i n	
19	1	NN1218-4131	TRTPN	3	2	3	4					5	
20	1	NN1218-4131	REGION1	4	ASIA (EXCLUDING JAPAN)	EUROPE	JAPAN	NORTH AMERICA				49	
21	1	NN1218-4131	BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	CARBOHYDRATE COUNTING (FLEXIBLE)	BOLUS INSULI	85					

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nn1218/nn1218-4131/ctr_20180214_er
10FEB2018:18:44:27 - a 797pp stat diff.sas/a 9pp ppginc stat on_fas app.txt
```

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Dimensions

Parameter Code=P9PGIBU Parameter=PPG increment breakfast (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Covariance Parameters	1
2	1	NN1218-4131	Columns in X	10
3	1	NN1218-4131	Columns in Z	0
4	1	NN1218-4131	Subjects	1
5	1	NN1218-4131	Max Obs per Subject	986

Parameter Code=P9PGIEU Parameter=PPG increment main evening meal (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
6	1	NN1218-4131	Covariance Parameters	1
7	1	NN1218-4131	Columns in X	10
8	1	NN1218-4131	Columns in Z	0
9	1	NN1218-4131	Subjects	1
10	1	NN1218-4131	Max Obs per Subject	979

Parameter Code=P9PGILU Parameter=PPG increment lunch (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
11	1	NN1218-4131	Covariance Parameters	1
12	1	NN1218-4131	Columns in X	10
13	1	NN1218-4131	Columns in Z	0
14	1	NN1218-4131	Subjects	1
15	1	NN1218-4131	Max Obs per Subject	982

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Dimensions

Parameter Code=P9PGINC Parameter=PPG increment all meals (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
16	1	NN1218-4131	Covariance Parameters	1
17	1	NN1218-4131	Columns in X	10
18	1	NN1218-4131	Columns in Z	0
19	1	NN1218-4131	Subjects	1
20	1	NN1218-4131	Max Obs per Subject	974

Parameter Code=P9PGINCB Parameter=PPG increment breakfast (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
21	1	NN1218-4131	Covariance Parameters	1
22	1	NN1218-4131	Columns in X	10
23	1	NN1218-4131	Columns in Z	0
24	1	NN1218-4131	Subjects	1
25	1	NN1218-4131	Max Obs per Subject	986

Parameter Code=P9PGINCE Parameter=PPG increment main evening meal (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
26	1	NN1218-4131	Covariance Parameters	1
27	1	NN1218-4131	Columns in X	10
28	1	NN1218-4131	Columns in Z	0
29	1	NN1218-4131	Subjects	1
30	1	NN1218-4131	Max Obs per Subject	979

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Dimensions

Parameter Code=P9PGINCL Parameter=PPG increment lunch (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
31	1	NN1218-4131	Covariance Parameters	1
32	1	NN1218-4131	Columns in X	10
33	1	NN1218-4131	Columns in Z	0
34	1	NN1218-4131	Subjects	1
35	1	NN1218-4131	Max Obs per Subject	982

Parameter Code=P9PGIU Parameter=PPG increment all meals (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
36	1	NN1218-4131	Covariance Parameters	1
37	1	NN1218-4131	Columns in X	10
38	1	NN1218-4131	Columns in Z	0
39	1	NN1218-4131	Subjects	1
40	1	NN1218-4131	Max Obs per Subject	974

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Number of Observations

Parameter Code=P9PGIBU Parameter=PPG increment breakfast (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
1	1	NN1218-4131	Number of Observations Read	986	986	986	986	986
2	1	NN1218-4131	Number of Observations Used	986	986	986	986	986
3	1	NN1218-4131	Number of Observations Not Used	0	986	986	986	986

Parameter Code=P9PGIEU Parameter=PPG increment main evening meal (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
4	1	NN1218-4131	Number of Observations Read	979	979	979	979	979
5	1	NN1218-4131	Number of Observations Used	979	979	979	979	979
6	1	NN1218-4131	Number of Observations Not Used	0	979	979	979	979

Parameter Code=P9PGILU Parameter=PPG increment lunch (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
7	1	NN1218-4131	Number of Observations Read	982	982	982	982	982
8	1	NN1218-4131	Number of Observations Used	982	982	982	982	982
9	1	NN1218-4131	Number of Observations Not Used	0	982	982	982	982

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Number of Observations

Parameter Code=P9PGINC Parameter=PPG increment all meals (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
10	1	NN1218-4131	Number of Observations Read	974	974	974	974	974
11	1	NN1218-4131	Number of Observations Used	974	974	974	974	974
12	1	NN1218-4131	Number of Observations Not Used	0	974	974	974	974

Parameter Code=P9PGINCB Parameter=PPG increment breakfast (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
13	1	NN1218-4131	Number of Observations Read	986	986	986	986	986
14	1	NN1218-4131	Number of Observations Used	986	986	986	986	986
15	1	NN1218-4131	Number of Observations Not Used	0	986	986	986	986

Parameter Code=P9PGINCE Parameter=PPG increment main evening meal (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
16	1	NN1218-4131	Number of Observations Read	979	979	979	979	979
17	1	NN1218-4131	Number of Observations Used	979	979	979	979	979
18	1	NN1218-4131	Number of Observations Not Used	0	979	979	979	979

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Number of Observations

Parameter Code=P9PGINCL Parameter=PPG increment lunch (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
19	1	NN1218-4131	Number of Observations Read	982	982	982	982	982
20	1	NN1218-4131	Number of Observations Used	982	982	982	982	982
21	1	NN1218-4131	Number of Observations Not Used	0	982	982	982	982

Parameter Code=P9PGIU Parameter=PPG increment all meals (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
22	1	NN1218-4131	Number of Observations Read	974	974	974	974	974
23	1	NN1218-4131	Number of Observations Used	974	974	974	974	974
24	1	NN1218-4131	Number of Observations Not Used	0	974	974	974	974

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Covariance Parameter Estimates

Parameter Code=P9PGIBU Parameter=PPG increment breakfast (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	CovParm	Estimate
1	1	NN1218-4131	Residual	2157.02

Parameter Code=P9PGIEU Parameter=PPG increment main evening meal (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	CovParm	Estimate
20001	1	NN1218-4131	Residual	2501.76

Parameter Code=P9PGILU Parameter=PPG increment lunch (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	CovParm	Estimate
40001	1	NN1218-4131	Residual	2038.14

Parameter Code=P9PGINC Parameter=PPG increment all meals (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	CovParm	Estimate
60001	1	NN1218-4131	Residual	2.7130

Parameter Code=P9PGINCB Parameter=PPG increment breakfast (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	CovParm	Estimate
80001	1	NN1218-4131	Residual	6.6427

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The Mixed procedure
Covariance Parameter Estimates

Parameter Code=P9PGINCE Parameter=PPG increment main evening meal (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	CovParm	Estimate
100001	1	NN1218-4131	Residual	7.7044

Parameter Code=P9PGINCL Parameter=PPG increment lunch (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	CovParm	Estimate
120001	1	NN1218-4131	Residual	6.2766

Parameter Code=P9PGIU Parameter=PPG increment all meals (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	CovParm	Estimate
140001	1	NN1218-4131	Residual	880.97

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The Mixed procedure
Fit Statistics

Parameter Code=P9PGIBU Parameter=PPG increment breakfast (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	-2 Res Log Likelihood	10335.6
2	1	NN1218-4131	AIC (Smaller is Better)	10337.6
3	1	NN1218-4131	AICC (Smaller is Better)	10337.6
4	1	NN1218-4131	BIC (Smaller is Better)	10342.4

Parameter Code=P9PGIEU Parameter=PPG increment main evening meal (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
5	1	NN1218-4131	-2 Res Log Likelihood	10405.8
6	1	NN1218-4131	AIC (Smaller is Better)	10407.8
7	1	NN1218-4131	AICC (Smaller is Better)	10407.8
8	1	NN1218-4131	BIC (Smaller is Better)	10412.7

Parameter Code=P9PGILU Parameter=PPG increment lunch (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
9	1	NN1218-4131	-2 Res Log Likelihood	10237.9
10	1	NN1218-4131	AIC (Smaller is Better)	10239.9
11	1	NN1218-4131	AICC (Smaller is Better)	10240.0
12	1	NN1218-4131	BIC (Smaller is Better)	10244.8

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Fit Statistics

Parameter Code=P9PGINC Parameter=PPG increment all meals (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
13	1	NN1218-4131	-2 Res Log Likelihood	3751.2
14	1	NN1218-4131	AIC (Smaller is Better)	3753.2
15	1	NN1218-4131	AICC (Smaller is Better)	3753.2
16	1	NN1218-4131	BIC (Smaller is Better)	3758.1

Parameter Code=P9PGINCB Parameter=PPG increment breakfast (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
17	1	NN1218-4131	-2 Res Log Likelihood	4674.0
18	1	NN1218-4131	AIC (Smaller is Better)	4676.0
19	1	NN1218-4131	AICC (Smaller is Better)	4676.0
20	1	NN1218-4131	BIC (Smaller is Better)	4680.9

Parameter Code=P9PGINCE Parameter=PPG increment main evening meal (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
21	1	NN1218-4131	-2 Res Log Likelihood	4784.8
22	1	NN1218-4131	AIC (Smaller is Better)	4786.8
23	1	NN1218-4131	AICC (Smaller is Better)	4786.8
24	1	NN1218-4131	BIC (Smaller is Better)	4791.6

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The Mixed procedure
Fit Statistics

Parameter Code=P9PGINCL Parameter=PPG increment lunch (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
25	1	NN1218-4131	-2 Res Log Likelihood	4599.6
26	1	NN1218-4131	AIC (Smaller is Better)	4601.6
27	1	NN1218-4131	AICC (Smaller is Better)	4601.6
28	1	NN1218-4131	BIC (Smaller is Better)	4606.4

Parameter Code=P9PGIU Parameter=PPG increment all meals (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
29	1	NN1218-4131	-2 Res Log Likelihood	9343.4
30	1	NN1218-4131	AIC (Smaller is Better)	9345.4
31	1	NN1218-4131	AICC (Smaller is Better)	9345.4
32	1	NN1218-4131	BIC (Smaller is Better)	9350.2

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The Mixed procedure
Solution for Fixed Effects

Parameter Code=P9PGIBU Parameter=PPG increment breakfast (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
1	1	NN1218-4131	TRTPN	2				
2	1	NN1218-4131	TRTPN	3				
3	1	NN1218-4131	TRTPN	4				
4	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
5	1	NN1218-4131	REGION1	—	EUROPE			
6	1	NN1218-4131	REGION1	—	JAPAN			
7	1	NN1218-4131	REGION1	—	NORTH AMERICA			
8	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
9	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
10	1	NN1218-4131	BASE	—				

Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	9.9382	3.7851	978	2.63	0.0088	0.05	2.5103	17.3661
2	27.4316	3.7975	978	7.22	<.0001	0.05	19.9795	34.8838
3	20.4773	3.8067	978	5.38	<.0001	0.05	13.0071	27.9475
4	5.4399	5.4258	978	1.00	0.3163	0.05	-5.2076	16.0874
5	1.8181	3.8575	978	0.47	0.6375	0.05	-5.7518	9.3881
6	14.4444	4.2968	978	3.36	0.0008	0.05	6.0123	22.8764
7	0
8	-7.5612	3.3509	978	-2.26	0.0243	0.05	-14.1370	-0.9854
9	0
10	-0.7196	0.02635	978	-27.31	<.0001	0.05	-0.7713	-0.6679

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Solution for Fixed Effects

Parameter Code=P9PGIEU Parameter=PPG increment main evening meal (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1			BOLAD1
11	1	NN1218-4131	TRTPN	2				
12	1	NN1218-4131	TRTPN	3				
13	1	NN1218-4131	TRTPN	4				
14	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
15	1	NN1218-4131	REGION1	—	EUROPE			
16	1	NN1218-4131	REGION1	—	JAPAN			
17	1	NN1218-4131	REGION1	—	NORTH AMERICA			
18	1	NN1218-4131	BOLAD1	—				BOLUS INSULIN ALGORITHM (SLIDING SCALE)
19	1	NN1218-4131	BOLAD1	—				CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY
20	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
11	10.8651	3.9270	971	2.77	0.0058	0.05	3.1587	18.5716
12	23.9101	3.9960	971	5.98	<.0001	0.05	16.0683	31.7519
13	16.6643	3.9685	971	4.20	<.0001	0.05	8.8765	24.4521
14	-19.2555	5.8554	971	-3.29	0.0010	0.05	-30.7461	-7.7649
15	-3.7180	4.1722	971	-0.89	0.3731	0.05	-11.9054	4.4695
16	-1.4156	4.6395	971	-0.31	0.7603	0.05	-10.5203	7.6890
17	0
18	3.3084	3.6202	971	0.91	0.3610	0.05	-3.7960	10.4128
19	0
20	-0.7521	0.02943	971	-25.55	<.0001	0.05	-0.8099	-0.6943

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Solution for Fixed Effects

Parameter Code=P9PGILU Parameter=PPG increment lunch (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
21	1	NN1218-4131	TRTPN	2				
22	1	NN1218-4131	TRTPN	3				
23	1	NN1218-4131	TRTPN	4				
24	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
25	1	NN1218-4131	REGION1	—	EUROPE			
26	1	NN1218-4131	REGION1	—	JAPAN			
27	1	NN1218-4131	REGION1	—	NORTH AMERICA			
28	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
29	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
30	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
21	14.2162	3.6222	974	3.92	<.0001	0.05	7.1079	21.3245
22	23.9098	3.6718	974	6.51	<.0001	0.05	16.7043	31.1154
23	20.4752	3.6396	974	5.63	<.0001	0.05	13.3328	27.6176
24	-1.8919	5.2770	974	-0.36	0.7200	0.05	-12.2475	8.4636
25	-8.1482	3.7586	974	-2.17	0.0304	0.05	-15.5240	-0.7723
26	10.7228	4.2632	974	2.52	0.0121	0.05	2.3568	19.0889
27	0
28	0.8344	3.2607	974	0.26	0.7981	0.05	-5.5645	7.2332
29	0
30	-0.7245	0.02989	974	-24.24	<.0001	0.05	-0.7831	-0.6658

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Parameter Code=P9PPGINC Parameter=PPG increment all meals (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1		BOLAD1
31	1	NN1218-4131	TRTPN	2			
32	1	NN1218-4131	TRTPN	3			
33	1	NN1218-4131	TRTPN	4			
34	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)		
35	1	NN1218-4131	REGION1	—	EUROPE		
36	1	NN1218-4131	REGION1	—	JAPAN		
37	1	NN1218-4131	REGION1	—	NORTH AMERICA		
38	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	
39	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY	
40	1	NN1218-4131	BASE	—			

Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
31	0.3767	0.1368	966	2.75	0.0060	0.05	0.1083	0.6451
32	1.1022	0.1383	966	7.97	<.0001	0.05	0.8308	1.3736
33	0.8619	0.1362	966	6.33	<.0001	0.05	0.5946	1.1292
34	-0.2063	0.1930	966	-1.07	0.2852	0.05	-0.5850	0.1723
35	-0.1076	0.1378	966	-0.78	0.4351	0.05	-0.3781	0.1629
36	0.4275	0.1553	966	2.75	0.0060	0.05	0.1228	0.7322
37	0
38	-0.03904	0.1200	966	-0.33	0.7450	0.05	-0.2746	0.1965
39	0
40	-0.6055	0.02687	966	-22.53	<.0001	0.05	-0.6583	-0.5528

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Solution for Fixed Effects

Parameter Code=P9PGINCB Parameter=PPG increment breakfast (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
41	1	NN1218-4131	TRTPN	2				
42	1	NN1218-4131	TRTPN	3				
43	1	NN1218-4131	TRTPN	4				
44	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
45	1	NN1218-4131	REGION1	—	EUROPE			
46	1	NN1218-4131	REGION1	—	JAPAN			
47	1	NN1218-4131	REGION1	—	NORTH AMERICA			
48	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
49	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
50	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
41	0.5515	0.2101	978	2.63	0.0088	0.05	0.1393	0.9637
42	1.5223	0.2107	978	7.22	<.0001	0.05	1.1087	1.9358
43	1.1364	0.2112	978	5.38	<.0001	0.05	0.7218	1.5509
44	0.3019	0.3011	978	1.00	0.3163	0.05	-0.2890	0.8928
45	0.1009	0.2141	978	0.47	0.6375	0.05	-0.3192	0.5210
46	0.8016	0.2384	978	3.36	0.0008	0.05	0.3336	1.2695
47	0
48	-0.4196	0.1860	978	-2.26	0.0243	0.05	-0.7845	-0.05468
49	0
50	-0.7196	0.02635	978	-27.31	<.0001	0.05	-0.7713	-0.6679

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Solution for Fixed Effects

Parameter Code=P9PGINCE Parameter=PPG increment main evening meal (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
51	1	NN1218-4131	TRTPN	2				
52	1	NN1218-4131	TRTPN	3				
53	1	NN1218-4131	TRTPN	4				
54	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
55	1	NN1218-4131	REGION1	—	EUROPE			
56	1	NN1218-4131	REGION1	—	JAPAN			
57	1	NN1218-4131	REGION1	—	NORTH AMERICA			
58	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
59	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
60	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
51	0.6029	0.2179	971	2.77	0.0058	0.05	0.1753	1.0306
52	1.3269	0.2218	971	5.98	<.0001	0.05	0.8917	1.7620
53	0.9248	0.2202	971	4.20	<.0001	0.05	0.4926	1.3569
54	-1.0686	0.3249	971	-3.29	0.0010	0.05	-1.7062	-0.4309
55	-0.2063	0.2315	971	-0.89	0.3731	0.05	-0.6607	0.2480
56	-0.07856	0.2575	971	-0.31	0.7603	0.05	-0.5838	0.4267
57	0
58	0.1836	0.2009	971	0.91	0.3610	0.05	-0.2107	0.5778
59	0
60	-0.7521	0.02943	971	-25.55	<.0001	0.05	-0.8099	-0.6943

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Parameter Code=P9PGINCL Parameter=PPG increment lunch (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
61	1	NN1218-4131	TRTPN	2				
62	1	NN1218-4131	TRTPN	3				
63	1	NN1218-4131	TRTPN	4				
64	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
65	1	NN1218-4131	REGION1	—	EUROPE			
66	1	NN1218-4131	REGION1	—	JAPAN			
67	1	NN1218-4131	REGION1	—	NORTH AMERICA			
68	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
69	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
70	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
61	0.7889	0.2010	974	3.92	<.0001	0.05	0.3944	1.1834
62	1.3269	0.2038	974	6.51	<.0001	0.05	0.9270	1.7267
63	1.1362	0.2020	974	5.63	<.0001	0.05	0.7399	1.5326
64	-0.1050	0.2928	974	-0.36	0.7200	0.05	-0.6797	0.4697
65	-0.4522	0.2086	974	-2.17	0.0304	0.05	-0.8615	-0.04286
66	0.5951	0.2366	974	2.52	0.0121	0.05	0.1308	1.0593
67	0
68	0.04630	0.1810	974	0.26	0.7981	0.05	-0.3088	0.4014
69	0
70	-0.7245	0.02989	974	-24.24	<.0001	0.05	-0.7831	-0.6658

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Solution for Fixed Effects

Parameter Code=P9PGIU Parameter=PPG increment all meals (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
71	1	NN1218-4131	TRTPN	2				
72	1	NN1218-4131	TRTPN	3				
73	1	NN1218-4131	TRTPN	4				
74	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
75	1	NN1218-4131	REGION1	—	EUROPE			
76	1	NN1218-4131	REGION1	—	JAPAN			
77	1	NN1218-4131	REGION1	—	NORTH AMERICA			
78	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
79	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
80	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
71	6.7879	2.4648	966	2.75	0.0060	0.05	1.9510	11.6249
72	19.8620	2.4922	966	7.97	<.0001	0.05	14.9712	24.7528
73	15.5313	2.4549	966	6.33	<.0001	0.05	10.7138	20.3488
74	-3.7184	3.4771	966	-1.07	0.2852	0.05	-10.5418	3.1051
75	-1.9392	2.4838	966	-0.78	0.4351	0.05	-6.8133	2.9350
76	7.7039	2.7980	966	2.75	0.0060	0.05	2.2130	13.1947
77	0
78	-0.7035	2.1627	966	-0.33	0.7450	0.05	-4.9477	3.5406
79	0
80	-0.6055	0.02687	966	-22.53	<.0001	0.05	-0.6583	-0.5528

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation -
statistical analysis - on-treatment - full analysis set

The Mixed procedure
Least Squares Means

Obs	_Imputation_	PARAMCD	PARAM	STUDYID	Effect
1	1	P9PGIBU	PPG increment breakfast (SMPG) (mg/dL)	NN1218-4131	TRTPN
2	1	P9PGIBU	PPG increment breakfast (SMPG) (mg/dL)	NN1218-4131	TRTPN
3	1	P9PGIBU	PPG increment breakfast (SMPG) (mg/dL)	NN1218-4131	TRTPN
4	1	P9PGIEU	PPG increment main evening meal (SMPG) (mg/dL)	NN1218-4131	TRTPN
5	1	P9PGIEU	PPG increment main evening meal (SMPG) (mg/dL)	NN1218-4131	TRTPN
6	1	P9PGIEU	PPG increment main evening meal (SMPG) (mg/dL)	NN1218-4131	TRTPN
7	1	P9PGILU	PPG increment lunch (SMPG) (mg/dL)	NN1218-4131	TRTPN
8	1	P9PGILU	PPG increment lunch (SMPG) (mg/dL)	NN1218-4131	TRTPN
9	1	P9PGILU	PPG increment lunch (SMPG) (mg/dL)	NN1218-4131	TRTPN
10	1	P9PGINC	PPG increment all meals (SMPG) (mmol/L)	NN1218-4131	TRTPN
11	1	P9PGINC	PPG increment all meals (SMPG) (mmol/L)	NN1218-4131	TRTPN
12	1	P9PGINC	PPG increment all meals (SMPG) (mmol/L)	NN1218-4131	TRTPN
13	1	P9PGINCB	PPG increment breakfast (SMPG) (mmol/L)	NN1218-4131	TRTPN
14	1	P9PGINCB	PPG increment breakfast (SMPG) (mmol/L)	NN1218-4131	TRTPN

Obs	TRTPN	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	2	WORK.IMPUTE	-16.3271	2.5763	978	-6.34	<.0001	0.05	-21.3828	-11.2714
2	3	WORK.IMPUTE	1.1663	2.5553	978	0.46	0.6482	0.05	-3.8481	6.1807
3	4	WORK.IMPUTE	-5.7880	2.5626	978	-2.26	0.0241	0.05	-10.8168	-0.7592
4	2	WORK.IMPUTE	-4.2884	2.7790	971	-1.54	0.1231	0.05	-9.7420	1.1653
5	3	WORK.IMPUTE	8.7566	2.7732	971	3.16	0.0016	0.05	3.3145	14.1988
6	4	WORK.IMPUTE	1.5108	2.7653	971	0.55	0.5850	0.05	-3.9159	6.9375
7	2	WORK.IMPUTE	-9.5949	2.5009	974	-3.84	0.0001	0.05	-14.5027	-4.6872
8	3	WORK.IMPUTE	0.09870	2.5027	974	0.04	0.9685	0.05	-4.8125	5.0099
9	4	WORK.IMPUTE	-3.3359	2.4922	974	-1.34	0.1810	0.05	-8.2267	1.5548
10	2	WORK.IMPUTE	-0.5865	0.09181	966	-6.39	<.0001	0.05	-0.7667	-0.4063
11	3	WORK.IMPUTE	0.1390	0.09173	966	1.52	0.1299	0.05	-0.04098	0.3190
12	4	WORK.IMPUTE	-0.1013	0.09108	966	-1.11	0.2663	0.05	-0.2800	0.07743
13	2	WORK.IMPUTE	-0.9061	0.1430	978	-6.34	<.0001	0.05	-1.1866	-0.6255
14	3	WORK.IMPUTE	0.06472	0.1418	978	0.46	0.6482	0.05	-0.2135	0.3430

nn1218/nn1218-4131/ctr_20180214_er
10FEB2018:18:44:27 - a_797pp_stat_diff.sas/a_9pp_ppginc_stat_on_fas_app.txt

Fast-acting insulin aspart
NN1218-4131

Clinical Trial Report
Statistical document

Date:
Version:

14 February 2018
1.0

Status:
Page:

Final
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Novo Nordisk

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation -
statistical analysis - on-treatment - full analysis set

The Mixed procedure
Least Squares Means

Obs	_Imputation_	PARAMCD	PARAM	STUDYID	Effect
15	1	P9PGINCB	PPG increment breakfast (SMPG) (mmol/L)	NN1218-4131	TRTPN
16	1	P9PGINCE	PPG increment main evening meal (SMPG) (mmol/L)	NN1218-4131	TRTPN
17	1	P9PGINCE	PPG increment main evening meal (SMPG) (mmol/L)	NN1218-4131	TRTPN
18	1	P9PGINCE	PPG increment main evening meal (SMPG) (mmol/L)	NN1218-4131	TRTPN
19	1	P9PGINCL	PPG increment lunch (SMPG) (mmol/L)	NN1218-4131	TRTPN
20	1	P9PGINCL	PPG increment lunch (SMPG) (mmol/L)	NN1218-4131	TRTPN
21	1	P9PGINCL	PPG increment lunch (SMPG) (mmol/L)	NN1218-4131	TRTPN
22	1	P9PGIU	PPG increment all meals (SMPG) (mg/dL)	NN1218-4131	TRTPN
23	1	P9PGIU	PPG increment all meals (SMPG) (mg/dL)	NN1218-4131	TRTPN
24	1	P9PGIU	PPG increment all meals (SMPG) (mg/dL)	NN1218-4131	TRTPN

Obs	TRTPN	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
15	4	WORK.IMPUTE	-0.3212	0.1422	978	-2.26	0.0241	0.05	-0.6003	-0.04213
16	2	WORK.IMPUTE	-0.2380	0.1542	971	-1.54	0.1231	0.05	-0.5406	0.06466
17	3	WORK.IMPUTE	0.4859	0.1539	971	3.16	0.0016	0.05	0.1839	0.7879
18	4	WORK.IMPUTE	0.08384	0.1535	971	0.55	0.5850	0.05	-0.2173	0.3850
19	2	WORK.IMPUTE	-0.5325	0.1388	974	-3.84	0.0001	0.05	-0.8048	-0.2601
20	3	WORK.IMPUTE	0.005477	0.1389	974	0.04	0.9685	0.05	-0.2671	0.2780
21	4	WORK.IMPUTE	-0.1851	0.1383	974	-1.34	0.1810	0.05	-0.4565	0.08628
22	2	WORK.IMPUTE	-10.5688	1.6545	966	-6.39	<.0001	0.05	-13.8155	-7.3220
23	3	WORK.IMPUTE	2.5053	1.6529	966	1.52	0.1299	0.05	-0.7384	5.7490
24	4	WORK.IMPUTE	-1.8254	1.6412	966	-1.11	0.2663	0.05	-5.0461	1.3953

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Least Squares Means Estimate

Parameter Code=P9PGIBU Parameter=PPG increment breakfast (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
1	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
2	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	WORK.IMPUTE	-10.5391	3.6363	978	-2.90	0.0038	0.05	-17.6749	-3.4034
2	WORK.IMPUTE	6.9543	3.6193	978	1.92	0.0550	0.05	-0.1482	14.0568

Parameter Code=P9PGIEU Parameter=PPG increment main evening meal (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
3	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
4	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
3	WORK.IMPUTE	-5.7992	3.9241	971	-1.48	0.1398	0.05	-13.4999	1.9016
4	WORK.IMPUTE	7.2458	3.9178	971	1.85	0.0647	0.05	-0.4425	14.9341

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Least Squares Means Estimate

Parameter Code=P9PGILU Parameter=PPG increment lunch (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
5	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
6	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
5	WORK.IMPUTE	-6.2590	3.5344	974	-1.77	0.0769	0.05	-13.1950	0.6770
6	WORK.IMPUTE	3.4346	3.5327	974	0.97	0.3312	0.05	-3.4981	10.3673

Parameter Code=P9PGINC Parameter=PPG increment all meals (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
7	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
8	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
7	WORK.IMPUTE	-0.4852	0.1295	966	-3.75	0.0002	0.05	-0.7393	-0.2311
8	WORK.IMPUTE	0.2403	0.1293	966	1.86	0.0634	0.05	-0.01340	0.4941

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Least Squares Means Estimate

Parameter Code=P9PGINCB Parameter=PPG increment breakfast (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
9	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
10	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
9	WORK.IMPUTE	-0.5849	0.2018	978	-2.90	0.0038	0.05	-0.9808	-0.1889
10	WORK.IMPUTE	0.3859	0.2008	978	1.92	0.0550	0.05	-0.00822	0.7801

Parameter Code=P9PGINCE Parameter=PPG increment main evening meal (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
11	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
12	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
11	WORK.IMPUTE	-0.3218	0.2178	971	-1.48	0.1398	0.05	-0.7492	0.1055
12	WORK.IMPUTE	0.4021	0.2174	971	1.85	0.0647	0.05	-0.02455	0.8288

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Least Squares Means Estimate

Parameter Code=P9PGINCL Parameter=PPG increment lunch (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
13	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
14	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
13	WORK.IMPUTE	-0.3473	0.1961	974	-1.77	0.0769	0.05	-0.7322	0.03757
14	WORK.IMPUTE	0.1906	0.1960	974	0.97	0.3312	0.05	-0.1941	0.5753

Parameter Code=P9PGIU Parameter=PPG increment all meals (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
15	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
16	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
15	WORK.IMPUTE	-8.7433	2.3331	966	-3.75	0.0002	0.05	-13.3219	-4.1647
16	WORK.IMPUTE	4.3307	2.3298	966	1.86	0.0634	0.05	-0.2414	8.9029

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9PGIBU Parameter=PPG increment breakfast (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.599212	6.700760	7.300002	2.97E6	0.089429	0.082088	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-16.787665	2.701852	-22.0832	-11.4921	2.97E6	-19.834413	-13.657912

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-6.21	<.0001

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9PGIEU Parameter=PPG increment main evening meal (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.570580	7.647514	8.218123	4.15E6	0.074614	0.069433	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-4.002324	2.866727	-9.62101	1.616359	4.15E6	-7.075971	-0.978398

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-1.40	0.1627

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2618 of 4425	Novo Nordisk
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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9PGILU Parameter=PPG increment lunch (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.509065	6.367411	6.876501	3.65E6	0.079952	0.074034	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-9.587754	2.622308	-14.7274	-4.44812	3.65E6	-12.410399	-6.827441

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-3.66	0.0003

nn1218/nn1218-4131/ctr_20180214_er
10FEB2018:18:44:27 - a_797pp_stat_diff.sas/a_9pp_ppginc_stat_on_fas_app.txt

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2619 of 4425	Novo Nordisk
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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9PPGINC Parameter=PPG increment all meals (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000772	0.008481	0.009253	2.87E6	0.091032	0.083438	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.594095	0.096193	-0.78263	-0.40556	2.87E6	-0.712684	-0.481714

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-6.18	<.0001

nn1218/nn1218-4131/ctr_20180214_er
10FEB2018:18:44:27 - a_797pp_stat_diff.sas/a_9pp_ppginc_stat_on_fas_app.txt

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9PGINCB Parameter=PPG increment breakfast (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.001845	0.020635	0.022481	2.97E6	0.089429	0.082088	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.931613	0.149936	-1.22548	-0.63774	2.97E6	-1.100689	-0.757931

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-6.21	<.0001

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2621 of 4425	Novo Nordisk
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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9PGINCE Parameter=PPG increment main evening meal (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.001757	0.023551	0.025308	4.15E6	0.074614	0.069433	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.222105	0.159086	-0.53391	0.089698	4.15E6	-0.392673	-0.054295

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-1.40	0.1627

nn1218/nn1218-4131/ctr_20180214_er
10FEB2018:18:44:27 - a_797pp_stat_diff.sas/a_9pp_ppginc_stat_on_fas_app.txt

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9PGINCL Parameter=PPG increment lunch (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.001568	0.019609	0.021177	3.65E6	0.079952	0.074034	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.532062	0.145522	-0.81728	-0.24684	3.65E6	-0.688701	-0.378881

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-3.66	0.0003

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9PGIU Parameter=PPG increment all meals (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.250688	2.753972	3.004672	2.87E6	0.091032	0.083438	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-10.705594	1.733399	-14.1030	-7.30819	2.87E6	-12.842569	-8.680482

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-6.18	<.0001

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9PGIBU Parameter=PPG increment breakfast (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.322706	6.591789	6.914511	9.18E6	0.048958	0.046673	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.819385	2.629546	-4.33443	5.973200	9.18E6	-1.198061	3.072058

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	0.31	0.7553

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9PGIEU Parameter=PPG increment main evening meal (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.352347	7.615373	7.967738	1.02E7	0.046270	0.044224	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits	DF	Minimum	Maximum
Estimate	8.215983	2.822718	2.683556 13.74841	1.02E7	5.843601	10.457198

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	2.91	0.0036

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9PGILU Parameter=PPG increment lunch (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.348279	6.376317	6.724614	7.45E6	0.054624	0.051795	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits	DF	Minimum	Maximum
Estimate	-0.313452	2.593186	-5.39600 4.769100	7.45E6	-2.764391	1.955886

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-0.12	0.9038

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9PGINC Parameter=PPG increment all meals (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000419	0.008465	0.008884	8.97E6	0.049548	0.047209	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.134958	0.094258	-0.04978	0.319700	8.97E6	0.053034	0.213660

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	1.43	0.1522

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9PGINCB Parameter=PPG increment breakfast (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000994	0.020300	0.021294	9.18E6	0.048958	0.046673	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.045471	0.145924	-0.24053	0.331476	9.18E6	-0.066485	0.170480

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	0.31	0.7553

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9PPGINCE Parameter=PPG increment main evening meal (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.001085	0.023452	0.024537	1.02E7	0.046270	0.044224	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.455937	0.156644	0.148921	0.762953	1.02E7	0.324284	0.580311

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	2.91	0.0036

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Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2630 of 4425	Novo Nordisk
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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9PGINCL Parameter=PPG increment lunch (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.001073	0.019636	0.020709	7.45E6	0.054624	0.051795	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.017395	0.143906	-0.29945	0.264656	7.45E6	-0.153407	0.108540

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-0.12	0.9038

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Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2631 of 4425	Novo Nordisk
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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9PGIU Parameter=PPG increment all meals (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.136189	2.748781	2.884977	8.97E6	0.049548	0.047209	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	2.431946	1.698522	-0.89710	5.760988	8.97E6	0.955664	3.850158

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	1.43	0.1522

nn1218/nn1218-4131/ctr_20180214_er
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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9PGIBU Parameter=PPG increment breakfast (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.517793	6.629678	7.147496	3.81E6	0.078106	0.072448	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-6.328698	2.673480	-11.5686	-1.08877	3.81E6	-9.195792	-3.608365

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-2.37	0.0179

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9PGIEU Parameter=PPG increment main evening meal (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.602256	7.572279	8.174565	3.68E6	0.079538	0.073679	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	2.532898	2.859120	-3.07088	8.136671	3.68E6	-0.416992	5.635171

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	0.89	0.3757

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9PGILU Parameter=PPG increment lunch (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.518870	6.323220	6.842116	3.48E6	0.082062	0.075839	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-2.886167	2.615744	-8.01293	2.240598	3.48E6	-5.744078	-0.145204

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-1.10	0.2699

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Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2635 of 4425	Novo Nordisk
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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9PPGINC Parameter=PPG increment all meals (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000738	0.008346	0.009084	3.03E6	0.088478	0.081286	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.120427	0.095309	-0.30723	0.066376	3.03E6	-0.230519	-0.001612

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-1.26	0.2064

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Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2636 of 4425	Novo Nordisk
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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9PGINCB Parameter=PPG increment breakfast (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.001595	0.020417	0.022011	3.81E6	0.078106	0.072448	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.351204	0.148362	-0.64199	-0.06042	3.81E6	-0.510310	-0.200242

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-2.37	0.0179

nn1218/nn1218-4131/ctr_20180214_er
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Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2637 of 4425	Novo Nordisk
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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9PGINCE Parameter=PPG increment main evening meal (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.001855	0.023319	0.025174	3.68E6	0.079538	0.073679	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.140560	0.158664	-0.17041	0.451536	3.68E6	-0.023141	0.312718

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	0.89	0.3757

nn1218/nn1218-4131/ctr_20180214_er
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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9PGINCL Parameter=PPG increment lunch (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.001598	0.019473	0.021071	3.48E6	0.082062	0.075839	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.160165	0.145158	-0.44467	0.124340	3.48E6	-0.318761	-0.008058

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-1.10	0.2699

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2639 of 4425	Novo Nordisk
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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9PGIU Parameter=PPG increment all meals (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.239758	2.709957	2.949727	3.03E6	0.088478	0.081286	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-2.170099	1.717477	-5.53629	1.196095	3.03E6	-4.153958	-0.029053

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-1.26	0.2064

nn1218/nn1218-4131/ctr_20180214_er
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Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2640 of 4425	Novo Nordisk
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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=P9PGIBU Label=Faster aspart (meal) - NovoRapid (meal) Parameter=PPG increment breakfast (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	1.136830	13.348801	14.485688	3.25E6	0.085168	0.078484	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-10.458967	3.806007	-17.9186	-2.99933	3.25E6	-14.562379	-6.324453

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-2.75	0.0060

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=P9PGIBU Label=Faster aspart (post) - NovoRapid (meal) Parameter=PPG increment breakfast (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.844909	13.224580	14.069532	5.55E6	0.063892	0.060056	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits	DF	Minimum	Maximum
Estimate	7.148083	3.750937	-0.20362 14.49979	5.55E6	2.612340	10.987624

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	1.91	0.0567

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2642 of 4425	Novo Nordisk
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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=P9PGIEU Label=Faster aspart (meal) - NovoRapid (meal) Parameter=PPG increment main evening meal (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	1.186655	15.248139	16.434854	3.84E6	0.077827	0.072208	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-6.535222	4.053992	-14.4809	1.410460	3.84E6	-10.500234	-2.135364

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-1.61	0.1070

nn1218/nn1218-4131/ctr_20180214_er
10FEB2018:18:44:27 - a_797pp_stat_diff.sas/a_9pp_ppginc_stat_on_fas_app.txt

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2643 of 4425	Novo Nordisk
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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=P9PGIEU Label=Faster aspart (post) - NovoRapid (meal) Parameter=PPG increment main evening meal (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.956789	15.198804	16.155641	5.7E6	0.062955	0.059227	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits	DF	Minimum	Maximum
Estimate	5.683085	4.019408	-2.19481 13.56098	5.7E6	1.869245	9.352429

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	1.41	0.1574

nn1218/nn1218-4131/ctr_20180214_er
10FEB2018:18:44:27 - a_797pp_stat_diff.sas/a_9pp_ppginc_stat_on_fas_app.txt

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2644 of 4425	Novo Nordisk
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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=P9PGILU Label=Faster aspart (meal) - NovoRapid (meal) Parameter=PPG increment lunch (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	1.046232	12.717748	13.764033	3.46E6	0.082270	0.076016	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-6.701587	3.709991	-13.9730	0.569864	3.46E6	-10.968608	-2.308270

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-1.81	0.0709

nn1218/nn1218-4131/ctr_20180214_er
10FEB2018:18:44:27 - a_797pp_stat_diff.sas/a_9pp_ppginc_stat_on_fas_app.txt

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2645 of 4425	Novo Nordisk
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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=P9PGILU Label=Faster aspart (post) - NovoRapid (meal) Parameter=PPG increment lunch (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.866451	12.705547	13.572041	4.91E6	0.068198	0.063844	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	2.572715	3.684025	-4.64784	9.793273	4.91E6	-1.181537	6.198023

Parameter Estimates

Parameter	Theta0	t for H0: Parameter=Theta0	Pr > t
Estimate	0	0.70	0.4850

nn1218/nn1218-4131/ctr_20180214_er
10FEB2018:18:44:27 - a_797pp_stat_diff.sas/a_9pp_ppginc_stat_on_fas_app.txt

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2646 of 4425	Novo Nordisk
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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=P9PGINC Label=Faster aspart (meal) - NovoRapid (meal) Parameter=PPG increment all meals (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.001541	0.016866	0.018407	2.85E6	0.091371	0.083722	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.473668	0.135674	-0.73958	-0.20775	2.85E6	-0.645569	-0.298728

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-3.49	0.0005

nn1218/nn1218-4131/ctr_20180214_er
10FEB2018:18:44:27 - a_797pp_stat_diff.sas/a_9pp_ppginc_stat_on_fas_app.txt

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2647 of 4425	Novo Nordisk
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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=P9PGINC Label=Faster aspart (post) - NovoRapid (meal) Parameter=PPG increment all meals (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.001166	0.016819	0.017985	4.76E6	0.069325	0.064831	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.255385	0.134107	-0.00746	0.518231	4.76E6	0.100238	0.391029

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	1.90	0.0569

nn1218/nn1218-4131/ctr_20180214_er
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Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2648 of 4425	Novo Nordisk
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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=P9PGINCB Label=Faster aspart (meal) - NovoRapid (meal) Parameter=PPG increment breakfast (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.003501	0.041109	0.044610	3.25E6	0.085168	0.078484	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.580409	0.211210	-0.99437	-0.16644	3.25E6	-0.808123	-0.350969

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-2.75	0.0060

nn1218/nn1218-4131/ctr_20180214_er
10FEB2018:18:44:27 - a_797pp_stat_diff.sas/a_9pp_ppginc_stat_on_fas_app.txt

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2649 of 4425	Novo Nordisk
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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=P9PGINCB Label=Faster aspart (post) - NovoRapid (meal) Parameter=PPG increment breakfast (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.002602	0.040726	0.043328	5.55E6	0.063892	0.060056	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.396675	0.208154	-0.01130	0.804650	5.55E6	0.144969	0.609746

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	1.91	0.0567

nn1218/nn1218-4131/ctr_20180214_er
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Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2650 of 4425	Novo Nordisk
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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=P9PGINCE Label=Faster aspart (meal) - NovoRapid (meal) Parameter=PPG increment main evening meal (SMPG) (mmol/

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.003654	0.046958	0.050612	3.84E6	0.077827	0.072208	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.362665	0.224972	-0.80360	0.078272	3.84E6	-0.582699	-0.118500

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-1.61	0.1070

nn1218/nn1218-4131/ctr_20180214_er
10FEB2018:18:44:27 - a_797pp_stat_diff.sas/a_9pp_ppginc_stat_on_fas_app.txt

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2651 of 4425	Novo Nordisk
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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=P9PGINCE Label=Faster aspart (post) - NovoRapid (meal) Parameter=PPG increment main evening meal (SMPG) (mmol/

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.002947	0.046806	0.049752	5.7E6	0.062955	0.059227	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.315377	0.223053	-0.12180	0.752552	5.7E6	0.103732	0.519003

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	1.41	0.1574

nn1218/nn1218-4131/ctr_20180214_er
10FEB2018:18:44:27 - a_797pp_stat_diff.sas/a_9pp_ppginc_stat_on_fas_app.txt

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2652 of 4425	Novo Nordisk
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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=P9PGINCL Label=Faster aspart (meal) - NovoRapid (meal) Parameter=PPG increment lunch (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.003222	0.039165	0.042387	3.46E6	0.082270	0.076016	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.371897	0.205882	-0.77542	0.031624	3.46E6	-0.608691	-0.128095

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-1.81	0.0709

nn1218/nn1218-4131/ctr_20180214_er
10FEB2018:18:44:27 - a_797pp_stat_diff.sas/a_9pp_ppginc_stat_on_fas_app.txt

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2653 of 4425	Novo Nordisk
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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=P9PGINCL Label=Faster aspart (post) - NovoRapid (meal) Parameter=PPG increment lunch (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.002668	0.039128	0.041796	4.91E6	0.068198	0.063844	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.142770	0.204441	-0.25793	0.543467	4.91E6	-0.065568	0.343952

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	0.70	0.4850

nn1218/nn1218-4131/ctr_20180214_er
10FEB2018:18:44:27 - a_797pp_stat_diff.sas/a_9pp_ppginc_stat_on_fas_app.txt

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2654 of 4425	Novo Nordisk
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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=P9PGIU Label=Faster aspart (meal) - NovoRapid (meal) Parameter=PPG increment all meals (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.500394	5.476811	5.977230	2.85E6	0.091371	0.083722	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-8.535495	2.444838	-13.3273	-3.74370	2.85E6	-11.633158	-5.383077

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-3.49	0.0005

nn1218/nn1218-4131/ctr_20180214_er
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Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2655 of 4425	Novo Nordisk
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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=P9PGIU Label=Faster aspart (post) - NovoRapid (meal) Parameter=PPG increment all meals (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.378593	5.461399	5.840011	4.76E6	0.069325	0.064831	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	4.602045	2.416611	-0.13443	9.338518	4.76E6	1.806297	7.046343

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	1.90	0.0569

nn1218/nn1218-4131/ctr_20180214_er
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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure Model Information

Parameter Code=P9PGIBU Parameter=PPG increment breakfast (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Data Set	WORK.IMPUTE_ABS
2	1	NN1218-4131	Dependent Variable	eotVisitAbs
3	1	NN1218-4131	Covariance Structure	Diagonal
4	1	NN1218-4131	Estimation Method	REML
5	1	NN1218-4131	Residual Variance Method	Profile
6	1	NN1218-4131	Fixed Effects SE Method	Model-Based
7	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=P9PGIEU Parameter=PPG increment main evening meal (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
8	1	NN1218-4131	Data Set	WORK.IMPUTE_ABS
9	1	NN1218-4131	Dependent Variable	eotVisitAbs
10	1	NN1218-4131	Covariance Structure	Diagonal
11	1	NN1218-4131	Estimation Method	REML
12	1	NN1218-4131	Residual Variance Method	Profile
13	1	NN1218-4131	Fixed Effects SE Method	Model-Based
14	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=P9PGILU Parameter=PPG increment lunch (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
15	1	NN1218-4131	Data Set	WORK.IMPUTE_ABS
16	1	NN1218-4131	Dependent Variable	eotVisitAbs
17	1	NN1218-4131	Covariance Structure	Diagonal

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Model Information

Parameter Code=P9PGILU Parameter=PPG increment lunch (SMPG) (mg/dL)

(continued)

Obs	_Imputation_	STUDYID	Descr	Value
18	1	NN1218-4131	Estimation Method	REML
19	1	NN1218-4131	Residual Variance Method	Profile
20	1	NN1218-4131	Fixed Effects SE Method	Model-Based
21	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=P9PGINC Parameter=PPG increment all meals (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
22	1	NN1218-4131	Data Set	WORK.IMPUTE_ABS
23	1	NN1218-4131	Dependent Variable	eotVisitAbs
24	1	NN1218-4131	Covariance Structure	Diagonal
25	1	NN1218-4131	Estimation Method	REML
26	1	NN1218-4131	Residual Variance Method	Profile
27	1	NN1218-4131	Fixed Effects SE Method	Model-Based
28	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=P9PGINCB Parameter=PPG increment breakfast (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
29	1	NN1218-4131	Data Set	WORK.IMPUTE_ABS
30	1	NN1218-4131	Dependent Variable	eotVisitAbs
31	1	NN1218-4131	Covariance Structure	Diagonal
32	1	NN1218-4131	Estimation Method	REML

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Model Information

Parameter Code=P9PGINCB Parameter=PPG increment breakfast (SMPG) (mmol/L)

(continued)

Obs	_Imputation_	STUDYID	Descr	Value
33	1	NN1218-4131	Residual Variance Method	Profile
34	1	NN1218-4131	Fixed Effects SE Method	Model-Based
35	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=P9PGINCE Parameter=PPG increment main evening meal (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
36	1	NN1218-4131	Data Set	WORK.IMPUTE_ABS
37	1	NN1218-4131	Dependent Variable	eotVisitAbs
38	1	NN1218-4131	Covariance Structure	Diagonal
39	1	NN1218-4131	Estimation Method	REML
40	1	NN1218-4131	Residual Variance Method	Profile
41	1	NN1218-4131	Fixed Effects SE Method	Model-Based
42	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=P9PGINCL Parameter=PPG increment lunch (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
43	1	NN1218-4131	Data Set	WORK.IMPUTE_ABS
44	1	NN1218-4131	Dependent Variable	eotVisitAbs
45	1	NN1218-4131	Covariance Structure	Diagonal
46	1	NN1218-4131	Estimation Method	REML
47	1	NN1218-4131	Residual Variance Method	Profile

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Model Information

Parameter Code=P9PGINCL Parameter=PPG increment lunch (SMPG) (mmol/L)

(continued)

Obs	_Imputation_	STUDYID	Descr	Value
48	1	NN1218-4131	Fixed Effects SE Method	Model-Based
49	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=P9PGIU Parameter=PPG increment all meals (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
50	1	NN1218-4131	Data Set	WORK.IMPUTE_ABS
51	1	NN1218-4131	Dependent Variable	eotVisitAbs
52	1	NN1218-4131	Covariance Structure	Diagonal
53	1	NN1218-4131	Estimation Method	REML
54	1	NN1218-4131	Residual Variance Method	Profile
55	1	NN1218-4131	Fixed Effects SE Method	Model-Based
56	1	NN1218-4131	Degrees of Freedom Method	Residual

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Class Level Information

Parameter Code=P9PGIEU Parameter=PPG increment main evening meal (SMPG) (mg/dL)

Ob- s	—	Input ID	STUDY	Class	Level	Values	Unit
4	1	NN1218-4131	TRTPN		3 2 3 4		5
5	1	NN1218-4131	REGION1		4 ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA		49
6	1	NN1218-4131	BOLAD1		2 BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULI		85

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Class Level Information

Parameter Code=P9PGILU Parameter=PPG increment lunch (SMPG) (mg/dL)

Obs	Input	STUDY ID	Class	Level	Values	min
7	1	NN1218-4131	TRTPN	3	2 3 4	5
8	1	NN1218-4131	REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA	49
9	1	NN1218-4131	BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULI	85

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Class Level Information

Parameter Code=P9PGINCB Parameter=PPG increment breakfast (SMPG) (mmol/L)

Obs	Inpution	STUDY ID	Classs	Level	Values	min
13	1	NN1218-4131	TRTPN	3 2 3 4		5
14	1	NN1218-4131	REGION1	4 ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA		49
15	1	NN1218-4131	BOLAD1	2 BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULI		85

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Class Level Information

Parameter Code=P9PGINCE Parameter=PPG increment main evening meal (SMPG) (mmol/L)

		Input		Output		Level		Variable		Missing	
		O		n		D		I		s	
		s		-		D		s		s	
16	1	NN1218-4131	TRTPN	3	2	3	4				5
17	1	NN1218-4131	REGION1	4	ASIA (EXCLUDING JAPAN)	EUROPE	JAPAN	NORTH AMERICA			49
18	1	NN1218-4131	BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	CARBOHYDRATE COUNTING (FLEXIBLE)	BOLUS INSULI				85

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nn1218/nn1218-4131/ctr_20180214_er
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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Class Level Information

Parameter Code=P9PGIU Parameter=PPG increment all meals (SMPG) (mg/dL)

		Input		Output		Level		Variable		Measure	
O	b	s	—	S	T	C	L	V	a	l	g
				U	D	a	e	l			t
				Y	I	s	s	u			
				D	D	s	s	s			h
22	1	NN1218-4131	TRTPN				3 2 3 4				5
23	1	NN1218-4131	REGION1				4 ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA				49
24	1	NN1218-4131	BOLAD1				2 BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULI				85

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Dimensions

Parameter Code=P9PGIBU Parameter=PPG increment breakfast (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Covariance Parameters	1
2	1	NN1218-4131	Columns in X	10
3	1	NN1218-4131	Columns in Z	0
4	1	NN1218-4131	Subjects	1
5	1	NN1218-4131	Max Obs per Subject	986

Parameter Code=P9PGIEU Parameter=PPG increment main evening meal (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
6	1	NN1218-4131	Covariance Parameters	1
7	1	NN1218-4131	Columns in X	10
8	1	NN1218-4131	Columns in Z	0
9	1	NN1218-4131	Subjects	1
10	1	NN1218-4131	Max Obs per Subject	979

Parameter Code=P9PGILU Parameter=PPG increment lunch (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
11	1	NN1218-4131	Covariance Parameters	1
12	1	NN1218-4131	Columns in X	10
13	1	NN1218-4131	Columns in Z	0
14	1	NN1218-4131	Subjects	1
15	1	NN1218-4131	Max Obs per Subject	982

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Dimensions

Parameter Code=P9PGINC Parameter=PPG increment all meals (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
16	1	NN1218-4131	Covariance Parameters	1
17	1	NN1218-4131	Columns in X	10
18	1	NN1218-4131	Columns in Z	0
19	1	NN1218-4131	Subjects	1
20	1	NN1218-4131	Max Obs per Subject	974

Parameter Code=P9PGINCB Parameter=PPG increment breakfast (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
21	1	NN1218-4131	Covariance Parameters	1
22	1	NN1218-4131	Columns in X	10
23	1	NN1218-4131	Columns in Z	0
24	1	NN1218-4131	Subjects	1
25	1	NN1218-4131	Max Obs per Subject	986

Parameter Code=P9PGINCE Parameter=PPG increment main evening meal (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
26	1	NN1218-4131	Covariance Parameters	1
27	1	NN1218-4131	Columns in X	10
28	1	NN1218-4131	Columns in Z	0
29	1	NN1218-4131	Subjects	1
30	1	NN1218-4131	Max Obs per Subject	979

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Dimensions

Parameter Code=P9PGINCL Parameter=PPG increment lunch (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
31	1	NN1218-4131	Covariance Parameters	1
32	1	NN1218-4131	Columns in X	10
33	1	NN1218-4131	Columns in Z	0
34	1	NN1218-4131	Subjects	1
35	1	NN1218-4131	Max Obs per Subject	982

Parameter Code=P9PGIU Parameter=PPG increment all meals (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
36	1	NN1218-4131	Covariance Parameters	1
37	1	NN1218-4131	Columns in X	10
38	1	NN1218-4131	Columns in Z	0
39	1	NN1218-4131	Subjects	1
40	1	NN1218-4131	Max Obs per Subject	974

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Number of Observations

Parameter Code=P9PGIBU Parameter=PPG increment breakfast (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
1	1	NN1218-4131	Number of Observations Read	986	986	986	986	986
2	1	NN1218-4131	Number of Observations Used	986	986	986	986	986
3	1	NN1218-4131	Number of Observations Not Used	0	986	986	986	986

Parameter Code=P9PGIEU Parameter=PPG increment main evening meal (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
4	1	NN1218-4131	Number of Observations Read	979	979	979	979	979
5	1	NN1218-4131	Number of Observations Used	979	979	979	979	979
6	1	NN1218-4131	Number of Observations Not Used	0	979	979	979	979

Parameter Code=P9PGILU Parameter=PPG increment lunch (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
7	1	NN1218-4131	Number of Observations Read	982	982	982	982	982
8	1	NN1218-4131	Number of Observations Used	982	982	982	982	982
9	1	NN1218-4131	Number of Observations Not Used	0	982	982	982	982

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Number of Observations

Parameter Code=P9PGINC Parameter=PPG increment all meals (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
10	1	NN1218-4131	Number of Observations Read	974	974	974	974	974
11	1	NN1218-4131	Number of Observations Used	974	974	974	974	974
12	1	NN1218-4131	Number of Observations Not Used	0	974	974	974	974

Parameter Code=P9PGINCB Parameter=PPG increment breakfast (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
13	1	NN1218-4131	Number of Observations Read	986	986	986	986	986
14	1	NN1218-4131	Number of Observations Used	986	986	986	986	986
15	1	NN1218-4131	Number of Observations Not Used	0	986	986	986	986

Parameter Code=P9PGINCE Parameter=PPG increment main evening meal (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
16	1	NN1218-4131	Number of Observations Read	979	979	979	979	979
17	1	NN1218-4131	Number of Observations Used	979	979	979	979	979
18	1	NN1218-4131	Number of Observations Not Used	0	979	979	979	979

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Number of Observations

Parameter Code=P9PGINCL Parameter=PPG increment lunch (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
19	1	NN1218-4131	Number of Observations Read	982	982	982	982	982
20	1	NN1218-4131	Number of Observations Used	982	982	982	982	982
21	1	NN1218-4131	Number of Observations Not Used	0	982	982	982	982

Parameter Code=P9PGIU Parameter=PPG increment all meals (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
22	1	NN1218-4131	Number of Observations Read	974	974	974	974	974
23	1	NN1218-4131	Number of Observations Used	974	974	974	974	974
24	1	NN1218-4131	Number of Observations Not Used	0	974	974	974	974

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Covariance Parameter Estimates

Parameter Code=P9PGIBU Parameter=PPG increment breakfast (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	CovParm	Estimate
1	1	NN1218-4131	Residual	2157.02

Parameter Code=P9PGIEU Parameter=PPG increment main evening meal (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	CovParm	Estimate
20001	1	NN1218-4131	Residual	2501.76

Parameter Code=P9PGILU Parameter=PPG increment lunch (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	CovParm	Estimate
40001	1	NN1218-4131	Residual	2038.14

Parameter Code=P9PGINC Parameter=PPG increment all meals (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	CovParm	Estimate
60001	1	NN1218-4131	Residual	2.7130

Parameter Code=P9PGINCB Parameter=PPG increment breakfast (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	CovParm	Estimate
80001	1	NN1218-4131	Residual	6.6427

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Covariance Parameter Estimates

Parameter Code=P9PGINCE Parameter=PPG increment main evening meal (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	CovParm	Estimate
100001	1	NN1218-4131	Residual	7.7044

Parameter Code=P9PGINCL Parameter=PPG increment lunch (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	CovParm	Estimate
120001	1	NN1218-4131	Residual	6.2766

Parameter Code=P9PGIU Parameter=PPG increment all meals (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	CovParm	Estimate
140001	1	NN1218-4131	Residual	880.97

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Fit Statistics

Parameter Code=P9PGIBU Parameter=PPG increment breakfast (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	-2 Res Log Likelihood	10335.6
2	1	NN1218-4131	AIC (Smaller is Better)	10337.6
3	1	NN1218-4131	AICC (Smaller is Better)	10337.6
4	1	NN1218-4131	BIC (Smaller is Better)	10342.4

Parameter Code=P9PGIEU Parameter=PPG increment main evening meal (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
5	1	NN1218-4131	-2 Res Log Likelihood	10405.8
6	1	NN1218-4131	AIC (Smaller is Better)	10407.8
7	1	NN1218-4131	AICC (Smaller is Better)	10407.8
8	1	NN1218-4131	BIC (Smaller is Better)	10412.7

Parameter Code=P9PGILU Parameter=PPG increment lunch (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
9	1	NN1218-4131	-2 Res Log Likelihood	10237.9
10	1	NN1218-4131	AIC (Smaller is Better)	10239.9
11	1	NN1218-4131	AICC (Smaller is Better)	10240.0
12	1	NN1218-4131	BIC (Smaller is Better)	10244.8

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The Mixed procedure
Fit Statistics

Parameter Code=P9PGINC Parameter=PPG increment all meals (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
13	1	NN1218-4131	-2 Res Log Likelihood	3751.2
14	1	NN1218-4131	AIC (Smaller is Better)	3753.2
15	1	NN1218-4131	AICC (Smaller is Better)	3753.2
16	1	NN1218-4131	BIC (Smaller is Better)	3758.1

Parameter Code=P9PGINCB Parameter=PPG increment breakfast (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
17	1	NN1218-4131	-2 Res Log Likelihood	4674.0
18	1	NN1218-4131	AIC (Smaller is Better)	4676.0
19	1	NN1218-4131	AICC (Smaller is Better)	4676.0
20	1	NN1218-4131	BIC (Smaller is Better)	4680.9

Parameter Code=P9PGINCE Parameter=PPG increment main evening meal (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
21	1	NN1218-4131	-2 Res Log Likelihood	4784.8
22	1	NN1218-4131	AIC (Smaller is Better)	4786.8
23	1	NN1218-4131	AICC (Smaller is Better)	4786.8
24	1	NN1218-4131	BIC (Smaller is Better)	4791.6

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The Mixed procedure
Fit Statistics

Parameter Code=P9PGINCL Parameter=PPG increment lunch (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
25	1	NN1218-4131	-2 Res Log Likelihood	4599.6
26	1	NN1218-4131	AIC (Smaller is Better)	4601.6
27	1	NN1218-4131	AICC (Smaller is Better)	4601.6
28	1	NN1218-4131	BIC (Smaller is Better)	4606.4

Parameter Code=P9PGIU Parameter=PPG increment all meals (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
29	1	NN1218-4131	-2 Res Log Likelihood	9343.4
30	1	NN1218-4131	AIC (Smaller is Better)	9345.4
31	1	NN1218-4131	AICC (Smaller is Better)	9345.4
32	1	NN1218-4131	BIC (Smaller is Better)	9350.2

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The Mixed procedure
Solution for Fixed Effects

Parameter Code=P9PGIBU Parameter=PPG increment breakfast (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1		BOLAD1	
1	1	NN1218-4131	TRTPN	2				
2	1	NN1218-4131	TRTPN	3				
3	1	NN1218-4131	TRTPN	4				
4	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
5	1	NN1218-4131	REGION1	—	EUROPE			
6	1	NN1218-4131	REGION1	—	JAPAN			
7	1	NN1218-4131	REGION1	—	NORTH AMERICA			
8	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
9	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
10	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	9.9382	3.7851	978	2.63	0.0088	0.05	2.5103	17.3661
2	27.4316	3.7975	978	7.22	<.0001	0.05	19.9795	34.8838
3	20.4773	3.8067	978	5.38	<.0001	0.05	13.0071	27.9475
4	5.4399	5.4258	978	1.00	0.3163	0.05	-5.2076	16.0874
5	1.8181	3.8575	978	0.47	0.6375	0.05	-5.7518	9.3881
6	14.4444	4.2968	978	3.36	0.0008	0.05	6.0123	22.8764
7	0
8	-7.5612	3.3509	978	-2.26	0.0243	0.05	-14.1370	-0.9854
9	0
10	0.2804	0.02635	978	10.64	<.0001	0.05	0.2287	0.3321

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The Mixed procedure
Solution for Fixed Effects

Parameter Code=P9PGIEU Parameter=PPG increment main evening meal (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1			BOLAD1
11	1	NN1218-4131	TRTPN	2				
12	1	NN1218-4131	TRTPN	3				
13	1	NN1218-4131	TRTPN	4				
14	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
15	1	NN1218-4131	REGION1	—	EUROPE			
16	1	NN1218-4131	REGION1	—	JAPAN			
17	1	NN1218-4131	REGION1	—	NORTH AMERICA			
18	1	NN1218-4131	BOLAD1	—				BOLUS INSULIN ALGORITHM (SLIDING SCALE)
19	1	NN1218-4131	BOLAD1	—				CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY
20	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
11	10.8651	3.9270	971	2.77	0.0058	0.05	3.1587	18.5716
12	23.9101	3.9960	971	5.98	<.0001	0.05	16.0683	31.7519
13	16.6643	3.9685	971	4.20	<.0001	0.05	8.8765	24.4521
14	-19.2555	5.8554	971	-3.29	0.0010	0.05	-30.7461	-7.7649
15	-3.7180	4.1722	971	-0.89	0.3731	0.05	-11.9054	4.4695
16	-1.4156	4.6395	971	-0.31	0.7603	0.05	-10.5203	7.6890
17	0
18	3.3084	3.6202	971	0.91	0.3610	0.05	-3.7960	10.4128
19	0
20	0.2479	0.02943	971	8.42	<.0001	0.05	0.1901	0.3057

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The Mixed procedure
Solution for Fixed Effects

Parameter Code=P9PGILU Parameter=PPG increment lunch (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1			BOLAD1
21	1	NN1218-4131	TRTPN	2				
22	1	NN1218-4131	TRTPN	3				
23	1	NN1218-4131	TRTPN	4				
24	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
25	1	NN1218-4131	REGION1	—	EUROPE			
26	1	NN1218-4131	REGION1	—	JAPAN			
27	1	NN1218-4131	REGION1	—	NORTH AMERICA			
28	1	NN1218-4131	BOLAD1	—				BOLUS INSULIN ALGORITHM (SLIDING SCALE)
29	1	NN1218-4131	BOLAD1	—				CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY
30	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
21	14.2162	3.6222	974	3.92	<.0001	0.05	7.1079	21.3245
22	23.9098	3.6718	974	6.51	<.0001	0.05	16.7043	31.1154
23	20.4752	3.6396	974	5.63	<.0001	0.05	13.3328	27.6176
24	-1.8919	5.2770	974	-0.36	0.7200	0.05	-12.2475	8.4636
25	-8.1482	3.7586	974	-2.17	0.0304	0.05	-15.5240	-0.7723
26	10.7228	4.2632	974	2.52	0.0121	0.05	2.3568	19.0889
27	0
28	0.8344	3.2607	974	0.26	0.7981	0.05	-5.5645	7.2332
29	0
30	0.2755	0.02989	974	9.22	<.0001	0.05	0.2169	0.3342

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The Mixed procedure
Solution for Fixed Effects

Parameter Code=P9PPGINC Parameter=PPG increment all meals (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1
31	1	NN1218-4131	TRTPN	2		
32	1	NN1218-4131	TRTPN	3		
33	1	NN1218-4131	TRTPN	4		
34	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)	
35	1	NN1218-4131	REGION1	—	EUROPE	
36	1	NN1218-4131	REGION1	—	JAPAN	
37	1	NN1218-4131	REGION1	—	NORTH AMERICA	
38	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)
39	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY
40	1	NN1218-4131	BASE	—		

Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
31	0.3767	0.1368	966	2.75	0.0060	0.05	0.1083	0.6451
32	1.1022	0.1383	966	7.97	<.0001	0.05	0.8308	1.3736
33	0.8619	0.1362	966	6.33	<.0001	0.05	0.5946	1.1292
34	-0.2063	0.1930	966	-1.07	0.2852	0.05	-0.5850	0.1723
35	-0.1076	0.1378	966	-0.78	0.4351	0.05	-0.3781	0.1629
36	0.4275	0.1553	966	2.75	0.0060	0.05	0.1228	0.7322
37	0
38	-0.03904	0.1200	966	-0.33	0.7450	0.05	-0.2746	0.1965
39	0
40	0.3945	0.02687	966	14.68	<.0001	0.05	0.3417	0.4472

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The Mixed procedure
Solution for Fixed Effects

Parameter Code=P9PGINCB Parameter=PPG increment breakfast (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1			BOLAD1
41	1	NN1218-4131	TRTPN	2				
42	1	NN1218-4131	TRTPN	3				
43	1	NN1218-4131	TRTPN	4				
44	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
45	1	NN1218-4131	REGION1	—	EUROPE			
46	1	NN1218-4131	REGION1	—	JAPAN			
47	1	NN1218-4131	REGION1	—	NORTH AMERICA			
48	1	NN1218-4131	BOLAD1	—				BOLUS INSULIN ALGORITHM (SLIDING SCALE)
49	1	NN1218-4131	BOLAD1	—				CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY
50	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
41	0.5515	0.2101	978	2.63	0.0088	0.05	0.1393	0.9637
42	1.5223	0.2107	978	7.22	<.0001	0.05	1.1087	1.9358
43	1.1364	0.2112	978	5.38	<.0001	0.05	0.7218	1.5509
44	0.3019	0.3011	978	1.00	0.3163	0.05	-0.2890	0.8928
45	0.1009	0.2141	978	0.47	0.6375	0.05	-0.3192	0.5210
46	0.8016	0.2384	978	3.36	0.0008	0.05	0.3336	1.2695
47	0
48	-0.4196	0.1860	978	-2.26	0.0243	0.05	-0.7845	-0.05468
49	0
50	0.2804	0.02635	978	10.64	<.0001	0.05	0.2287	0.3321

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Solution for Fixed Effects

Parameter Code=P9PGINCE Parameter=PPG increment main evening meal (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
51	1	NN1218-4131	TRTPN	2				
52	1	NN1218-4131	TRTPN	3				
53	1	NN1218-4131	TRTPN	4				
54	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
55	1	NN1218-4131	REGION1	—	EUROPE			
56	1	NN1218-4131	REGION1	—	JAPAN			
57	1	NN1218-4131	REGION1	—	NORTH AMERICA			
58	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
59	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
60	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
51	0.6029	0.2179	971	2.77	0.0058	0.05	0.1753	1.0306
52	1.3269	0.2218	971	5.98	<.0001	0.05	0.8917	1.7620
53	0.9248	0.2202	971	4.20	<.0001	0.05	0.4926	1.3569
54	-1.0686	0.3249	971	-3.29	0.0010	0.05	-1.7062	-0.4309
55	-0.2063	0.2315	971	-0.89	0.3731	0.05	-0.6607	0.2480
56	-0.07856	0.2575	971	-0.31	0.7603	0.05	-0.5838	0.4267
57	0
58	0.1836	0.2009	971	0.91	0.3610	0.05	-0.2107	0.5778
59	0
60	0.2479	0.02943	971	8.42	<.0001	0.05	0.1901	0.3057

Fast-acting insulin aspart
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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Solution for Fixed Effects

Parameter Code=P9PGINCL Parameter=PPG increment lunch (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
61	1	NN1218-4131	TRTPN	2				
62	1	NN1218-4131	TRTPN	3				
63	1	NN1218-4131	TRTPN	4				
64	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
65	1	NN1218-4131	REGION1	—	EUROPE			
66	1	NN1218-4131	REGION1	—	JAPAN			
67	1	NN1218-4131	REGION1	—	NORTH AMERICA			
68	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
69	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
70	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
61	0.7889	0.2010	974	3.92	<.0001	0.05	0.3944	1.1834
62	1.3269	0.2038	974	6.51	<.0001	0.05	0.9270	1.7267
63	1.1362	0.2020	974	5.63	<.0001	0.05	0.7399	1.5326
64	-0.1050	0.2928	974	-0.36	0.7200	0.05	-0.6797	0.4697
65	-0.4522	0.2086	974	-2.17	0.0304	0.05	-0.8615	-0.04286
66	0.5951	0.2366	974	2.52	0.0121	0.05	0.1308	1.0593
67	0
68	0.04630	0.1810	974	0.26	0.7981	0.05	-0.3088	0.4014
69	0
70	0.2755	0.02989	974	9.22	<.0001	0.05	0.2169	0.3342

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Solution for Fixed Effects

Parameter Code=P9PGIU Parameter=PPG increment all meals (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
71	1	NN1218-4131	TRTPN	2				
72	1	NN1218-4131	TRTPN	3				
73	1	NN1218-4131	TRTPN	4				
74	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
75	1	NN1218-4131	REGION1	—	EUROPE			
76	1	NN1218-4131	REGION1	—	JAPAN			
77	1	NN1218-4131	REGION1	—	NORTH AMERICA			
78	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
79	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
80	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
71	6.7879	2.4648	966	2.75	0.0060	0.05	1.9510	11.6249
72	19.8620	2.4922	966	7.97	<.0001	0.05	14.9712	24.7528
73	15.5313	2.4549	966	6.33	<.0001	0.05	10.7138	20.3488
74	-3.7184	3.4771	966	-1.07	0.2852	0.05	-10.5418	3.1051
75	-1.9392	2.4838	966	-0.78	0.4351	0.05	-6.8133	2.9350
76	7.7039	2.7980	966	2.75	0.0060	0.05	2.2130	13.1947
77	0
78	-0.7035	2.1627	966	-0.33	0.7450	0.05	-4.9477	3.5406
79	0
80	0.3945	0.02687	966	14.68	<.0001	0.05	0.3417	0.4472

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Least Squares Means

Obs	_Imputation_	PARAMCD	PARAM	STUDYID	Effect
1	1	P9PGIBU	PPG increment breakfast (SMPG) (mg/dL)	NN1218-4131	TRTPN
20001	1	P9PGIEU	PPG increment main evening meal (SMPG) (mg/dL)	NN1218-4131	TRTPN
40001	1	P9PGILU	PPG increment lunch (SMPG) (mg/dL)	NN1218-4131	TRTPN
60001	1	P9PGINC	PPG increment all meals (SMPG) (mmol/L)	NN1218-4131	TRTPN
80001	1	P9PGINCB	PPG increment breakfast (SMPG) (mmol/L)	NN1218-4131	TRTPN
100001	1	P9PGINCE	PPG increment main evening meal (SMPG) (mmol/L)	NN1218-4131	TRTPN
120001	1	P9PGINCL	PPG increment lunch (SMPG) (mmol/L)	NN1218-4131	TRTPN
140001	1	P9PGIU	PPG increment all meals (SMPG) (mg/dL)	NN1218-4131	TRTPN
160001	1	P9PGIBU	PPG increment breakfast (SMPG) (mg/dL)	NN1218-4131	TRTPN
180001	1	P9PGIEU	PPG increment main evening meal (SMPG) (mg/dL)	NN1218-4131	TRTPN
200001	1	P9PGILU	PPG increment lunch (SMPG) (mg/dL)	NN1218-4131	TRTPN
220001	1	P9PGINC	PPG increment all meals (SMPG) (mmol/L)	NN1218-4131	TRTPN
240001	1	P9PGINCB	PPG increment breakfast (SMPG) (mmol/L)	NN1218-4131	TRTPN
260001	1	P9PGINCE	PPG increment main evening meal (SMPG) (mmol/L)	NN1218-4131	TRTPN

Obs	TRTPN	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	2	WORK.IMPUTE	-16.3271	2.5763	978	-6.34	<.0001	0.05	-21.3828	-11.2714
20001	2	WORK.IMPUTE	-4.2884	2.7790	971	-1.54	0.1231	0.05	-9.7420	1.1653
40001	2	WORK.IMPUTE	-9.5949	2.5009	974	-3.84	0.0001	0.05	-14.5027	-4.6872
60001	2	WORK.IMPUTE	-0.5865	0.09181	966	-6.39	<.0001	0.05	-0.7667	-0.4063
80001	2	WORK.IMPUTE	-0.9061	0.1430	978	-6.34	<.0001	0.05	-1.1866	-0.6255
100001	2	WORK.IMPUTE	-0.2380	0.1542	971	-1.54	0.1231	0.05	-0.5406	0.06466
120001	2	WORK.IMPUTE	-0.5325	0.1388	974	-3.84	0.0001	0.05	-0.8048	-0.2601
140001	2	WORK.IMPUTE	-10.5688	1.6545	966	-6.39	<.0001	0.05	-13.8155	-7.3220
160001	3	WORK.IMPUTE	1.1663	2.5553	978	0.46	0.6482	0.05	-3.8481	6.1807
180001	3	WORK.IMPUTE	8.7566	2.7732	971	3.16	0.0016	0.05	3.3145	14.1988
200001	3	WORK.IMPUTE	0.09870	2.5027	974	0.04	0.9685	0.05	-4.8125	5.0099
220001	3	WORK.IMPUTE	0.1390	0.09173	966	1.52	0.1299	0.05	-0.04098	0.3190
240001	3	WORK.IMPUTE	0.06472	0.1418	978	0.46	0.6482	0.05	-0.2135	0.3430
260001	3	WORK.IMPUTE	0.4859	0.1539	971	3.16	0.0016	0.05	0.1839	0.7879

Fast-acting insulin aspart
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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Least Squares Means

Obs	_Imputation_	PARAMCD	PARAM	STUDYID	Effect
280001	1	P9PGINCL	PPG increment lunch (SMPG) (mmol/L)	NN1218-4131	TRTPN
300001	1	P9PGIU	PPG increment all meals (SMPG) (mg/dL)	NN1218-4131	TRTPN
320001	1	P9PGIBU	PPG increment breakfast (SMPG) (mg/dL)	NN1218-4131	TRTPN
340001	1	P9PGIEU	PPG increment main evening meal (SMPG) (mg/dL)	NN1218-4131	TRTPN
360001	1	P9PGILU	PPG increment lunch (SMPG) (mg/dL)	NN1218-4131	TRTPN
380001	1	P9PGINC	PPG increment all meals (SMPG) (mmol/L)	NN1218-4131	TRTPN
400001	1	P9PGINCB	PPG increment breakfast (SMPG) (mmol/L)	NN1218-4131	TRTPN
420001	1	P9PGINCE	PPG increment main evening meal (SMPG) (mmol/L)	NN1218-4131	TRTPN
440001	1	P9PGINCL	PPG increment lunch (SMPG) (mmol/L)	NN1218-4131	TRTPN
460001	1	P9PGIU	PPG increment all meals (SMPG) (mg/dL)	NN1218-4131	TRTPN

Obs	TRTPN	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
280001	3	WORK.IMPUTE	0.005477	0.1389	974	0.04	0.9685	0.05	-0.2671	0.2780
300001	3	WORK.IMPUTE	2.5053	1.6529	966	1.52	0.1299	0.05	-0.7384	5.7490
320001	4	WORK.IMPUTE	-5.7880	2.5626	978	-2.26	0.0241	0.05	-10.8168	-0.7592
340001	4	WORK.IMPUTE	1.5108	2.7653	971	0.55	0.5850	0.05	-3.9159	6.9375
360001	4	WORK.IMPUTE	-3.3359	2.4922	974	-1.34	0.1810	0.05	-8.2267	1.5548
380001	4	WORK.IMPUTE	-0.1013	0.09108	966	-1.11	0.2663	0.05	-0.2800	0.07743
400001	4	WORK.IMPUTE	-0.3212	0.1422	978	-2.26	0.0241	0.05	-0.6003	-0.04213
420001	4	WORK.IMPUTE	0.08384	0.1535	971	0.55	0.5850	0.05	-0.2173	0.3850
440001	4	WORK.IMPUTE	-0.1851	0.1383	974	-1.34	0.1810	0.05	-0.4565	0.08628
460001	4	WORK.IMPUTE	-1.8254	1.6412	966	-1.11	0.2663	0.05	-5.0461	1.3953

nn1218/nn1218-4131/ctr_20180214_er
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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Least Squares Means Estimate

Parameter Code=P9PGIBU Parameter=PPG increment breakfast (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
1	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
20001	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	WORK.IMPUTE	-10.5391	3.6363	978	-2.90	0.0038	0.05	-17.6749	-3.4034
20001	WORK.IMPUTE	6.9543	3.6193	978	1.92	0.0550	0.05	-0.1482	14.0568

Parameter Code=P9PGIEU Parameter=PPG increment main evening meal (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
40001	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
60001	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
40001	WORK.IMPUTE	-5.7992	3.9241	971	-1.48	0.1398	0.05	-13.4999	1.9016
60001	WORK.IMPUTE	7.2458	3.9178	971	1.85	0.0647	0.05	-0.4425	14.9341

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Least Squares Means Estimate

Parameter Code=P9PGILU Parameter=PPG increment lunch (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
80001	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
100001	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
80001	WORK.IMPUTE	-6.2590	3.5344	974	-1.77	0.0769	0.05	-13.1950	0.6770
100001	WORK.IMPUTE	3.4346	3.5327	974	0.97	0.3312	0.05	-3.4981	10.3673

Parameter Code=P9PGINC Parameter=PPG increment all meals (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
120001	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
140001	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
120001	WORK.IMPUTE	-0.4852	0.1295	966	-3.75	0.0002	0.05	-0.7393	-0.2311
140001	WORK.IMPUTE	0.2403	0.1293	966	1.86	0.0634	0.05	-0.01340	0.4941

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Least Squares Means Estimate

Parameter Code=P9PGINCB Parameter=PPG increment breakfast (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
160001	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
180001	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
160001	WORK.IMPUTE	-0.5849	0.2018	978	-2.90	0.0038	0.05	-0.9808	-0.1889
180001	WORK.IMPUTE	0.3859	0.2008	978	1.92	0.0550	0.05	-0.00822	0.7801

Parameter Code=P9PGINCE Parameter=PPG increment main evening meal (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
200001	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
220001	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
200001	WORK.IMPUTE	-0.3218	0.2178	971	-1.48	0.1398	0.05	-0.7492	0.1055
220001	WORK.IMPUTE	0.4021	0.2174	971	1.85	0.0647	0.05	-0.02455	0.8288

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Least Squares Means Estimate

Parameter Code=P9PGINCL Parameter=PPG increment lunch (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
240001	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
260001	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
240001	WORK.IMPUTE	-0.3473	0.1961	974	-1.77	0.0769	0.05	-0.7322	0.03757
260001	WORK.IMPUTE	0.1906	0.1960	974	0.97	0.3312	0.05	-0.1941	0.5753

Parameter Code=P9PGIU Parameter=PPG increment all meals (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
280001	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
300001	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
280001	WORK.IMPUTE	-8.7433	2.3331	966	-3.75	0.0002	0.05	-13.3219	-4.1647
300001	WORK.IMPUTE	4.3307	2.3298	966	1.86	0.0634	0.05	-0.2414	8.9029

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9PGIBU Parameter=PPG increment breakfast (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.599212	6.700760	7.300002	2.97E6	0.089429	0.082088	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	20.460281	2.701852	15.16475	25.75581	2.97E6	17.413533	23.590034

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	7.57	<.0001

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9PGIEU Parameter=PPG increment main evening meal (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.570580	7.647514	8.218123	4.15E6	0.074614	0.069433	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	13.111215	2.866727	7.492532	18.72990	4.15E6	10.037567	16.135140

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	4.57	<.0001

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9PGILU Parameter=PPG increment lunch (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.509065	6.367411	6.876501	3.65E6	0.079952	0.074034	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	23.451550	2.622308	18.31192	28.59118	3.65E6	20.628905	26.211863

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	8.94	<.0001

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9PPGINC Parameter=PPG increment all meals (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000772	0.008481	0.009253	2.87E6	0.091032	0.083438	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	1.027990	0.096193	0.839455	1.216525	2.87E6	0.909401	1.140371

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	10.69	<.0001

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9PGINCB Parameter=PPG increment breakfast (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.001845	0.020635	0.022481	2.97E6	0.089429	0.082088	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	1.135421	0.149936	0.841551	1.429290	2.97E6	0.966345	1.309103

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	7.57	<.0001

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9PGINCE Parameter=PPG increment main evening meal (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.001757	0.023551	0.025308	4.15E6	0.074614	0.069433	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits	DF	Minimum	Maximum
Estimate	0.727592	0.159086	0.415790 1.039395	4.15E6	0.557024	0.895402

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	4.57	<.0001

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9PGINCL Parameter=PPG increment lunch (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.001568	0.019609	0.021177	3.65E6	0.079952	0.074034	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	1.301418	0.145522	1.016200	1.586636	3.65E6	1.144778	1.454598

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	8.94	<.0001

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9PGIU Parameter=PPG increment all meals (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.250688	2.753972	3.004672	2.87E6	0.091032	0.083438	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	18.524375	1.733399	15.12697	21.92178	2.87E6	16.387400	20.549487

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	10.69	<.0001

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9PGIBU Parameter=PPG increment breakfast (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.322706	6.591789	6.914511	9.18E6	0.048958	0.046673	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits	DF	Minimum	Maximum
Estimate	38.067330	2.629546	32.91351 43.22115	9.18E6	36.049885	40.320004

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	14.48	<.0001

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9PGIEU Parameter=PPG increment main evening meal (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.352347	7.615373	7.967738	1.02E7	0.046270	0.044224	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	25.329521	2.822718	19.79709	30.86195	1.02E7	22.957139	27.570736

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	8.97	<.0001

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9PGILU Parameter=PPG increment lunch (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.348279	6.376317	6.724614	7.45E6	0.054624	0.051795	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	32.725852	2.593186	27.64330	37.80840	7.45E6	30.274912	34.995189

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	12.62	<.0001

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9PGINC Parameter=PPG increment all meals (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000419	0.008465	0.008884	8.97E6	0.049548	0.047209	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	1.757043	0.094258	1.572301	1.941785	8.97E6	1.675118	1.835745

Parameter Estimates

Parameter	Theta0	t for H0: Parameter=Theta0	Pr > t
Estimate	0	18.64	<.0001

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Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2705 of 4425	Novo Nordisk
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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9PGINCB Parameter=PPG increment breakfast (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000994	0.020300	0.021294	9.18E6	0.048958	0.046673	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	2.112504	0.145924	1.826499	2.398510	9.18E6	2.000549	2.237514

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	14.48	<.0001

nn1218/nn1218-4131/ctr_20180214_er
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Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2706 of 4425	Novo Nordisk
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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9PGINCE Parameter=PPG increment main evening meal (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.001085	0.023452	0.024537	1.02E7	0.046270	0.044224	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	1.405634	0.156644	1.098618	1.712650	1.02E7	1.273981	1.530008

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	8.97	<.0001

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9PGINCL Parameter=PPG increment lunch (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.001073	0.019636	0.020709	7.45E6	0.054624	0.051795	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	1.816085	0.143906	1.534034	2.098136	7.45E6	1.680073	1.942019

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	12.62	<.0001

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9PGIU Parameter=PPG increment all meals (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.136189	2.748781	2.884977	8.97E6	0.049548	0.047209	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	31.661915	1.698522	28.33287	34.99096	8.97E6	30.185633	33.080127

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	18.64	<.0001

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9PGIBU Parameter=PPG increment breakfast (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.517793	6.629678	7.147496	3.81E6	0.078106	0.072448	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	30.919248	2.673480	25.67932	36.15917	3.81E6	28.052153	33.639581

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	11.57	<.0001

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9PGIEU Parameter=PPG increment main evening meal (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.602256	7.572279	8.174565	3.68E6	0.079538	0.073679	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	19.646436	2.859120	14.04266	25.25021	3.68E6	16.696546	22.748709

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	6.87	<.0001

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Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2711 of 4425	Novo Nordisk
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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9PGILU Parameter=PPG increment lunch (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.518870	6.323220	6.842116	3.48E6	0.082062	0.075839	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	30.153137	2.615744	25.02637	35.27990	3.48E6	27.295226	32.894099

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	11.53	<.0001

nn1218/nn1218-4131/ctr_20180214_er
10FEB2018:18:44:27 - a_797pp_stat_diff.sas/a_9pp_ppginc_stat_on_fas_app.txt

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9PGINC Parameter=PPG increment all meals (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000738	0.008346	0.009084	3.03E6	0.088478	0.081286	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	1.501658	0.095309	1.314854	1.688461	3.03E6	1.391566	1.620473

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	15.76	<.0001

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9PGINCB Parameter=PPG increment breakfast (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.001595	0.020417	0.022011	3.81E6	0.078106	0.072448	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	1.715830	0.148362	1.425046	2.006613	3.81E6	1.556723	1.866791

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	11.57	<.0001

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9PGINCE Parameter=PPG increment main evening meal (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.001855	0.023319	0.025174	3.68E6	0.079538	0.073679	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	1.090257	0.158664	0.779282	1.401233	3.68E6	0.926556	1.262414

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	6.87	<.0001

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Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9PGINCL Parameter=PPG increment lunch (SMPG) (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.001598	0.019473	0.021071	3.48E6	0.082062	0.075839	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	1.673315	0.145158	1.388811	1.957819	3.48E6	1.514718	1.825422

Parameter Estimates

Parameter	Theta0	t for H0: Parameter=Theta0	Pr > t
Estimate	0	11.53	<.0001

Postprandial glucose increments in 7-9-7-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9PGIU Parameter=PPG increment all meals (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.239758	2.709957	2.949727	3.03E6	0.088478	0.081286	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	27.059870	1.717477	23.69368	30.42606	3.03E6	25.076011	29.200916

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	15.76	<.0001

26: Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=P9GIN4BU Planned Treatment for Period 30 (N)=2

Obs	PARAM					Description	Value
1	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mg/dL)		Data Set	WORK.ENDPOINT_PARAM
2	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mg/dL)		Method	Monotone-data_MCMC
3	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mg/dL)		Multiple Imputation Chain	Multiple Chains
4	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mg/dL)		Initial Estimates for MCMC	EM Posterior Mode
5	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mg/dL)		Start	Starting Value
6	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mg/dL)		Prior	Jeffreys
7	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mg/dL)		Number of Imputations	20000
8	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mg/dL)		Number of Burn-in Iterations	200
9	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mg/dL)		Seed for random number generator	1234

Parameter Code=P9GIN4BU Planned Treatment for Period 30 (N)=3

Obs	PARAM					Description	Value
10	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mg/dL)		Data Set	WORK.ENDPOINT_PARAM
11	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mg/dL)		Method	Monotone-data_MCMC
12	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mg/dL)		Multiple Imputation Chain	Multiple Chains
13	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mg/dL)		Initial Estimates for MCMC	EM Posterior Mode
14	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mg/dL)		Start	Starting Value
15	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mg/dL)		Prior	Jeffreys
16	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mg/dL)		Number of Imputations	20000
17	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mg/dL)		Number of Burn-in Iterations	200
18	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mg/dL)		Seed for random number generator	272786455

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=P9GIN4BU Planned Treatment for Period 30 (N)=4

Obs	PARAM				Description	Value
19	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mg/dL)	Data Set	WORK.ENDPOINT_PARAM
20	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mg/dL)	Method	Monotone-data_MCMC
21	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mg/dL)	Multiple Imputation Chain	Multiple Chains
22	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
23	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mg/dL)	Start	Starting Value
24	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mg/dL)	Prior	Jeffreys
25	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mg/dL)	Number of Imputations	20000
26	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mg/dL)	Number of Burn-in Iterations	200
27	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mg/dL)	Seed for random number generator	340126552

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with MCMC
Missing data pattern

Parameter Code=P9GIN4BU Planned Treatment for Period 30 (N)=2

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss
1	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	1	X	X
2	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	2	X	X
3	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	3	X	.
4	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	4	X	O

Obs	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
1	X	143	61.11	-23.426699	12.929622	10.651203
2	O	29	12.39	-35.839241	35.845379	.
3	X	30	12.82	-40.894133	.	35.429733
4	O	32	13.68	-34.428500	.	.

Parameter Code=P9GIN4BU Planned Treatment for Period 30 (N)=3

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss
5	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	1	X	X
6	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	2	X	X

Obs	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
5	X	169	64.50	-30.968450	21.937266	21.342355
6	O	25	9.54	-24.185040	14.459040	.

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with MCMC
Missing data pattern

Parameter Code=P9GIN4BU Planned Treatment for Period 30 (N)=3

(continued)

Obs	PARAM				Group	BASE_ Miss	visit2200_ Miss
7	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mg/dL)	3	X	.
8	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mg/dL)	4	X	0
Obs	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600	
7	X	37	14.12	-20.415892	.	3.706973	
8	0	31	11.83	-33.654903	.	.	

Parameter Code=P9GIN4BU Planned Treatment for Period 30 (N)=4

Obs	PARAM				Group	BASE_ Miss	visit2200_ Miss
9	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mg/dL)	1	X	X
10	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mg/dL)	2	X	X
11	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mg/dL)	3	X	.
Obs	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600	
9	X	154	63.37	-15.978701	-3.629987	-6.536909	
10	0	33	13.58	-34.535273	-5.649576	.	
11	X	32	13.17	-23.953875	.	18.157125	

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with MCMC
Missing data pattern

Parameter Code=P9GIN4BU Planned Treatment for Period 30 (N)=4

(continued)

Obs	PARAM				Group	BASE_ Miss	visit2200_ Miss
12	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)				4	X	O
Obs	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600	
12	O	24	9.88	-10.618083	.	.	

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The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9GIN4BU Planned Treatment for Period 30 (N)=2

	O	b	s	I	m	p	u	t	a	t	i	o	n	—	P	A	R	A	M	D	e	s	c	r	i	p	t	i	o	n	V	a	l	u	e
1	1			Nocturnal	increment	(04:00	to	breakfast)	(SMPG)	(mg/dL)	Data Set			WORK.MONO_SORT_TRT																					
2	1			Nocturnal	increment	(04:00	to	breakfast)	(SMPG)	(mg/dL)	Method			Monotone																					
3	1			Nocturnal	increment	(04:00	to	breakfast)	(SMPG)	(mg/dL)	Number of Imputations			1																					
4	1			Nocturnal	increment	(04:00	to	breakfast)	(SMPG)	(mg/dL)	Seed for random number generator			4321																					

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=P9GIN4BU Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM					Group	REGION1_ Miss	BOLAD1_ Miss
1	1	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mg/dL)		1	X	X
2	1	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mg/dL)		2	X	X
3	1	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mg/dL)		3	X	X

Obs	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
1	X	X	X	173	73.93	-26.455734	13.695162	14.948058
2	X	X	.	29	12.39	-35.839241	35.845379	.
3	X	.	.	32	13.68	-34.428500	.	.

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9GIN4BU Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	Intercept	
2	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	REGION1	EUROPE
4	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	REGION1	JAPAN
5	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	BOLAD1	
6	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	BASE	

Obs	BOLAD1	ObsVal	_1
1		0.00738	0.042673
2		0.02104	0.048334
3		-0.08663	-0.233295
4		0.07613	0.038237
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.02966	-0.025061
6		-0.71230	-0.731930

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9GIN4BU Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

Imputed									
Observations									
		P		E		R	B	O	
		A		f		E	O	b	
		R		f		G	L	s	
		A		e		O	A	V	
		A		c		N	D	a	
		M		t		1	1	1	\bar{I}
7	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	Intercept					0.04739	-0.035121
8	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	REGION1 ASIA (EXCLUDING JAPAN)					0.10070	0.163232
9	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	REGION1 EUROPE					0.02597	0.077447

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9GIN4BU Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM	Effect
10	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	REGION1
11	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	BOLAD1
12	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	BASE
13	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	visit2200

Obs	REGION1	BOLAD1	ObsVal	_1
10	JAPAN		0.00332	-0.159373
11		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.11696	-0.081882
12			-0.58650	-0.549837
13			0.22648	0.202666

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9GIN4BU Planned Treatment for Period 30 (N)=3

Obs	Imputation	P A R A M						Description	Value
1	1	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mg/dL)	Data Set		WORK.MONO_SORT_TRT	
2	1	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mg/dL)	Method		Monotone	
3	1	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mg/dL)	Number of Imputations		1	
4	1	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mg/dL)	Seed for random number generator		4322	

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=P9GIN4BU Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM					Group	REGION1_ Miss	BOLAD1_ Miss
1	1	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mg/dL)		1	X	X
2	1	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mg/dL)		2	X	X
3	1	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mg/dL)		3	X	X

Obs	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
1	X	X	X	206	78.63	-29.073087	16.658041	18.174835
2	X	X	.	25	9.54	-24.185040	14.459040	.
3	X	.	.	31	11.83	-33.654903	.	.

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9GIN4BU Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	Intercept	
2	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	REGION1	EUROPE
4	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	REGION1	JAPAN
5	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	BOLAD1	
6	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	BASE	

Obs	BOLAD1	ObsVal	_1
1		0.00368	0.118932
2		0.01247	0.174907
3		0.06381	0.066572
4		-0.04683	-0.161897
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.01506	0.048426
6		-0.58040	-0.636581

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The MI Procedure with Monotone Regression Regression Information

Parameter Code=P9GIN4BU Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

				P	E	R	B	O	
				A	f	E	O	b	
				R	e	G	L	s	
O o b n s _				A	c	I	A	V	
				M	t	N	D	a	T
						l	l	l	
7 1	Nocturnal increment	(04:00 to breakfast)	(SMPG) (mg/dL)		Intercept			0.01708	-0.064580
8 1	Nocturnal increment	(04:00 to breakfast)	(SMPG) (mg/dL)		REGION1 ASIA (EXCLUDING JAPAN)			0.06208	0.118361
9 1	Nocturnal increment	(04:00 to breakfast)	(SMPG) (mq/dL)		REGION1 EUROPE			-0.11941	-0.142637

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9GIN4BU Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM	Effect
10	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	REGION1
11	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	BOLAD1
12	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	BASE
13	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	visit2200

Obs	REGION1	BOLAD1	ObsVal	_1
10	JAPAN		-0.00445	-0.048901
11		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.03866	0.033378
12			-0.64548	-0.662057
13			0.09028	0.074354

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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9GIN4BU Planned Treatment for Period 30 (N)=4

	O	b	s	I	m	p	u	t	a	t	i	o	n	—	P	A	R	A	M	D	e	s	c	r	i	p	t	i	o	n	V	a	l	u	e
1	1			Nocturnal	increment	(04:00	to	breakfast)	(SMPG)	(mg/dL)	Data Set			WORK.MONO_SORT_TRT																					
2	1			Nocturnal	increment	(04:00	to	breakfast)	(SMPG)	(mg/dL)	Method			Monotone																					
3	1			Nocturnal	increment	(04:00	to	breakfast)	(SMPG)	(mg/dL)	Number of Imputations			1																					
4	1			Nocturnal	increment	(04:00	to	breakfast)	(SMPG)	(mg/dL)	Seed for random number generator			4323																					

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=P9GIN4BU Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM					Group	REGION1_ Miss	BOLAD1_ Miss
1	1	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mg/dL)		1	X	X
2	1	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mg/dL)		2	X	X
3	1	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mg/dL)		3	X	X

Obs	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
1	X	X	X	186	76.54	-17.350774	-3.330247	-2.288473
2	X	X	.	33	13.58	-34.535273	-5.649576	.
3	X	.	.	24	9.88	-10.618083	.	.

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9GIN4BU Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	Intercept	
2	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	REGION1	EUROPE
4	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	REGION1	JAPAN
5	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	BOLAD1	
6	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	BASE	

Obs	BOLAD1	ObsVal	_1
1		-0.0002599	-0.046591
2		0.05953	0.113761
3		-0.08843	-0.212204
4		0.00110	0.053507
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.01709	-0.001465
6		-0.71962	-0.791343

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The MI Procedure with Monotone Regression Regression Information

Parameter Code=P9GIN4BU Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

	O	P	E	R	B	O	
I	b	A	f	E	O	b	
m	n	M	e	G	L	s	
p	s_		c	I	A	V	
u			t	N	D	a	
t				l	l	l	T
a							
t							
i							
7 1 Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)			Intercept				0.060258
8 1 Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)			REGION1 ASIA (EXCLUDING JAPAN)			0.03823	0.27700
9 1 Nocturnal increment (04:00 to breakfast) (SMPG) (mq/dL)			REGION1 EUROPE			-0.09003	-0.132811

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9GIN4BU Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM	Effect
10	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	REGION1
11	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	BOLAD1
12	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	BASE
13	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	visit2200

Obs	REGION1	BOLAD1	ObsVal	_1
10	JAPAN		0.10856	0.187216
11		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.08459	-0.096189
12			-0.65962	-0.717258
13			0.05537	-0.014129

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=P9PGIN4B Planned Treatment for Period 30 (N)=2

Obs	PARAM				Description	Value
1	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)	Data Set	WORK.ENDPOINT_PARAM
2	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)	Method	Monotone-data_MCMC
3	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)	Multiple Imputation Chain	Multiple Chains
4	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
5	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)	Start	Starting Value
6	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)	Prior	Jeffreys
7	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)	Number of Imputations	20000
8	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)	Number of Burn-in Iterations	200
9	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)	Seed for random number generator	1234

Parameter Code=P9PGIN4B Planned Treatment for Period 30 (N)=3

Obs	PARAM				Description	Value
10	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)	Data Set	WORK.ENDPOINT_PARAM
11	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)	Method	Monotone-data_MCMC
12	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)	Multiple Imputation Chain	Multiple Chains
13	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
14	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)	Start	Starting Value
15	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)	Prior	Jeffreys
16	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)	Number of Imputations	20000
17	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)	Number of Burn-in Iterations	200
18	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)	Seed for random number generator	272786455

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The MI Procedure with MCMC
Model Information

Parameter Code=P9PGIN4B Planned Treatment for Period 30 (N)=4

Obs	PARAM				Description	Value
19	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)	Data Set	WORK.ENDPOINT_PARAM
20	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)	Method	Monotone-data_MCMC
21	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)	Multiple Imputation Chain	Multiple Chains
22	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
23	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)	Start	Starting Value
24	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)	Prior	Jeffreys
25	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)	Number of Imputations	20000
26	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)	Number of Burn-in Iterations	200
27	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)	Seed for random number generator	340126552

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with MCMC
Missing data pattern

Parameter Code=P9PGIN4B Planned Treatment for Period 30 (N)=2

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss
1	Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)	1	X	X
2	Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)	2	X	X
3	Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)	3	X	.
4	Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)	4	X	O

Obs	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
1	X	143	61.11	-1.300039	0.717515	0.591077
2	O	29	12.39	-1.988859	1.989200	.
3	X	30	12.82	-2.269375	.	1.966134
4	O	32	13.68	-1.910572	.	.

Parameter Code=P9PGIN4B Planned Treatment for Period 30 (N)=3

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss
5	Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)	1	X	X
6	Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)	2	X	X

Obs	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
5	X	169	64.50	-1.718560	1.217384	1.184370
6	O	25	9.54	-1.342122	0.802388	.

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with MCMC
Missing data pattern

Parameter Code=P9PGIN4B Planned Treatment for Period 30 (N)=3

(continued)

Obs	PARAM				Group	BASE_ Miss	visit2200_ Miss
7	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)	3	X	.
8	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)	4	X	O

Obs	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
7	X	37	14.12	-1.132957	.	0.205714
8	O	31	11.83	-1.867642	.	.

Parameter Code=P9PGIN4B Planned Treatment for Period 30 (N)=4

Obs	PARAM				Group	BASE_ Miss	visit2200_ Miss
9	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)	1	X	X
10	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)	2	X	X
11	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)	3	X	.

Obs	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
9	X	154	63.37	-0.886720	-0.201442	-0.362759
10	O	33	13.58	-1.916497	-0.313517	.
11	X	32	13.17	-1.329294	.	1.007610

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with MCMC
Missing data pattern

Parameter Code=P9PGIN4B Planned Treatment for Period 30 (N)=4

(continued)

Obs	PARAM				Group	BASE_ Miss	visit2200_ Miss
12	Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)				4	X	O
Obs	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600	
12	O	24	9.88	-0.589239	.	.	

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression Model Information

Parameter Code=P9PGIN4B Planned Treatment for Period 30 (N)=2

O b s	I m p u t a t i o n —			P A R A M				D e s c r i p t i o n	V a l u e
1	1	Nocturnal	increment	(04:00 to breakfast)	(SMPG)	(mmol/L)	Data Set		WORK.MONO_SORT_TRT
2	1	Nocturnal	increment	(04:00 to breakfast)	(SMPG)	(mmol/L)	Method		Monotone
3	1	Nocturnal	increment	(04:00 to breakfast)	(SMPG)	(mmol/L)	Number of Imputations		1
4	1	Nocturnal	increment	(04:00 to breakfast)	(SMPG)	(mmol/L)	Seed for random number generator		4321

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=P9PGIN4B Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM					Group	REGION1_ Miss	BOLAD1_ Miss
1	1	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)		1	X	X
2	1	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)		2	X	X
3	1	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)		3	X	X

Obs	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
1	X	X	X	173	73.93	-1.468132	0.759998	0.829526
2	X	X	.	29	12.39	-1.988859	1.989200	.
3	X	.	.	32	13.68	-1.910572	.	.

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGIN4B Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2200

Obs	_Imputation_	PARAM				Effect	REGION1
1	1	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)	Intercept	
2	1	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)	REGION1	EUROPE
4	1	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)	REGION1	JAPAN
5	1	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)	BOLAD1	
6	1	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)	BASE	
Obs	BOLAD1		ObsVal		_1		
1			0.00738		0.042673		
2			0.02104		0.048334		
3			-0.08663		-0.233295		
4			0.07613		0.038237		
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.02966		-0.025061		
6			-0.71230		-0.731930		

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGIN4B Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM	Effect
10	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)	REGION1
11	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)	BOLAD1
12	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)	BASE
13	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)	visit2200

Obs	REGION1	BOLAD1	ObsVal	_1
10	JAPAN		0.00332	-0.159373
11		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.11696	-0.081882
12			-0.58650	-0.549837
13			0.22648	0.202666

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression Model Information

Parameter Code=P9PGIN4B Planned Treatment for Period 30 (N)=3

O b s	I m p u t a t i o n —			P A R A M				D e s c r i p t i o n	V a l u e
1	1	Nocturnal	increment	(04:00 to breakfast)	(SMPG)	(mmol/L)	Data Set		WORK.MONO_SORT_TRT
2	1	Nocturnal	increment	(04:00 to breakfast)	(SMPG)	(mmol/L)	Method		Monotone
3	1	Nocturnal	increment	(04:00 to breakfast)	(SMPG)	(mmol/L)	Number of Imputations		1
4	1	Nocturnal	increment	(04:00 to breakfast)	(SMPG)	(mmol/L)	Seed for random number generator		4322

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=P9PGIN4B Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM					Group	REGION1_ Miss	BOLAD1_ Miss
1	1	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)		1	X	X
2	1	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)		2	X	X
3	1	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)		3	X	X

Obs	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
1	X	X	X	206	78.63	-1.613379	0.924420	1.008592
2	X	X	.	25	9.54	-1.342122	0.802388	.
3	X	.	.	31	11.83	-1.867642	.	.

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGIN4B Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)	Intercept	
2	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)	REGION1	EUROPE
4	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)	REGION1	JAPAN
5	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)	BOLAD1	
6	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)	BASE	

Obs	BOLAD1	ObsVal	_1
1		0.00368	0.118932
2		0.01247	0.174907
3		0.06381	0.066572
4		-0.04683	-0.161897
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.01506	0.048426
6		-0.58040	-0.636581

nn1218/nn1218-4131/ctr_20180214_er
10FEB2018:06:42:09 - a_797pp_stat_diff.sas/a_9pp_noct_stat_in_fas_app.txt

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGIN4B Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM	Effect
10	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)	REGION1
11	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)	BOLAD1
12	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)	BASE
13	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)	visit2200

Obs	REGION1	BOLAD1	ObsVal	_1
10	JAPAN		-0.00445	-0.048901
11		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.03866	0.033378
12			-0.64548	-0.662057
13			0.09028	0.074354

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The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PGIN4B Planned Treatment for Period 30 (N)=4

	O b s	I m p u t a t i o n s	P A R A M				D e s c r i p t i o n	V a l u e
1	1	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)	Data Set		WORK.MONO_SORT_TRT
2	1	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)	Method		Monotone
3	1	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)	Number of Imputations		1
4	1	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)	Seed for random number generator		4323

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=P9PGIN4B Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM					Group	REGION1_ Miss	BOLAD1_ Miss
1	1	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)		1	X	X
2	1	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)		2	X	X
3	1	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)		3	X	X

Obs	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
1	X	X	X	186	76.54	-0.962862	-0.184808	-0.126996
2	X	X	.	33	13.58	-1.916497	-0.313517	.
3	X	.	.	24	9.88	-0.589239	.	.

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGIN4B Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)	Intercept	
2	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)	REGION1	EUROPE
4	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)	REGION1	JAPAN
5	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)	BOLAD1	
6	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)	BASE	

Obs	BOLAD1	ObsVal	_1
1		-0.0002599	-0.046591
2		0.05953	0.113761
3		-0.08843	-0.212204
4		0.00110	0.053507
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.01709	-0.001465
6		-0.71962	-0.791343

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10FEB2018:06:42:09 - a_797pp_stat_diff.sas/a_9pp_noct_stat_in_fas_app.txt

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGIN4B Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM	Effect
10	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)	REGION1
11	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)	BOLAD1
12	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)	BASE
13	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)	visit2200

Obs	REGION1	BOLAD1	ObsVal	_1
10	JAPAN		0.10856	0.187216
11		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.08459	-0.096189
12			-0.65962	-0.717258
13			0.05537	-0.014129

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=P9GINB4U Planned Treatment for Period 30 (N)=2

Obs	PARAM				Description	Value
1	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mg/dL)	Data Set	WORK.ENDPOINT_PARAM
2	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mg/dL)	Method	Monotone-data MCMC
3	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mg/dL)	Multiple Imputation Chain	Multiple Chains
4	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
5	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mg/dL)	Start	Starting Value
6	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mg/dL)	Prior	Jeffreys
7	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mg/dL)	Number of Imputations	20000
8	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mg/dL)	Number of Burn-in Iterations	200
9	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mg/dL)	Seed for random number generator	1234

Parameter Code=P9GINB4U Planned Treatment for Period 30 (N)=3

Obs	PARAM				Description	Value
10	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mg/dL)	Data Set	WORK.ENDPOINT_PARAM
11	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mg/dL)	Method	Monotone-data MCMC
12	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mg/dL)	Multiple Imputation Chain	Multiple Chains
13	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
14	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mg/dL)	Start	Starting Value
15	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mg/dL)	Prior	Jeffreys
16	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mg/dL)	Number of Imputations	20000
17	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mg/dL)	Number of Burn-in Iterations	200
18	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mg/dL)	Seed for random number generator	1013599241

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=P9GINB4U Planned Treatment for Period 30 (N)=4

Obs	PARAM				Description	Value
19	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mg/dL)	Data Set	WORK.ENDPOINT_PARAM
20	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mg/dL)	Method	Monotone-data MCMC
21	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mg/dL)	Multiple Imputation Chain	Multiple Chains
22	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
23	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mg/dL)	Start	Starting Value
24	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mg/dL)	Prior	Jeffreys
25	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mg/dL)	Number of Imputations	20000
26	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mg/dL)	Number of Burn-in Iterations	200
27	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mg/dL)	Seed for random number generator	2024401714

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with MCMC
Missing data pattern

Parameter Code=P9GINB4U Planned Treatment for Period 30 (N)=2

				v v i i s s i i t t B 2 3 A 2 6 S 0 0 E 0 0						v i s i t 2 2 0 0			v i s i t 3 6 0 0		
				P A R A M			G r o u p			F r e q			B A S E		
				\bar{M} \bar{M} \bar{M}			i i i			s s s			s s s		
				1 X X X			2 X X O			3 X . X			4 X O O		
1	Nocturnal increment	(bedtime to 04:00)	(SMPG) (mg/dL)	1	X	X	X	139	59.40	-11.937194	10.189180	3.933986			
2	Nocturnal increment	(bedtime to 04:00)	(SMPG) (mg/dL)	2	X	X	O	27	11.54	-19.310667	22.221185	.			
3	Nocturnal increment	(bedtime to 04:00)	(SMPG) (mg/dL)	3	X	.	X	35	14.96	7.305543	.	-14.306629			
4	Nocturnal increment	(bedtime to 04:00)	(SMPG) (mg/dL)	4	X	O	O	33	14.10	-17.304000	.	.			

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with MCMC
Missing data pattern

Parameter Code=P9GINB4U Planned Treatment for Period 30 (N)=3

				v v i i s s i i t t B 2 3 A 2 6 S 0 0 E 0 0						v i s i t 2 2 0 0			v i s i t 3 6 0 0		
				P A R A M			G r o u p			F r e q			B A S E		
				M M M i i i s s s s s s											
5	Nocturnal increment	(bedtime to 04:00)	(SMPG) (mg/dL)	1	X	X	X	169	65.50	-8.442592	1.607456	-6.663373			
6	Nocturnal increment	(bedtime to 04:00)	(SMPG) (mg/dL)	2	X	X	O	26	10.08	-10.415000	5.826692	.			
7	Nocturnal increment	(bedtime to 04:00)	(SMPG) (mg/dL)	3	X	.	X	36	13.95	-51.204333	.	45.345611			
8	Nocturnal increment	(bedtime to 04:00)	(SMPG) (mg/dL)	4	X	O	O	27	10.47	-13.684370	.	.			

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with MCMC
Missing data pattern

Parameter Code=P9GINB4U Planned Treatment for Period 30 (N)=4

				v v i i s s i i t t B 2 3 A 2 6 S 0 0 E 0 0						v i s i t 2 2 0 0			v i s i t 3 6 0 0		
				P A R A M			G r o u p			F r e q			B A S E		
				M M M i i i s s s s s s											
9	Nocturnal increment	(bedtime to 04:00)	(SMPG) (mg/dL)	1	X	X	X	152	64.96	-12.720539	-2.301171	4.154697			
10	Nocturnal increment	(bedtime to 04:00)	(SMPG) (mg/dL)	2	X	X	O	27	11.54	-15.312444	49.832444	.			
11	Nocturnal increment	(bedtime to 04:00)	(SMPG) (mg/dL)	3	X	.	X	32	13.68	-10.916125	.	31.613500			
12	Nocturnal increment	(bedtime to 04:00)	(SMPG) (mg/dL)	4	X	O	O	23	9.83	-11.421043	.	.			

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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9GINB4U Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM	Description	Value
1	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	Method	Monotone
3	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	Number of Imputations	1
4	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	Seed for random number generator	4321

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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=P9GINB4U Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM				Group	REGION1_	BOLAD1_
							Miss	Miss
1	1	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mg/dL)	1	X	X
2	1	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mg/dL)	2	X	X
3	1	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mg/dL)	3	X	X

Obs	BASE_	visit2200_	visit3600_	Freq	Percent	BASE	visit2200	visit3600
	Miss	Miss	Miss					
1	X	X	X	174	74.36	-8.066529	7.514766	0.264897
2	X	X	.	27	11.54	-19.310667	22.221185	.
3	X	.	.	33	14.10	-17.304000	.	.

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9GINB4U Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2200

Obs	_Imputation_	PARAM				Effect	REGION1
1	1	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mg/dL)	Intercept	
2	1	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mg/dL)	REGION1	EUROPE
4	1	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mg/dL)	REGION1	JAPAN
5	1	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mg/dL)	BOLAD1	
6	1	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mg/dL)	BASE	
Obs		BOLAD1		ObsVal		_1	
1				-0.02007	0.017451		
2				-0.12057	-0.091676		
3				0.14256	-0.014209		
4				-0.04809	-0.087268		
5		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.08594	0.026151		
6				-0.62508	-0.650577		

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression Regression Information

Parameter Code=P9GINB4U Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

	O	b	s	I m p u t o n	P A R A M	E f f e c t	R E G I O N	B O L D	O b s V a l	T
7	1	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mg/dL)	Intercept			0.01958	0.084871
8	1	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mg/dL)	REGION1 ASIA (EXCLUDING JAPAN)			-0.00572	0.141814
9	1	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mg/dL)	REGION1 EUROPE			0.01851	-0.182770

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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9GINB4U Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM	Effect
10	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	REGION1
11	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	BOLAD1
12	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	BASE
13	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	visit2200

Obs	REGION1	BOLAD1	ObsVal	_1
10	JAPAN		0.07962	0.137311
11		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.01920	-0.038829
12			-0.61717	-0.652217
13			0.20331	0.111997

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The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9GINB4U Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM	Description	Value
1	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	Method	Monotone
3	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	Number of Imputations	1
4	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	Seed for random number generator	4322

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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=P9GINB4U Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM				Group	REGION1_	BOLAD1_
							Miss	Miss
1	1	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mg/dL)	1	X	X
2	1	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mg/dL)	2	X	X
3	1	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mg/dL)	3	X	X

Obs	BASE_	visit2200_	visit3600_	Freq	Percent	BASE	visit2200	visit3600
	Miss	Miss	Miss					
1	X	X	X	205	79.46	-15.951971	9.237580	2.469912
2	X	X	.	26	10.08	-10.415000	5.826692	.
3	X	.	.	27	10.47	-13.684370	.	.

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9GINB4U Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	Intercept	
2	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	REGION1	EUROPE
4	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	REGION1	JAPAN
5	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	BOLAD1	
6	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	BASE	

Obs	BOLAD1	ObsVal	_1
1		-0.08689	0.018048
2		-0.41681	-0.267222
3		0.14115	0.142993
4		0.11817	0.013072
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.08945	0.121909
6		-0.65057	-0.686002

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression Regression Information

Parameter Code=P9GINB4U Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

					P A R A M		E f f e c t	R E G I O N 1	B O L D 1	O b s V a l	T m p u t a t i o n s _
7	1	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mg/dL)	Intercept				-0.04421	-0.123045
8	1	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mg/dL)	REGION1 ASIA (EXCLUDING JAPAN)				-0.18204	-0.100522
9	1	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mg/dL)	REGION1 EUROPE				0.05375	0.082058

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9GINB4U Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM	Effect
10	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	REGION1
11	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	BOLAD1
12	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	BASE
13	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	visit2200

Obs	REGION1	BOLAD1	ObsVal	_1
10	JAPAN		0.01756	-0.077672
11		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.09339	0.036745
12			-0.63027	-0.554583
13			0.15275	0.197138

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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9GINB4U Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM	Description	Value
1	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	Method	Monotone
3	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	Number of Imputations	1
4	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	Seed for random number generator	4323

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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=P9GINB4U Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM				Group	REGION1_	BOLAD1_
							Miss	Miss
1	1	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mg/dL)	1	X	X
2	1	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mg/dL)	2	X	X
3	1	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mg/dL)	3	X	X

Obs	BASE_	visit2200_	visit3600_	Freq	Percent	BASE	visit2200	visit3600
	Miss	Miss	Miss					
1	X	X	X	184	78.63	-12.406728	-0.955165	8.930141
2	X	X	.	27	11.54	-15.312444	49.832444	.
3	X	.	.	23	9.83	-11.421043	.	.

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9GINB4U Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	Intercept	
2	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	REGION1	EUROPE
4	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	REGION1	JAPAN
5	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	BOLAD1	
6	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	BASE	

Obs	BOLAD1	ObsVal	_1
1		0.01067	-0.035466
2		0.08254	0.140435
3		0.02889	-0.100484
4		-0.00884	0.044554
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.05532	-0.074456
6		-0.72749	-0.795996

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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression Regression Information

Parameter Code=P9GINB4U Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

		O b s						T i m p u t a t i o n s		P A R A M		E f f e c t		R E G I O N		B O L D		O b s		I	
7	1	Nocturnal	increment	(bedtime	to	04:00)	(SMPG)	(mg/dL)	Intercept												
8	1	Nocturnal	increment	(bedtime	to	04:00)	(SMPG)	(mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)									0.01510	0.058853	
9	1	Nocturnal	increment	(bedtime	to	04:00)	(SMPG)	(mg/dL)	REGION1	EUROPE									-0.04449	0.028591	
																			0.04343	0.076529	

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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9GINB4U Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM	Effect
10	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	REGION1
11	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	BOLAD1
12	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	BASE
13	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	visit2200

Obs	REGION1	BOLAD1	ObsVal	_1
10	JAPAN		-0.11688	-0.170402
11		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.06241	0.112592
12			-0.45316	-0.404290
13			0.28243	0.273955

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=P9PGINB4 Planned Treatment for Period 30 (N)=2

Obs	PARAM				Description	Value
1	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mmol/L)	Data Set	WORK.ENDPOINT_PARAM
2	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mmol/L)	Method	Monotone-data_MCMC
3	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mmol/L)	Multiple Imputation Chain	Multiple Chains
4	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
5	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mmol/L)	Start	Starting Value
6	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mmol/L)	Prior	Jeffreys
7	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mmol/L)	Number of Imputations	20000
8	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mmol/L)	Number of Burn-in Iterations	200
9	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mmol/L)	Seed for random number generator	1234

Parameter Code=P9PGINB4 Planned Treatment for Period 30 (N)=3

Obs	PARAM				Description	Value
10	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mmol/L)	Data Set	WORK.ENDPOINT_PARAM
11	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mmol/L)	Method	Monotone-data_MCMC
12	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mmol/L)	Multiple Imputation Chain	Multiple Chains
13	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
14	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mmol/L)	Start	Starting Value
15	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mmol/L)	Prior	Jeffreys
16	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mmol/L)	Number of Imputations	20000
17	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mmol/L)	Number of Burn-in Iterations	200
18	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mmol/L)	Seed for random number generator	1013599241

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=P9PGINB4 Planned Treatment for Period 30 (N)=4

Obs	PARAM				Description	Value
19	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mmol/L)	Data Set	WORK.ENDPOINT_PARAM
20	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mmol/L)	Method	Monotone-data MCMC
21	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mmol/L)	Multiple Imputation Chain	Multiple Chains
22	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
23	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mmol/L)	Start	Starting Value
24	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mmol/L)	Prior	Jeffreys
25	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mmol/L)	Number of Imputations	20000
26	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mmol/L)	Number of Burn-in Iterations	200
27	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mmol/L)	Seed for random number generator	2024401714

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with MCMC

Missing data pattern

Parameter Code=P9PGINB4 Planned Treatment for Period 30 (N)=3

O b s						v i s i t B A S E			v i s i t v i s i t			v i s i t		
						2 2 0 0			P e r c e n t			B A S E		
						P A R A M			G r o u p			F r e q		
						M M M i i i s s s								
5	Nocturnal	increment	(bedtime to 04:00)	(SMPG)	(mmol/L)	1	X	X	X	169	65.50	-0.468512	0.089204	-0.369777
6	Nocturnal	increment	(bedtime to 04:00)	(SMPG)	(mmol/L)	2	X	X	O	26	10.08	-0.577969	0.323346	.
7	Nocturnal	increment	(bedtime to 04:00)	(SMPG)	(mmol/L)	3	X	.	X	36	13.95	-2.841528	.	2.516405
8	Nocturnal	increment	(bedtime to 04:00)	(SMPG)	(mmol/L)	4	X	O	O	27	10.47	-0.759399	.	

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with MCMC

Missing data pattern

Parameter Code=P9PGINB4 Planned Treatment for Period 30 (N)=4

O b s							v i s i t t						v i s i t t											
							B A S E						v i s i t t											
							P A R A M						P e r c e n t											
							G r o u p			F r e q			B A S E											
							\bar{M}	\bar{M}	\bar{M}				\bar{M}	\bar{M}	\bar{M}									
							i	i	i				s	s	s									
							s	s	s				s	s	s									
9	Nocturnal	increment	(bedtime to 04:00)	(SMPG)	(mmol/L)		1	X	X	X	152	64.96	-0.705912	-0.127701	0.230560									
10	Nocturnal	increment	(bedtime to 04:00)	(SMPG)	(mmol/L)		2	X	X	O	27	11.54	-0.849747	2.765396	.									
11	Nocturnal	increment	(bedtime to 04:00)	(SMPG)	(mmol/L)		3	X	.	X	32	13.68	-0.605778	.	1.754356									
12	Nocturnal	increment	(bedtime to 04:00)	(SMPG)	(mmol/L)		4	X	O	O	23	9.83	-0.633798	.										

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The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PGINB4 Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM	Description	Value
1	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	Method	Monotone
3	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	Number of Imputations	1
4	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	Seed for random number generator	4321

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The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=P9PGINB4 Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM				Group	REGION1_ Miss -	BOLAD1_ Miss -
1	1	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mmol/L)	1	X	X
2	1	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mmol/L)	2	X	X
3	1	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mmol/L)	3	X	X

Obs	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
1	X	X	X	174	74.36	-0.447643	0.417024	0.014700
2	X	X	.	27	11.54	-1.071624	1.233140	.
3	X	.	.	33	14.10	-0.960266	.	.

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGINB4 Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	Intercept	
2	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	REGION1	EUROPE
4	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	REGION1	JAPAN
5	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	BOLAD1	
6	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	BASE	

Obs	BOLAD1	ObsVal	_1
1		-0.02007	0.017451
2		-0.12057	-0.091676
3		0.14256	-0.014209
4		-0.04809	-0.087268
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.08594	0.026151
6		-0.62508	-0.650577

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGINB4 Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

								I m p u t a t i o n s																	
								P A R A M		E f f e c t		R E G I O N 1		B O L D 1		O b s V a l				I					
7	1	Nocturnal	increment	(bedtime	to	04:00)	(SMPG)	(mmol/L)	Intercept													0.01958		0.084871	
8	1	Nocturnal	increment	(bedtime	to	04:00)	(SMPG)	(mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)												-0.00572		0.141814	
9	1	Nocturnal	increment	(bedtime	to	04:00)	(SMPG)	(mmol/L)	REGION1	EUROPE												0.01851		-0.182770	

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGINB4 Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM	Effect
10	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	REGION1
11	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	BOLAD1
12	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	BASE
13	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	visit2200

Obs	REGION1	BOLAD1	ObsVal	_1
10	JAPAN		0.07962	0.137311
11		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.01920	-0.038829
12			-0.61717	-0.652217
13			0.20331	0.111997

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The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PGINB4 Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM	Description	Value
1	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	Method	Monotone
3	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	Number of Imputations	1
4	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	Seed for random number generator	4322

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The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=P9PGINB4 Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM				Group	REGION1_ Miss	BOLAD1_ Miss
1	1	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mmol/L)	1	X	X
2	1	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mmol/L)	2	X	X
3	1	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mmol/L)	3	X	X

Obs	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
1	X	X	X	205	79.46	-0.885237	0.512629	0.137065
2	X	X	.	26	10.08	-0.577969	0.323346	.
3	X	.	.	27	10.47	-0.759399	.	.

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGINB4 Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	Intercept	
2	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	REGION1	EUROPE
4	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	REGION1	JAPAN
5	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	BOLAD1	
6	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	BASE	

Obs	BOLAD1	ObsVal	_1
1		-0.08689	0.018048
2		-0.41681	-0.267222
3		0.14115	0.142993
4		0.11817	0.013072
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.08945	0.121909
6		-0.65057	-0.686002

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGINB4 Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

Imputed a t i o n s		P A R A M		E f f e c t		R E G I O N 1		B O D I L		O b s e r v e d		I	
7	1	Nocturnal increment	(bedtime to 04:00) (SMPG) (mmol/L)	Intercept						-0.04421		-0.123045	
8	1	Nocturnal increment	(bedtime to 04:00) (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)					-0.18204		-0.100522	
9	1	Nocturnal increment	(bedtime to 04:00) (SMPG) (mmol/L)	REGION1	EUROPE					0.05375		0.082058	

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGINB4 Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM	Effect
10	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	REGION1
11	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	BOLAD1
12	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	BASE
13	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	visit2200

Obs	REGION1	BOLAD1	ObsVal	_1
10	JAPAN		0.01756	-0.077672
11		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.09339	0.036745
12			-0.63027	-0.554583
13			0.15275	0.197138

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PGINB4 Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM	Description	Value
1	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	Method	Monotone
3	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	Number of Imputations	1
4	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	Seed for random number generator	4323

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The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=P9PGINB4 Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM				Group	REGION1_ Miss	BOLAD1_ Miss
1	1	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mmol/L)	1	X	X
2	1	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mmol/L)	2	X	X
3	1	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mmol/L)	3	X	X

Obs	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
1	X	X	X	184	78.63	-0.688498	-0.053006	0.495568
2	X	X	.	27	11.54	-0.849747	2.765396	.
3	X	.	.	23	9.83	-0.633798	.	.

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGINB4 Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	Intercept	
2	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	REGION1	EUROPE
4	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	REGION1	JAPAN
5	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	BOLAD1	
6	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	BASE	

Obs	BOLAD1	ObsVal	_1
1		0.01067	-0.035466
2		0.08254	0.140435
3		0.02889	-0.100484
4		-0.00884	0.044554
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.05532	-0.074456
6		-0.72749	-0.795996

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGINB4 Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

								I m p u t a t i o n s													
								P A R A M		E f f e c t		R E G I O N 1		B O L A D 1		O b s V a l				I	
7	1	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mmol/L)	Intercept										0.01510		0.058853			
8	1	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mmol/L)	REGION1 ASIA (EXCLUDING JAPAN)										-0.04449		0.028591			
9	1	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mmol/L)	REGION1 EUROPE										0.04343		0.076529			

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGINB4 Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM	Effect
10	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	REGION1
11	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	BOLAD1
12	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	BASE
13	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	visit2200

Obs	REGION1	BOLAD1	ObsVal	_1
10	JAPAN		-0.11688	-0.170402
11		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.06241	0.112592
12			-0.45316	-0.404290
13			0.28243	0.273955

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=P9GINBBU Planned Treatment for Period 30 (N)=2

Obs	PARAM				Description	Value
1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	Data Set	WORK.ENDPOINT_PARAM
2	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	Method	Monotone-data_MCMC
3	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	Multiple Imputation Chain	Multiple Chains
4	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
5	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	Start	Starting Value
6	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	Prior	Jeffreys
7	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	Number of Imputations	20000
8	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	Number of Burn-in Iterations	200
9	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	Seed for random number generator	1234

Parameter Code=P9GINBBU Planned Treatment for Period 30 (N)=3

Obs	PARAM				Description	Value
10	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	Data Set	WORK.ENDPOINT_PARAM
11	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	Method	Monotone-data_MCMC
12	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	Multiple Imputation Chain	Multiple Chains
13	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
14	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	Start	Starting Value
15	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	Prior	Jeffreys
16	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	Number of Imputations	20000
17	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	Number of Burn-in Iterations	200
18	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	Seed for random number generator	1588387068

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The MI Procedure with MCMC
Model Information

Parameter Code=P9GINBBU Planned Treatment for Period 30 (N)=4

Obs	PARAM				Description	Value
19	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	Data Set	WORK.ENDPOINT_PARAM
20	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	Method	Monotone-data_MCMC
21	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	Multiple Imputation Chain	Multiple Chains
22	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
23	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	Start	Starting Value
24	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	Prior	Jeffreys
25	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	Number of Imputations	20000
26	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	Number of Burn-in Iterations	200
27	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	Seed for random number generator	1567892126

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The MI Procedure with MCMC
Missing data pattern

Parameter Code=P9GINBBU Planned Treatment for Period 30 (N)=2

Obs	PARAM				Group	BASE_ Miss	visit2200_ Miss
1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	1	X	X
2	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	2	X	X
3	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	3	X	.
4	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	4	X	0

Obs	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
1	X	247	82.06	-37.135215	23.198340	18.464000
2	0	17	5.65	-35.201059	3.993647	.
3	X	23	7.64	-28.604870	.	-18.520000
4	0	14	4.65	-17.031000	.	.

Parameter Code=P9GINBBU Planned Treatment for Period 30 (N)=3

Obs	PARAM				Group	BASE_ Miss	visit2200_ Miss
5	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	1	X	X
6	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	2	X	X

Obs	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
5	X	246	82.27	-38.819707	20.026398	14.015195
6	0	17	5.69	-40.796824	1.499529	.

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The MI Procedure with MCMC
Missing data pattern

Parameter Code=P9GINBBU Planned Treatment for Period 30 (N)=3

(continued)

Obs	PARAM				Group	BASE_ Miss	visit2200_ Miss
7	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	3	X	.
8	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	4	X	0
Obs	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600	
7	X	26	8.70	-54.662385	.	49.195154	
8	0	10	3.34	-38.586200	.	.	

Parameter Code=P9GINBBU Planned Treatment for Period 30 (N)=4

Obs	PARAM				Group	BASE_ Miss	visit2200_ Miss
9	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	1	X	X
10	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	2	X	X
11	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	3	X	.
Obs	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600	
9	X	249	82.18	-29.026482	-0.873116	7.157735	
10	0	19	6.27	-81.583684	77.483053	.	
11	X	22	7.26	6.794364	.	-20.034182	

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The MI Procedure with MCMC
Missing data pattern

Parameter Code=P9GINBBU Planned Treatment for Period 30 (N)=4

(continued)

Obs	PARAM				Group	BASE_ Miss	visit2200_ Miss
12	Nocturnal increment (bedtime to breakfast) (SMPG) (mg/dL)				4	X	O
Obs	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600	
12	O	13	4.29	-51.815846	.	.	

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The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=P9GINBBU Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM					Group	REGION1_ Miss	BOLAD1_ Miss
1	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)		1	X	X
2	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)		2	X	X
3	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)		3	X	X

Obs	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
1	X	X	X	270	89.70	-36.408556	24.146906	15.313511
2	X	X	.	17	5.65	-35.201059	3.993647	.
3	X	.	.	14	4.65	-17.031000	.	.

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9GINBBU Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2200

Obs	_Imputation_	PARAM				Effect	REGION1
1	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	Intercept	
2	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	REGION1	EUROPE
4	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	REGION1	JAPAN
5	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	BOLAD1	
6	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	BASE	
Obs		BOLAD1		ObsVal	_1		
1				-0.00969	0.022407		
2				0.04614	0.076030		
3				0.03874	-0.088276		
4				-0.03168	-0.054656		
5		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.04968	0.002227		
6				-0.63783	-0.655501		

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9GINBBU Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM				Effect
10	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	REGION1
11	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	BOLAD1
12	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	BASE
13	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	visit2200
Obs	REGION1	BOLAD1			ObsVal	_1
10	JAPAN				0.08001	-0.022689
11		BOLUS INSULIN ALGORITHM (SLIDING SCALE)			-0.05507	-0.034379
12					-0.73632	-0.743073
13					-0.01148	-0.002881

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression Model Information

Parameter Code=P9GINBBU Planned Treatment for Period 30 (N)=3

O b s	I m p u t a t i o n —	P A R A M						D e s c r i p t i o n	V a l u e	
1	1	Nocturnal	increment	(bedtime	to	breakfast)	(SMPG)	(mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	Nocturnal	increment	(bedtime	to	breakfast)	(SMPG)	(mg/dL)	Method	Monotone
3	1	Nocturnal	increment	(bedtime	to	breakfast)	(SMPG)	(mg/dL)	Number of Imputations	1
4	1	Nocturnal	increment	(bedtime	to	breakfast)	(SMPG)	(mg/dL)	Seed for random number generator	4322

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=P9GINBBU Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM					Group	REGION1_ Miss	BOLAD1_ Miss
1	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)		1	X	X
2	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)		2	X	X
3	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)		3	X	X

Obs	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
1	X	X	X	272	90.97	-40.334081	23.253880	17.377985
2	X	X	.	17	5.69	-40.796824	1.499529	.
3	X	.	.	10	3.34	-38.586200	.	.

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9GINBBU Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2200

Obs	_Imputation_	PARAM				Effect	REGION1
1	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	Intercept	
2	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	REGION1	EUROPE
4	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	REGION1	JAPAN
5	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	BOLAD1	
6	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	BASE	
Obs		BOLAD1		ObsVal	_1		
1				-0.07587	0.019259		
2				-0.35310	-0.221030		
3				0.12929	0.128988		
4				0.09779	0.008012		
5		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.08201	0.106310		
6				-0.64327	-0.678593		

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression Regression Information

Parameter Code=P9GINBBU Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

				P A R A M	E f f e c t	R E G I O N 1	B O L D 1	O b s V a l 1	I
7	1	Nocturnal increment (bedtime to breakfast)	(SMPG)	(mg/dL)	Intercept			-0.02811	0.025383
8	1	Nocturnal increment (bedtime to breakfast)	(SMPG)	(mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)		-0.08660	-0.070762
9	1	Nocturnal increment (bedtime to breakfast)	(SMPG)	(mg/dL)	REGION1	EUROPE		0.02587	0.052957

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9GINBBU Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM				Effect
10	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	REGION1
11	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	BOLAD1
12	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	BASE
13	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	visit2200
Obs	REGION1	BOLAD1			ObsVal	_1
10	JAPAN				-0.06558	-0.165151
11		BOLUS INSULIN ALGORITHM (SLIDING SCALE)			0.11363	0.115823
12					-0.63392	-0.536478
13					0.15155	0.208733

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression Model Information

Parameter Code=P9GINBBU Planned Treatment for Period 30 (N)=4

O b s	I m p u t a t i o n —	P A R A M	D e s c r i p t i o n	V a l u e
1	1	Nocturnal increment (bedtime to breakfast) (SMPG) (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	Nocturnal increment (bedtime to breakfast) (SMPG) (mg/dL)	Method	Monotone
3	1	Nocturnal increment (bedtime to breakfast) (SMPG) (mg/dL)	Number of Imputations	1
4	1	Nocturnal increment (bedtime to breakfast) (SMPG) (mg/dL)	Seed for random number generator	4323

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=P9GINBBU Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM				Group	REGION1_ Miss	BOLAD1_ Miss
1	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	1	X	X
2	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	2	X	X
3	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	3	X	X

Obs	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
1	X	X	X	271	89.44	-26.118517	-3.293226	4.950273
2	X	X	.	19	6.27	-81.583684	77.483053	.
3	X	.	.	13	4.29	-51.815846	.	.

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9GINBBU Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2200

Obs	_Imputation_	PARAM				Effect	REGION1
1	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	Intercept	
2	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	REGION1	EUROPE
4	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	REGION1	JAPAN
5	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	BOLAD1	
6	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	BASE	
Obs		BOLAD1		ObsVal	_1		
1				0.01540	-0.023896		
2				0.10874	0.152560		
3				0.05487	-0.044217		
4				-0.02405	0.011639		
5		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.02061	0.016427		
6				-0.73489	-0.791426		

Fast-acting insulin aspart
NN1218-4131

Clinical Trial Report
Statistical document

Date:
Version:

14 February 2018
1.0

Status:
Page:

Final
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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9GINBBU Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

O b s _	I m p u t a t i o n			P A R A M		E f f e c t		R E G I O N	1	B O D Y	1	O b s _	O b s _	I
7	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	Intercept							0.03663	0.001770
8	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)						0.00847	0.023400
9	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	REGION1	EUROPE						0.05480	0.116817

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9GINBBU Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM				Effect
10	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	REGION1
11	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	BOLAD1
12	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	BASE
13	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	visit2200
Obs	REGION1	BOLAD1			ObsVal	_1
10	JAPAN				-0.04503	-0.081887
11		BOLUS INSULIN ALGORITHM (SLIDING SCALE)			0.02387	0.078980
12					-0.64577	-0.784411
13					0.15630	0.019081

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=P9PGINBB Planned Treatment for Period 30 (N)=2

Obs	PARAM					Description	Value
1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)		Data Set	WORK.ENDPOINT_PARAM
2	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)		Method	Monotone-data_MCMC
3	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)		Multiple Imputation Chain	Multiple Chains
4	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)		Initial Estimates for MCMC	EM Posterior Mode
5	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)		Start	Starting Value
6	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)		Prior	Jeffreys
7	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)		Number of Imputations	20000
8	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)		Number of Burn-in Iterations	200
9	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)		Seed for random number generator	1234

Parameter Code=P9PGINBB Planned Treatment for Period 30 (N)=3

Obs	PARAM					Description	Value
10	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)		Data Set	WORK.ENDPOINT_PARAM
11	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)		Method	Monotone-data_MCMC
12	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)		Multiple Imputation Chain	Multiple Chains
13	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)		Initial Estimates for MCMC	EM Posterior Mode
14	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)		Start	Starting Value
15	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)		Prior	Jeffreys
16	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)		Number of Imputations	20000
17	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)		Number of Burn-in Iterations	200
18	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)		Seed for random number generator	1588387068

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=P9PGINBB Planned Treatment for Period 30 (N)=4

Obs	PARAM				Description	Value
19	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	Data Set	WORK.ENDPOINT_PARAM
20	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	Method	Monotone-data_MCMC
21	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	Multiple Imputation Chain	Multiple Chains
22	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
23	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	Start	Starting Value
24	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	Prior	Jeffreys
25	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	Number of Imputations	20000
26	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	Number of Burn-in Iterations	200
27	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	Seed for random number generator	1567892126

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with MCMC
Missing data pattern

Parameter Code=P9PGINBB Planned Treatment for Period 30 (N)=2

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss
1	Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)	1	X	X
2	Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)	2	X	X
3	Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)	3	X	.
4	Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)	4	X	O

Obs	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
1	X	247	82.06	-2.060778	1.287366	1.024639
2	O	17	5.65	-1.953444	0.221623	.
3	X	23	7.64	-1.587396	.	-1.027747
4	O	14	4.65	-0.945117	.	.

Parameter Code=P9PGINBB Planned Treatment for Period 30 (N)=3

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss
5	Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)	1	X	X
6	Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)	2	X	X

Obs	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
5	X	246	82.27	-2.154257	1.111343	0.777758
6	O	17	5.69	-2.263975	0.083215	.

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with MCMC
Missing data pattern

Parameter Code=P9PGINBB Planned Treatment for Period 30 (N)=3

(continued)

Obs	PARAM				Group	BASE_ Miss	visit2200_ Miss
7	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	3	X	.
8	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	4	X	O
Obs	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600	
7	X	26	8.70	-3.033429	.	2.730031	
8	O	10	3.34	-2.141299	.	.	

Parameter Code=P9PGINBB Planned Treatment for Period 30 (N)=4

Obs	PARAM				Group	BASE_ Miss	visit2200_ Miss
9	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	1	X	X
10	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	2	X	X
11	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	3	X	.
Obs	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600	
9	X	249	82.18	-1.610793	-0.048453	0.397211	
10	O	19	6.27	-4.527396	4.299836	.	
11	X	22	7.26	0.377046	.	-1.111775	

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with MCMC
Missing data pattern

Parameter Code=P9PGINBB Planned Treatment for Period 30 (N)=4

(continued)

Obs	PARAM				Group	BASE_ Miss	visit2200_ Miss
12	Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)				4	X	O
Obs	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600	
12	O	13	4.29	-2.875463	.	.	

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PGINBB Planned Treatment for Period 30 (N)=2

Obs		Imputation				Descript		Variables	
		P	A	R	A	M			
1	1	Nocturnal increment (bedtime to breakfast)	(SMPG)	(mmol/L)	Data Set			WORK.MONO_SORT_TRT	
2	1	Nocturnal increment (bedtime to breakfast)	(SMPG)	(mmol/L)	Method			Monotone	
3	1	Nocturnal increment (bedtime to breakfast)	(SMPG)	(mmol/L)	Number of Imputations			1	
4	1	Nocturnal increment (bedtime to breakfast)	(SMPG)	(mmol/L)	Seed for random number generator			4321	

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=P9PGINBB Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM					Group	REGION1_ Miss	BOLAD1_ Miss
1	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)		1	X	X
2	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)		2	X	X
3	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)		3	X	X

Obs	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
1	X	X	X	270	89.70	-2.020453	1.340006	0.849806
2	X	X	.	17	5.65	-1.953444	0.221623	.
3	X	.	.	14	4.65	-0.945117	.	.

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGINBB Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2200

Obs	_Imputation_	PARAM				Effect	REGION1
1	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	Intercept	
2	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	REGION1	EUROPE
4	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	REGION1	JAPAN
5	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	BOLAD1	
6	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	BASE	
Obs	BOLAD1		ObsVal		_1		
1			-0.00969		0.022407		
2			0.04614		0.076030		
3			0.03874		-0.088276		
4			-0.03168		-0.054656		
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.04968		0.002227		
6			-0.63783		-0.655501		

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGINBB Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM				Effect
10	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	REGION1
11	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	BOLAD1
12	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	BASE
13	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	visit2200
Obs	REGION1	BOLAD1		ObsVal	_1	
10	JAPAN			0.08001	-0.022689	
11		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.05507	-0.034379	
12				-0.73632	-0.743073	
13				-0.01148	-0.002881	

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression Model Information

Parameter Code=P9PGINBB Planned Treatment for Period 30 (N)=3

O b s	I m p u t a t i o n _	P A R A M	D e s c r i p t i o n	V a l u e
1	1	Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)	Method	Monotone
3	1	Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)	Number of Imputations	1
4	1	Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)	Seed for random number generator	4322

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=P9PGINBB Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM				Group	REGION1_ Miss	BOLAD1_ Miss
1	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	1	X	X
2	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	2	X	X
3	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	3	X	X

Obs	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
1	X	X	X	272	90.97	-2.238295	1.290448	0.964372
2	X	X	.	17	5.69	-2.263975	0.083215	.
3	X	.	.	10	3.34	-2.141299	.	.

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGINBB Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2200

Obs	_Imputation_	PARAM				Effect	REGION1
1	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	Intercept	
2	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	REGION1	EUROPE
4	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	REGION1	JAPAN
5	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	BOLAD1	
6	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	BASE	
Obs	BOLAD1		ObsVal		_1		
1			-0.07587		0.019259		
2			-0.35310		-0.221030		
3			0.12929		0.128988		
4			0.09779		0.008012		
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.08201		0.106310		
6			-0.64327		-0.678593		

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression Regression Information

Parameter Code=P9PGINBB Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

				P		E	R	B	O	
				A		f	G	O	b	
				R		f	I	L	s	
				A		e	O	A	V	
O o b s _				M		c	N	D	a	\bar{I}
						t	1	1	1	
7 1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	Intercept				-0.02811	0.025383
8 1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	REGION1 ASIA (EXCLUDING JAPAN)				-0.08660	-0.070762
9 1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	REGION1 EUROPE				0.02587	0.052957

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGINBB Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM				Effect
10	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	REGION1
11	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	BOLAD1
12	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	BASE
13	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	visit2200
Obs	REGION1	BOLAD1			ObsVal	_1
10	JAPAN				-0.06558	-0.165151
11		BOLUS INSULIN ALGORITHM (SLIDING SCALE)			0.11363	0.115823
12					-0.63392	-0.536478
13					0.15155	0.208733

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression Model Information

Parameter Code=P9PGINBB Planned Treatment for Period 30 (N)=4

O b s	I m p u t a t i o n _	P A R A M	D e s c r i p t i o n	V a l u e
1	1	Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)	Method	Monotone
3	1	Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)	Number of Imputations	1
4	1	Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)	Seed for random number generator	4323

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=P9PGINBB Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM				Group	REGION1_ Miss	BOLAD1_ Miss
1	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	1	X	X
2	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	2	X	X
3	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	3	X	X

Obs	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
1	X	X	X	271	89.44	-1.449418	-0.182754	0.274710
2	X	X	.	19	6.27	-4.527396	4.299836	.
3	X	.	.	13	4.29	-2.875463	.	.

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGINBB Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2200

Obs	_Imputation_	PARAM				Effect	REGION1
1	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	Intercept	
2	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	REGION1	EUROPE
4	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	REGION1	JAPAN
5	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	BOLAD1	
6	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	BASE	
Obs	BOLAD1		ObsVal		_1		
1			0.01540		-0.023896		
2			0.10874		0.152560		
3			0.05487		-0.044217		
4			-0.02405		0.011639		
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.02061		0.016427		
6			-0.73489		-0.791426		

Fast-acting insulin aspart
NN1218-4131

Clinical Trial Report
Statistical document

Date: 14 February 2018
Version: 1.0

Status: Final
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Novo Nordisk

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGINBB Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

O o b n s _	I m p u t a t i o n s _	P A R A M	E f f e c t	R E G I O N	B O D Y	I	T
7 1	Nocturnal increment (bedtime to breakfast)	(SMPG)	(mmol/L)	Intercept		0.03663	0.001770
8 1	Nocturnal increment (bedtime to breakfast)	(SMPG)	(mmol/L)	REGION1 ASIA (EXCLUDING JAPAN)		0.00847	0.023400
9 1	Nocturnal increment (bedtime to breakfast)	(SMPG)	(mmol/L)	REGION1 EUROPE		0.05480	0.116817

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGINBB Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM				Effect
10	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	REGION1
11	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	BOLAD1
12	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	BASE
13	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	visit2200
Obs	REGION1	BOLAD1			ObsVal	_1
10	JAPAN				-0.04503	-0.081887
11		BOLUS INSULIN ALGORITHM (SLIDING SCALE)			0.02387	0.078980
12					-0.64577	-0.784411
13					0.15630	0.019081

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure Model Information

Parameter Code=P9GIN4BU Parameter=Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Data Set	WORK.IMPUTE
2	1	NN1218-4131	Dependent Variable	eotVisit
3	1	NN1218-4131	Covariance Structure	Diagonal
4	1	NN1218-4131	Estimation Method	REML
5	1	NN1218-4131	Residual Variance Method	Profile
6	1	NN1218-4131	Fixed Effects SE Method	Model-Based
7	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=P9GINB4U Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
8	1	NN1218-4131	Data Set	WORK.IMPUTE
9	1	NN1218-4131	Dependent Variable	eotVisit
10	1	NN1218-4131	Covariance Structure	Diagonal
11	1	NN1218-4131	Estimation Method	REML
12	1	NN1218-4131	Residual Variance Method	Profile
13	1	NN1218-4131	Fixed Effects SE Method	Model-Based
14	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=P9GINBBU Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
15	1	NN1218-4131	Data Set	WORK.IMPUTE
16	1	NN1218-4131	Dependent Variable	eotVisit
17	1	NN1218-4131	Covariance Structure	Diagonal

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Model Information

Parameter Code=P9GINBBU Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mg/dL)

(continued)

Obs	_Imputation_	STUDYID	Descr	Value
18	1	NN1218-4131	Estimation Method	REML
19	1	NN1218-4131	Residual Variance Method	Profile
20	1	NN1218-4131	Fixed Effects SE Method	Model-Based
21	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=P9PGIN4B Parameter=Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
22	1	NN1218-4131	Data Set	WORK.IMPUTE
23	1	NN1218-4131	Dependent Variable	eotVisit
24	1	NN1218-4131	Covariance Structure	Diagonal
25	1	NN1218-4131	Estimation Method	REML
26	1	NN1218-4131	Residual Variance Method	Profile
27	1	NN1218-4131	Fixed Effects SE Method	Model-Based
28	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=P9PGINB4 Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
29	1	NN1218-4131	Data Set	WORK.IMPUTE
30	1	NN1218-4131	Dependent Variable	eotVisit
31	1	NN1218-4131	Covariance Structure	Diagonal
32	1	NN1218-4131	Estimation Method	REML

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Model Information

Parameter Code=P9PGINB4 Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)

(continued)

Obs	_Imputation_	STUDYID	Descr	Value
33	1	NN1218-4131	Residual Variance Method	Profile
34	1	NN1218-4131	Fixed Effects SE Method	Model-Based
35	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=P9PGINBB Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
36	1	NN1218-4131	Data Set	WORK.IMPUTE
37	1	NN1218-4131	Dependent Variable	eotVisit
38	1	NN1218-4131	Covariance Structure	Diagonal
39	1	NN1218-4131	Estimation Method	REML
40	1	NN1218-4131	Residual Variance Method	Profile
41	1	NN1218-4131	Fixed Effects SE Method	Model-Based
42	1	NN1218-4131	Degrees of Freedom Method	Residual


```
nn1218/nn1218-4131/ctr_20180214_er
10FEB2018:06:42:09 - a 797pp stat diff.sas/a 9pp noct stat in_fas app.txt
```

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Class Level Information

Parameter Code=P9GINB4U Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)

Ob- s	—	Input ID	STUDY	Class	Level	Values	Unit
4	1	NN1218-4131	TRTPN		3 2 3 4		5
5	1	NN1218-4131	REGION1		4 ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA		49
6	1	NN1218-4131	BOLAD1		2 BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULI		85

```
nn1218/nn1218-4131/ctr_20180214_er
10FEB2018:06:42:09 - a 797pp stat diff.sas/a 9pp noct stat in_fas app.txt
```

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Class Level Information

Parameter Code=P9PGIN4B Parameter=Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)

Obs	Input	STUDY ID	Classes	Levels	Values	Unit
10	1	NN1218-4131	TRTPN	3 2 3 4		5
11	1	NN1218-4131	REGION1	4 ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA		49
12	1	NN1218-4131	BOLAD1	2 BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULI		85

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Class Level Information

Parameter Code=P9PGINB4 Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)

Obs	Inpution	STUDY ID	Classes	Levels	Values	min
13	1	NN1218-4131	TRTPN	3 2 3 4		5
14	1	NN1218-4131	REGION1	4 ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA		49
15	1	NN1218-4131	BOLAD1	2 BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULI		85

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Class Level Information

Parameter Code=P9PGINBB Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)

Obs	Input	STUDY ID	Class	Level	Values	min
16	1	NN1218-4131	TRTPN	3 2 3 4		5
17	1	NN1218-4131	REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA	49
18	1	NN1218-4131	BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULI	85

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Dimensions

Parameter Code=P9GIN4BU Parameter=Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Covariance Parameters	1
2	1	NN1218-4131	Columns in X	10
3	1	NN1218-4131	Columns in Z	0
4	1	NN1218-4131	Subjects	1
5	1	NN1218-4131	Max Obs per Subject	739

Parameter Code=P9GINB4U Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
6	1	NN1218-4131	Covariance Parameters	1
7	1	NN1218-4131	Columns in X	10
8	1	NN1218-4131	Columns in Z	0
9	1	NN1218-4131	Subjects	1
10	1	NN1218-4131	Max Obs per Subject	726

Parameter Code=P9GINBBU Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
11	1	NN1218-4131	Covariance Parameters	1
12	1	NN1218-4131	Columns in X	10
13	1	NN1218-4131	Columns in Z	0
14	1	NN1218-4131	Subjects	1
15	1	NN1218-4131	Max Obs per Subject	903

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Dimensions

Parameter Code=P9PGIN4B Parameter=Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
16	1	NN1218-4131	Covariance Parameters	1
17	1	NN1218-4131	Columns in X	10
18	1	NN1218-4131	Columns in Z	0
19	1	NN1218-4131	Subjects	1
20	1	NN1218-4131	Max Obs per Subject	739

Parameter Code=P9PGINB4 Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
21	1	NN1218-4131	Covariance Parameters	1
22	1	NN1218-4131	Columns in X	10
23	1	NN1218-4131	Columns in Z	0
24	1	NN1218-4131	Subjects	1
25	1	NN1218-4131	Max Obs per Subject	726

Parameter Code=P9PGINBB Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
26	1	NN1218-4131	Covariance Parameters	1
27	1	NN1218-4131	Columns in X	10
28	1	NN1218-4131	Columns in Z	0
29	1	NN1218-4131	Subjects	1
30	1	NN1218-4131	Max Obs per Subject	903

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Number of Observations

Parameter Code=P9GIN4BU Parameter=Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
1	1	NN1218-4131	Number of Observations Read	739	739	739	739	739
2	1	NN1218-4131	Number of Observations Used	739	739	739	739	739
3	1	NN1218-4131	Number of Observations Not Used	0	739	739	739	739

Parameter Code=P9GINB4U Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
4	1	NN1218-4131	Number of Observations Read	726	726	726	726	726
5	1	NN1218-4131	Number of Observations Used	726	726	726	726	726
6	1	NN1218-4131	Number of Observations Not Used	0	726	726	726	726

Parameter Code=P9GINBBU Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
7	1	NN1218-4131	Number of Observations Read	903	903	903	903	903
8	1	NN1218-4131	Number of Observations Used	903	903	903	903	903
9	1	NN1218-4131	Number of Observations Not Used	0	903	903	903	903

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Number of Observations

Parameter Code=P9PGIN4B Parameter=Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
10	1	NN1218-4131	Number of Observations Read	739	739	739	739	739
11	1	NN1218-4131	Number of Observations Used	739	739	739	739	739
12	1	NN1218-4131	Number of Observations Not Used	0	739	739	739	739

Parameter Code=P9PGINB4 Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
13	1	NN1218-4131	Number of Observations Read	726	726	726	726	726
14	1	NN1218-4131	Number of Observations Used	726	726	726	726	726
15	1	NN1218-4131	Number of Observations Not Used	0	726	726	726	726

Parameter Code=P9PGINBB Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
16	1	NN1218-4131	Number of Observations Read	903	903	903	903	903
17	1	NN1218-4131	Number of Observations Used	903	903	903	903	903
18	1	NN1218-4131	Number of Observations Not Used	0	903	903	903	903

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Covariance Parameter Estimates

Parameter Code=P9GIN4BU Parameter=Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	CovParm	Estimate
1	1	NN1218-4131	Residual	3249.44

Parameter Code=P9GINB4U Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	CovParm	Estimate
20001	1	NN1218-4131	Residual	5580.56

Parameter Code=P9GINBBU Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	CovParm	Estimate
40001	1	NN1218-4131	Residual	5504.40

Parameter Code=P9PGIN4B Parameter=Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	CovParm	Estimate
60001	1	NN1218-4131	Residual	10.0069

Parameter Code=P9PGINB4 Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	CovParm	Estimate
80001	1	NN1218-4131	Residual	17.1857

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Covariance Parameter Estimates

Parameter Code=P9PGINBB Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	CovParm	Estimate
100001	1	NN1218-4131	Residual	16.9512

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Fit Statistics

Parameter Code=P9GIN4BU Parameter=Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	-2 Res Log Likelihood	8036.1
2	1	NN1218-4131	AIC (Smaller is Better)	8038.1
3	1	NN1218-4131	AICC (Smaller is Better)	8038.1
4	1	NN1218-4131	BIC (Smaller is Better)	8042.7

Parameter Code=P9GINB4U Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
5	1	NN1218-4131	-2 Res Log Likelihood	8282.6
6	1	NN1218-4131	AIC (Smaller is Better)	8284.6
7	1	NN1218-4131	AICC (Smaller is Better)	8284.7
8	1	NN1218-4131	BIC (Smaller is Better)	8289.2

Parameter Code=P9GINBBU Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
9	1	NN1218-4131	-2 Res Log Likelihood	10301.5
10	1	NN1218-4131	AIC (Smaller is Better)	10303.5
11	1	NN1218-4131	AICC (Smaller is Better)	10303.5
12	1	NN1218-4131	BIC (Smaller is Better)	10308.3

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The Mixed procedure
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Parameter Code=P9PGIN4B Parameter=Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
13	1	NN1218-4131	-2 Res Log Likelihood	3803.0
14	1	NN1218-4131	AIC (Smaller is Better)	3805.0
15	1	NN1218-4131	AICC (Smaller is Better)	3805.0
16	1	NN1218-4131	BIC (Smaller is Better)	3809.6

Parameter Code=P9PGINB4 Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
17	1	NN1218-4131	-2 Res Log Likelihood	4124.7
18	1	NN1218-4131	AIC (Smaller is Better)	4126.7
19	1	NN1218-4131	AICC (Smaller is Better)	4126.7
20	1	NN1218-4131	BIC (Smaller is Better)	4131.3

Parameter Code=P9PGINBB Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
21	1	NN1218-4131	-2 Res Log Likelihood	5119.9
22	1	NN1218-4131	AIC (Smaller is Better)	5121.9
23	1	NN1218-4131	AICC (Smaller is Better)	5121.9
24	1	NN1218-4131	BIC (Smaller is Better)	5126.7

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The Mixed procedure
Solution for Fixed Effects

Parameter Code=P9GIN4BU Parameter=Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
1	1	NN1218-4131	TRTPN	2				
2	1	NN1218-4131	TRTPN	3				
3	1	NN1218-4131	TRTPN	4				
4	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
5	1	NN1218-4131	REGION1	—	EUROPE			
6	1	NN1218-4131	REGION1	—	JAPAN			
7	1	NN1218-4131	REGION1	—	NORTH AMERICA			
8	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
9	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
10	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	-10.7921	5.4213	731	-1.99	0.0469	0.05	-21.4353	-0.1489
2	-13.7342	5.3224	731	-2.58	0.0101	0.05	-24.1832	-3.2852
3	-25.4469	5.3242	731	-4.78	<.0001	0.05	-35.8995	-14.9944
4	27.7640	7.8827	731	3.52	0.0005	0.05	12.2886	43.2395
5	10.9428	5.6694	731	1.93	0.0540	0.05	-0.1875	22.0730
6	14.4381	5.9975	731	2.41	0.0163	0.05	2.6638	26.2124
7	0
8	-8.5002	4.7694	731	-1.78	0.0751	0.05	-17.8635	0.8631
9	0
10	-0.8181	0.03059	731	-26.75	<.0001	0.05	-0.8781	-0.7580

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The Mixed procedure
Solution for Fixed Effects

Parameter Code=P9GINB4U Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
11	1	NN1218-4131	TRTPN	2				
12	1	NN1218-4131	TRTPN	3				
13	1	NN1218-4131	TRTPN	4				
14	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
15	1	NN1218-4131	REGION1	—	EUROPE			
16	1	NN1218-4131	REGION1	—	JAPAN			
17	1	NN1218-4131	REGION1	—	NORTH AMERICA			
18	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
19	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
20	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
11	-7.4187	7.0304	718	-1.06	0.2917	0.05	-21.2212	6.3838
12	-17.6800	6.8550	718	-2.58	0.0101	0.05	-31.1382	-4.2218
13	-6.9531	6.9742	718	-1.00	0.3191	0.05	-20.6454	6.7392
14	-7.8419	10.4374	718	-0.75	0.4527	0.05	-28.3333	12.6495
15	3.0592	7.4787	718	0.41	0.6826	0.05	-11.6235	17.7420
16	-5.6068	7.9047	718	-0.71	0.4784	0.05	-21.1259	9.9122
17	0
18	11.7987	6.3054	718	1.87	0.0617	0.05	-0.5804	24.1779
19	0
20	-0.9090	0.03360	718	-27.05	<.0001	0.05	-0.9750	-0.8431

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Solution for Fixed Effects

Parameter Code=P9GINBBU Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1			BOLAD1
21	1	NN1218-4131	TRTPN	2				
22	1	NN1218-4131	TRTPN	3				
23	1	NN1218-4131	TRTPN	4				
24	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
25	1	NN1218-4131	REGION1	—	EUROPE			
26	1	NN1218-4131	REGION1	—	JAPAN			
27	1	NN1218-4131	REGION1	—	NORTH AMERICA			
28	1	NN1218-4131	BOLAD1	—				BOLUS INSULIN ALGORITHM (SLIDING SCALE)
29	1	NN1218-4131	BOLAD1	—				CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY
30	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
21	-26.6978	6.1681	895	-4.33	<.0001	0.05	-38.8034	-14.5922
22	-26.8685	6.3322	895	-4.24	<.0001	0.05	-39.2962	-14.4409
23	-27.7425	6.2094	895	-4.47	<.0001	0.05	-39.9292	-15.5558
24	5.5197	9.2088	895	0.60	0.5491	0.05	-12.5537	23.5932
25	12.9010	6.4902	895	1.99	0.0471	0.05	0.1633	25.6387
26	-0.4513	7.0974	895	-0.06	0.9493	0.05	-14.3807	13.4782
27	0
28	5.4938	5.5378	895	0.99	0.3214	0.05	-5.3748	16.3623
29	0
30	-0.9255	0.02891	895	-32.01	<.0001	0.05	-0.9822	-0.8687

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Parameter Code=P9PGIN4B Parameter=Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
31	1	NN1218-4131	TRTPN	2				
32	1	NN1218-4131	TRTPN	3				
33	1	NN1218-4131	TRTPN	4				
34	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
35	1	NN1218-4131	REGION1	—	EUROPE			
36	1	NN1218-4131	REGION1	—	JAPAN			
37	1	NN1218-4131	REGION1	—	NORTH AMERICA			
38	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
39	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
40	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
31	-0.5989	0.3009	731	-1.99	0.0469	0.05	-1.1895	-0.00826
32	-0.7622	0.2954	731	-2.58	0.0101	0.05	-1.3420	-0.1823
33	-1.4121	0.2955	731	-4.78	<.0001	0.05	-1.9922	-0.8321
34	1.5407	0.4374	731	3.52	0.0005	0.05	0.6819	2.3995
35	0.6073	0.3146	731	1.93	0.0540	0.05	-0.01040	1.2249
36	0.8012	0.3328	731	2.41	0.0163	0.05	0.1478	1.4546
37	0
38	-0.4717	0.2647	731	-1.78	0.0751	0.05	-0.9913	0.04790
39	0
40	-0.8181	0.03059	731	-26.75	<.0001	0.05	-0.8781	-0.7580

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Solution for Fixed Effects

Parameter Code=P9PGINB4 Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
41	1	NN1218-4131	TRTPN	2				
42	1	NN1218-4131	TRTPN	3				
43	1	NN1218-4131	TRTPN	4				
44	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
45	1	NN1218-4131	REGION1	—	EUROPE			
46	1	NN1218-4131	REGION1	—	JAPAN			
47	1	NN1218-4131	REGION1	—	NORTH AMERICA			
48	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
49	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
50	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
41	-0.4117	0.3901	718	-1.06	0.2917	0.05	-1.1776	0.3543
42	-0.9811	0.3804	718	-2.58	0.0101	0.05	-1.7280	-0.2343
43	-0.3859	0.3870	718	-1.00	0.3191	0.05	-1.1457	0.3740
44	-0.4352	0.5792	718	-0.75	0.4527	0.05	-1.5723	0.7020
45	0.1698	0.4150	718	0.41	0.6826	0.05	-0.6450	0.9846
46	-0.3111	0.4387	718	-0.71	0.4784	0.05	-1.1724	0.5501
47	0
48	0.6548	0.3499	718	1.87	0.0617	0.05	-0.03221	1.3417
49	0
50	-0.9090	0.03360	718	-27.05	<.0001	0.05	-0.9750	-0.8431

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The Mixed procedure
Solution for Fixed Effects

Parameter Code=P9PGINBB Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
51	1	NN1218-4131	TRTPN	2				
52	1	NN1218-4131	TRTPN	3				
53	1	NN1218-4131	TRTPN	4				
54	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
55	1	NN1218-4131	REGION1	—	EUROPE			
56	1	NN1218-4131	REGION1	—	JAPAN			
57	1	NN1218-4131	REGION1	—	NORTH AMERICA			
58	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
59	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
60	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
51	-1.4816	0.3423	895	-4.33	<.0001	0.05	-2.1534	-0.8098
52	-1.4910	0.3514	895	-4.24	<.0001	0.05	-2.1807	-0.8014
53	-1.5395	0.3446	895	-4.47	<.0001	0.05	-2.2158	-0.8632
54	0.3063	0.5110	895	0.60	0.5491	0.05	-0.6967	1.3093
55	0.7159	0.3602	895	1.99	0.0471	0.05	0.009061	1.4228
56	-0.02504	0.3939	895	-0.06	0.9493	0.05	-0.7980	0.7480
57	0
58	0.3049	0.3073	895	0.99	0.3214	0.05	-0.2983	0.9080
59	0
60	-0.9255	0.02891	895	-32.01	<.0001	0.05	-0.9822	-0.8687

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The Mixed procedure
Least Squares Means

Obs	_Imputation_	PARAMCD	PARAM	STUDYID
1	1	P9GIN4BU	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	NN1218-4131
2	1	P9GIN4BU	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	NN1218-4131
3	1	P9GIN4BU	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	NN1218-4131
4	1	P9GINB4U	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	NN1218-4131
5	1	P9GINB4U	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	NN1218-4131
6	1	P9GINB4U	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	NN1218-4131
7	1	P9GINBBU	Nocturnal increment (bedtime to breakfast) (SMPG) (mg/dL)	NN1218-4131
8	1	P9GINBBU	Nocturnal increment (bedtime to breakfast) (SMPG) (mg/dL)	NN1218-4131
9	1	P9GINBBU	Nocturnal increment (bedtime to breakfast) (SMPG) (mg/dL)	NN1218-4131
10	1	P9PGIN4B	Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)	NN1218-4131
11	1	P9PGIN4B	Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)	NN1218-4131
12	1	P9PGIN4B	Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)	NN1218-4131
13	1	P9PGINB4	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	NN1218-4131
14	1	P9PGINB4	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	NN1218-4131

Obs	Effect	TRTPN	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	TRTPN	2	WORK.IMPUTE	16.8212	3.7330	731	4.51	<.0001	0.05	9.4926	24.1499
2	TRTPN	3	WORK.IMPUTE	13.8791	3.5261	731	3.94	<.0001	0.05	6.9566	20.8016
3	TRTPN	4	WORK.IMPUTE	2.1664	3.6655	731	0.59	0.5547	0.05	-5.0297	9.3625
4	TRTPN	2	WORK.IMPUTE	9.1783	4.8907	718	1.88	0.0610	0.05	-0.4236	18.7801
5	TRTPN	3	WORK.IMPUTE	-1.0830	4.6569	718	-0.23	0.8162	0.05	-10.2258	8.0598
6	TRTPN	4	WORK.IMPUTE	9.6440	4.8919	718	1.97	0.0491	0.05	0.03991	19.2480
7	TRTPN	2	WORK.IMPUTE	14.2903	4.2816	895	3.34	0.0009	0.05	5.8872	22.6935
8	TRTPN	3	WORK.IMPUTE	14.1196	4.2975	895	3.29	0.0011	0.05	5.6852	22.5540
9	TRTPN	4	WORK.IMPUTE	13.2456	4.2677	895	3.10	0.0020	0.05	4.8697	21.6216
10	TRTPN	2	WORK.IMPUTE	0.9335	0.2072	731	4.51	<.0001	0.05	0.5268	1.3402
11	TRTPN	3	WORK.IMPUTE	0.7702	0.1957	731	3.94	<.0001	0.05	0.3861	1.1544
12	TRTPN	4	WORK.IMPUTE	0.1202	0.2034	731	0.59	0.5547	0.05	-0.2791	0.5196
13	TRTPN	2	WORK.IMPUTE	0.5093	0.2714	718	1.88	0.0610	0.05	-0.02350	1.0422
14	TRTPN	3	WORK.IMPUTE	-0.06010	0.2584	718	-0.23	0.8162	0.05	-0.5675	0.4473

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Obs	_Imputation_	PARAMCD	PARAM							STUDYID	
15	1	P9PGINB4	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)							NN1218-4131	
16	1	P9PGINBB	Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)							NN1218-4131	
17	1	P9PGINBB	Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)							NN1218-4131	
18	1	P9PGINBB	Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)							NN1218-4131	
Obs	Effect	TRTPN	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
15	TRTPN	4	WORK.IMPUTE	0.5352	0.2715	718	1.97	0.0491	0.05	0.002215	1.0681
16	TRTPN	2	WORK.IMPUTE	0.7930	0.2376	895	3.34	0.0009	0.05	0.3267	1.2593
17	TRTPN	3	WORK.IMPUTE	0.7836	0.2385	895	3.29	0.0011	0.05	0.3155	1.2516
18	TRTPN	4	WORK.IMPUTE	0.7351	0.2368	895	3.10	0.0020	0.05	0.2702	1.1999

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The Mixed procedure
Least Squares Means Estimate

Parameter Code=P9GIN4BU Parameter=Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
1	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
2	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	WORK.IMPUTE	14.6549	5.2389	731	2.80	0.0053	0.05	4.3697	24.9400
2	WORK.IMPUTE	11.7127	5.0911	731	2.30	0.0217	0.05	1.7178	21.7077

Parameter Code=P9GINB4U Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
3	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
4	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
3	WORK.IMPUTE	-0.4657	6.9234	718	-0.07	0.9464	0.05	-14.0581	13.1268
4	WORK.IMPUTE	-10.7269	6.7594	718	-1.59	0.1130	0.05	-23.9975	2.5437

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Parameter Code=P9GINBBU Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
5	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
6	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
5	WORK.IMPUTE	1.0447	6.0481	895	0.17	0.8629	0.05	-10.8254	12.9148
6	WORK.IMPUTE	0.8740	6.0617	895	0.14	0.8854	0.05	-11.0228	12.7707

Parameter Code=P9PGIN4B Parameter=Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
7	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
8	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
7	WORK.IMPUTE	0.8133	0.2907	731	2.80	0.0053	0.05	0.2425	1.3840
8	WORK.IMPUTE	0.6500	0.2825	731	2.30	0.0217	0.05	0.09532	1.2046

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Least Squares Means Estimate

Parameter Code=P9PGINB4 Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
9	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
10	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
9	WORK.IMPUTE	-0.02584	0.3842	718	-0.07	0.9464	0.05	-0.7801	0.7285
10	WORK.IMPUTE	-0.5953	0.3751	718	-1.59	0.1130	0.05	-1.3317	0.1412

Parameter Code=P9PGINBB Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
11	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
12	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
11	WORK.IMPUTE	0.05798	0.3356	895	0.17	0.8629	0.05	-0.6007	0.7167
12	WORK.IMPUTE	0.04850	0.3364	895	0.14	0.8854	0.05	-0.6117	0.7087

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2865 of 4425	Novo Nordisk
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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9GIN4BU Parameter=Nocturnal increment (04:00 to breakfast) (SMPG) (mg/d

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	5.651343	13.857421	19.509046	238305	0.407841	0.289699	0.999986

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits	DF	Minimum	Maximum
Estimate	14.097524	4.416905	5.440506 22.75454	238305	3.707998	25.191361

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	3.19	0.0014

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2866 of 4425	Novo Nordisk
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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9GINB4U Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	7.524085	23.745478	31.269940	345391	0.316880	0.240634	0.999988

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	4.187577	5.591953	-6.77249	15.14764	345391	-7.064663	14.660833

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	0.75	0.4539

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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9GINBBU Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mg

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	2.205188	18.035563	20.240861	1.68E6	0.122275	0.108954	0.999995

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits	DF	Minimum	Maximum
Estimate	13.860204	4.498984	5.042350 22.67806	1.68E6	7.172092	20.089209

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	3.08	0.0021

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2868 of 4425	Novo Nordisk
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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9PGIN4B Parameter=Nocturnal increment (04:00 to breakfast) (SMPG) (mmol

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.017404	0.042675	0.060080	238305	0.407841	0.289699	0.999986

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits	DF	Minimum	Maximum
Estimate	0.782327	0.245111	0.301915 1.262738	238305	0.205771	1.397967

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	3.19	0.0014

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Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2869 of 4425	Novo Nordisk
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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9PGINB4 Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.023171	0.073126	0.096298	345391	0.316880	0.240634	0.999988

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.232385	0.310319	-0.37583	0.840602	345391	-0.392046	0.813587

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	0.75	0.4539

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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9PGINBB Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mm

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.006791	0.055542	0.062333	1.68E6	0.122275	0.108954	0.999995

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits	DF	Minimum	Maximum
Estimate	0.769157	0.249666	0.279820 1.258494	1.68E6	0.398007	1.114828

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	3.08	0.0021

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2871 of 4425	Novo Nordisk
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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9GIN4BU Parameter=Nocturnal increment (04:00 to breakfast) (SMPG) (mg/d

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	3.434011	12.364030	15.798213	423231	0.277756	0.217382	0.999989

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	15.570900	3.974697	7.780615	23.36118	423231	8.413838	22.767824

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	3.92	<.0001

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2872 of 4425	Novo Nordisk
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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9GINB4U Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	6.093679	21.529352	27.623336	410921	0.283055	0.220614	0.999989

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.161232	5.255791	-10.4624	10.13996	410921	-9.359837	10.352676

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-0.03	0.9755

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2873 of 4425	Novo Nordisk
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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9GINBBU Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mg

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	1.908237	18.170109	20.078442	2.21E6	0.105026	0.095045	0.999995

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	12.713177	4.480897	3.930775	21.49558	2.21E6	6.646220	17.799108

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	2.84	0.0046

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2874 of 4425	Novo Nordisk
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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9PGIN4B Parameter=Nocturnal increment (04:00 to breakfast) (SMPG) (mmol

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.010575	0.038076	0.048652	423231	0.277756	0.217382	0.999989

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits	DF	Minimum	Maximum
Estimate	0.864090	0.220571	0.431777 1.296403	423231	0.466917	1.263475

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	3.92	<.0001

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2875 of 4425	Novo Nordisk
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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9PGINB4 Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.018766	0.066301	0.085068	410921	0.283055	0.220614	0.999989

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.008947	0.291664	-0.58060	0.562706	410921	-0.519414	0.574510

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-0.03	0.9755

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Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2876 of 4425	Novo Nordisk
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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9PGINBB Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mm

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.005877	0.055956	0.061833	2.21E6	0.105026	0.095045	0.999995

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits	DF	Minimum	Maximum
Estimate	0.705504	0.248662	0.218134 1.192873	2.21E6	0.368825	0.987742

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	2.84	0.0046

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2877 of 4425	Novo Nordisk
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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9GIN4BU Parameter=Nocturnal increment (04:00 to breakfast) (SMPG) (mg/d

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	3.847070	13.360793	17.208056	400100	0.287952	0.223577	0.999989

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	2.929267	4.148259	-5.20120	11.05973	400100	-5.362282	12.353682

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	0.71	0.4801

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2878 of 4425	Novo Nordisk
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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9GINB4U Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	7.238869	23.756358	30.995589	366626	0.304728	0.233561	0.999988

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits	DF	Minimum	Maximum
Estimate	11.717627	5.567368	0.805750 22.62950	366626	0.707349	22.416788

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	2.10	0.0353

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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9GINBBU Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mg

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	2.061874	17.918991	19.980968	1.88E6	0.115072	0.103198	0.999995

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits	DF	Minimum	Maximum
Estimate	14.112170	4.470008	5.351111 22.87323	1.88E6	8.910245	20.502985

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	3.16	0.0016

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2880 of 4425	Novo Nordisk
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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9PGIN4B Parameter=Nocturnal increment (04:00 to breakfast) (SMPG) (mmol

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.011847	0.041146	0.052993	400100	0.287952	0.223577	0.999989

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.162556	0.230203	-0.28863	0.613748	400100	-0.297574	0.685554

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	0.71	0.4801

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Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2881 of 4425	Novo Nordisk
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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9PGINB4 Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.022293	0.073159	0.095453	366626	0.304728	0.233561	0.999988

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits	DF	Minimum	Maximum
Estimate	0.650257	0.308955	0.044714 1.255799	366626	0.039254	1.243995

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	2.10	0.0353

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2882 of 4425	Novo Nordisk
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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9PGINBB Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mm

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.006350	0.055183	0.061533	1.88E6	0.115072	0.103198	0.999995

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits	DF	Minimum	Maximum
Estimate	0.783139	0.248058	0.296954 1.269325	1.88E6	0.494464	1.137791

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	3.16	0.0016

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Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2883 of 4425	Novo Nordisk
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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=P9GIN4BU Label=Faster aspart (meal) - NovoRapid (meal) Parameter=Nocturnal increment (04:00 to breakfast) (SMP

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	9.419316	27.293306	36.713093	303786	0.345132	0.256583	0.999987

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits	DF	Minimum	Maximum
Estimate	11.168257	6.059133	-0.70747 23.04399	303786	-1.163267	24.155456

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	1.84	0.0653

nn1218/nn1218-4131/ctr_20180214_er
10FEB2018:06:42:09 - a_797pp_stat_diff.sas/a_9pp_noct_stat_in_fas_app.txt

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2884 of 4425	Novo Nordisk
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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=P9GIN4BU Label=Faster aspart (post) - NovoRapid (meal) Parameter=Nocturnal increment (04:00 to breakfast) (SMP

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	7.245086	25.775017	33.020465	415379	0.281104	0.219427	0.999989

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	12.641632	5.746344	1.378973	23.90429	415379	1.174579	24.131948

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	2.20	0.0278

nn1218/nn1218-4131/ctr_20180214_er
10FEB2018:06:42:09 - a_797pp_stat_diff.sas/a_9pp_noct_stat_in_fas_app.txt

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2885 of 4425	Novo Nordisk
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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=P9GINB4U Label=Faster aspart (meal) - NovoRapid (meal) Parameter=Nocturnal increment (bedtime to 04:00) (SMPG)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	14.487200	47.584535	62.072460	367108	0.304467	0.233408	0.999988

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-7.530050	7.878608	-22.9719	7.911788	367108	-22.393103	7.930659

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-0.96	0.3392

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2886 of 4425	Novo Nordisk
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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=P9GINB4U Label=Faster aspart (post) - NovoRapid (meal) Parameter=Nocturnal increment (bedtime to 04:00) (SMPG)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	13.257592	45.357804	58.616059	390903	0.292304	0.226192	0.999989

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-11.878859	7.656113	-26.8846	3.126892	390903	-27.009609	3.289799

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-1.55	0.1208

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2887 of 4425	Novo Nordisk
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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=P9GINBBU Label=Faster aspart (meal) - NovoRapid (meal) Parameter=Nocturnal increment (bedtime to breakfast) (S

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	4.250526	35.987964	40.238703	1.79E6	0.118116	0.105639	0.999995

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.251967	6.343398	-12.6848	12.18087	1.79E6	-8.959151	7.173247

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-0.04	0.9683

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2888 of 4425	Novo Nordisk
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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=P9GINBBU Label=Faster aspart (post) - NovoRapid (meal) Parameter=Nocturnal increment (bedtime to breakfast) (S

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	3.993186	36.149593	40.142979	2.02E6	0.110468	0.099480	0.999995

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits	DF	Minimum	Maximum
Estimate	-1.398993	6.335849	-13.8170 11.01905	2.02E6	-11.033722	6.407154

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-0.22	0.8252

nn1218/nn1218-4131/ctr_20180214_er
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Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2889 of 4425	Novo Nordisk
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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=P9PGIN4B Label=Faster aspart (meal) - NovoRapid (meal) Parameter=Nocturnal increment (04:00 to breakfast) (SMP

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.029007	0.084052	0.113061	303786	0.345132	0.256583	0.999987

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits	DF	Minimum	Maximum
Estimate	0.619770	0.336245	-0.03926 1.278801	303786	-0.064554	1.340480

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	1.84	0.0653

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2890 of 4425	Novo Nordisk
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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=P9PGIN4B Label=Faster aspart (post) - NovoRapid (meal) Parameter=Nocturnal increment (04:00 to breakfast) (SMP

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.022312	0.079376	0.101689	415379	0.281104	0.219427	0.999989

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits	DF	Minimum	Maximum
Estimate	0.701533	0.318887	0.076525 1.326542	415379	0.065182	1.339176

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	2.20	0.0278

nn1218/nn1218-4131/ctr_20180214_er
10FEB2018:06:42:09 - a_797pp_stat_diff.sas/a_9pp_noct_stat_in_fas_app.txt

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2891 of 4425	Novo Nordisk
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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=P9PGINB4 Label=Faster aspart (meal) - NovoRapid (meal) Parameter=Nocturnal increment (bedtime to 04:00) (SMPG)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.044614	0.146540	0.191157	367108	0.304467	0.233408	0.999988

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.417872	0.437215	-1.27480	0.439056	367108	-1.242680	0.440103

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-0.96	0.3392

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2892 of 4425	Novo Nordisk
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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=P9PGINB4 Label=Faster aspart (post) - NovoRapid (meal) Parameter=Nocturnal increment (bedtime to 04:00) (SMPG)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.040828	0.139683	0.180512	390903	0.292304	0.226192	0.999989

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.659204	0.424868	-1.49193	0.173523	390903	-1.498868	0.182564

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-1.55	0.1208

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2893 of 4425	Novo Nordisk
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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=P9PGINBB Label=Faster aspart (meal) - NovoRapid (meal) Parameter=Nocturnal increment (bedtime to breakfast) (S

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.013090	0.110828	0.123918	1.79E6	0.118116	0.105639	0.999995

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.013983	0.352020	-0.70393	0.675964	1.79E6	-0.497178	0.398071

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-0.04	0.9683

nn1218/nn1218-4131/ctr_20180214_er
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Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2894 of 4425	Novo Nordisk
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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=P9PGINBB Label=Faster aspart (post) - NovoRapid (meal) Parameter=Nocturnal increment (bedtime to breakfast) (S

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.012297	0.111325	0.123623	2.02E6	0.110468	0.099480	0.999995

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.077636	0.351601	-0.76676	0.611490	2.02E6	-0.612304	0.355558

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-0.22	0.8252

nn1218/nn1218-4131/ctr_20180214_er
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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure Model Information

Parameter Code=P9GIN4BU Parameter=Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Data Set	WORK.IMPUTE_ABS
2	1	NN1218-4131	Dependent Variable	eotVisitAbs
3	1	NN1218-4131	Covariance Structure	Diagonal
4	1	NN1218-4131	Estimation Method	REML
5	1	NN1218-4131	Residual Variance Method	Profile
6	1	NN1218-4131	Fixed Effects SE Method	Model-Based
7	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=P9GINB4U Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
8	1	NN1218-4131	Data Set	WORK.IMPUTE_ABS
9	1	NN1218-4131	Dependent Variable	eotVisitAbs
10	1	NN1218-4131	Covariance Structure	Diagonal
11	1	NN1218-4131	Estimation Method	REML
12	1	NN1218-4131	Residual Variance Method	Profile
13	1	NN1218-4131	Fixed Effects SE Method	Model-Based
14	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=P9GINBBU Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
15	1	NN1218-4131	Data Set	WORK.IMPUTE_ABS
16	1	NN1218-4131	Dependent Variable	eotVisitAbs
17	1	NN1218-4131	Covariance Structure	Diagonal

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Model Information

Parameter Code=P9GINBBU Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mg/dL)

(continued)

Obs	_Imputation_	STUDYID	Descr	Value
18	1	NN1218-4131	Estimation Method	REML
19	1	NN1218-4131	Residual Variance Method	Profile
20	1	NN1218-4131	Fixed Effects SE Method	Model-Based
21	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=P9PGIN4B Parameter=Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
22	1	NN1218-4131	Data Set	WORK.IMPUTE_ABS
23	1	NN1218-4131	Dependent Variable	eotVisitAbs
24	1	NN1218-4131	Covariance Structure	Diagonal
25	1	NN1218-4131	Estimation Method	REML
26	1	NN1218-4131	Residual Variance Method	Profile
27	1	NN1218-4131	Fixed Effects SE Method	Model-Based
28	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=P9PGINB4 Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
29	1	NN1218-4131	Data Set	WORK.IMPUTE_ABS
30	1	NN1218-4131	Dependent Variable	eotVisitAbs
31	1	NN1218-4131	Covariance Structure	Diagonal
32	1	NN1218-4131	Estimation Method	REML

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Model Information

Parameter Code=P9PGINB4 Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)

(continued)

Obs	_Imputation_	STUDYID	Descr	Value
33	1	NN1218-4131	Residual Variance Method	Profile
34	1	NN1218-4131	Fixed Effects SE Method	Model-Based
35	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=P9PGINBB Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
36	1	NN1218-4131	Data Set	WORK.IMPUTE_ABS
37	1	NN1218-4131	Dependent Variable	eotVisitAbs
38	1	NN1218-4131	Covariance Structure	Diagonal
39	1	NN1218-4131	Estimation Method	REML
40	1	NN1218-4131	Residual Variance Method	Profile
41	1	NN1218-4131	Fixed Effects SE Method	Model-Based
42	1	NN1218-4131	Degrees of Freedom Method	Residual

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nn1218/nn1218-4131/ctr_20180214_er
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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Class Level Information

Parameter Code=P9GINB4U Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)

Ob- s	—	Input on ID	STUDY ID	Class s	Lev- els	Val- ues	mi- n
4	1	NN1218-4131	TRTPN		3 2 3 4		5
5	1	NN1218-4131	REGION1		4 ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA		49
6	1	NN1218-4131	BOLAD1		2 BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULI		85

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Class Level Information

Parameter Code=P9GINBBU Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mg/dL)

Ob- s	—	Input ID	STUDY	Class	Level	Values	Unit
7	1	NN1218-4131	TRTPN		3 2 3 4		5
8	1	NN1218-4131	REGION1		4 ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA		49
9	1	NN1218-4131	BOLAD1		2 BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULI		85

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Class Level Information

Parameter Code=P9PGIN4B Parameter=Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)

Ob	s	Input	STUDY ID	Class	Level	Values	Unit
10	1	NN1218-4131	TRTPN		3 2 3 4		5
11	1	NN1218-4131	REGION1		4 ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA		49
12	1	NN1218-4131	BOLAD1		2 BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULI		85

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nn1218/nn1218-4131/ctr_20180214_er
10FEB2018:06:42:09 - a 797pp stat diff.sas/a 9pp noct stat in_fas app.txt
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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Class Level Information

Parameter Code=P9PGINBB Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)

Obs	Input	STUDY ID	Class	Level	Values	Unit
16	1	NN1218-4131	TRTPN	3 2 3 4		5
17	1	NN1218-4131	REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA	49
18	1	NN1218-4131	BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULI	85

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Dimensions

Parameter Code=P9GIN4BU Parameter=Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Covariance Parameters	1
2	1	NN1218-4131	Columns in X	10
3	1	NN1218-4131	Columns in Z	0
4	1	NN1218-4131	Subjects	1
5	1	NN1218-4131	Max Obs per Subject	739

Parameter Code=P9GINB4U Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
6	1	NN1218-4131	Covariance Parameters	1
7	1	NN1218-4131	Columns in X	10
8	1	NN1218-4131	Columns in Z	0
9	1	NN1218-4131	Subjects	1
10	1	NN1218-4131	Max Obs per Subject	726

Parameter Code=P9GINBBU Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
11	1	NN1218-4131	Covariance Parameters	1
12	1	NN1218-4131	Columns in X	10
13	1	NN1218-4131	Columns in Z	0
14	1	NN1218-4131	Subjects	1
15	1	NN1218-4131	Max Obs per Subject	903

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Dimensions

Parameter Code=P9PGIN4B Parameter=Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
16	1	NN1218-4131	Covariance Parameters	1
17	1	NN1218-4131	Columns in X	10
18	1	NN1218-4131	Columns in Z	0
19	1	NN1218-4131	Subjects	1
20	1	NN1218-4131	Max Obs per Subject	739

Parameter Code=P9PGINB4 Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
21	1	NN1218-4131	Covariance Parameters	1
22	1	NN1218-4131	Columns in X	10
23	1	NN1218-4131	Columns in Z	0
24	1	NN1218-4131	Subjects	1
25	1	NN1218-4131	Max Obs per Subject	726

Parameter Code=P9PGINBB Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
26	1	NN1218-4131	Covariance Parameters	1
27	1	NN1218-4131	Columns in X	10
28	1	NN1218-4131	Columns in Z	0
29	1	NN1218-4131	Subjects	1
30	1	NN1218-4131	Max Obs per Subject	903

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Number of Observations

Parameter Code=P9GIN4BU Parameter=Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
1	1	NN1218-4131	Number of Observations Read	739	739	739	739	739
2	1	NN1218-4131	Number of Observations Used	739	739	739	739	739
3	1	NN1218-4131	Number of Observations Not Used	0	739	739	739	739

Parameter Code=P9GINB4U Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
4	1	NN1218-4131	Number of Observations Read	726	726	726	726	726
5	1	NN1218-4131	Number of Observations Used	726	726	726	726	726
6	1	NN1218-4131	Number of Observations Not Used	0	726	726	726	726

Parameter Code=P9GINBBU Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
7	1	NN1218-4131	Number of Observations Read	903	903	903	903	903
8	1	NN1218-4131	Number of Observations Used	903	903	903	903	903
9	1	NN1218-4131	Number of Observations Not Used	0	903	903	903	903

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The Mixed procedure
Number of Observations

Parameter Code=P9PGIN4B Parameter=Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
10	1	NN1218-4131	Number of Observations Read	739	739	739	739	739
11	1	NN1218-4131	Number of Observations Used	739	739	739	739	739
12	1	NN1218-4131	Number of Observations Not Used	0	739	739	739	739

Parameter Code=P9PGINB4 Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
13	1	NN1218-4131	Number of Observations Read	726	726	726	726	726
14	1	NN1218-4131	Number of Observations Used	726	726	726	726	726
15	1	NN1218-4131	Number of Observations Not Used	0	726	726	726	726

Parameter Code=P9PGINBB Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
16	1	NN1218-4131	Number of Observations Read	903	903	903	903	903
17	1	NN1218-4131	Number of Observations Used	903	903	903	903	903
18	1	NN1218-4131	Number of Observations Not Used	0	903	903	903	903

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The Mixed procedure
Covariance Parameter Estimates

Parameter Code=P9GIN4BU Parameter=Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	CovParm	Estimate
1	1	NN1218-4131	Residual	3249.44

Parameter Code=P9GINB4U Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	CovParm	Estimate
20001	1	NN1218-4131	Residual	5580.56

Parameter Code=P9GINBBU Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	CovParm	Estimate
40001	1	NN1218-4131	Residual	5504.40

Parameter Code=P9PGIN4B Parameter=Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	CovParm	Estimate
60001	1	NN1218-4131	Residual	10.0069

Parameter Code=P9PGINB4 Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	CovParm	Estimate
80001	1	NN1218-4131	Residual	17.1857

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The Mixed procedure
Covariance Parameter Estimates

Parameter Code=P9PGINBB Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	CovParm	Estimate
100001	1	NN1218-4131	Residual	16.9512

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The Mixed procedure
Fit Statistics

Parameter Code=P9GIN4BU Parameter=Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	-2 Res Log Likelihood	8036.1
2	1	NN1218-4131	AIC (Smaller is Better)	8038.1
3	1	NN1218-4131	AICC (Smaller is Better)	8038.1
4	1	NN1218-4131	BIC (Smaller is Better)	8042.7

Parameter Code=P9GINB4U Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
5	1	NN1218-4131	-2 Res Log Likelihood	8282.6
6	1	NN1218-4131	AIC (Smaller is Better)	8284.6
7	1	NN1218-4131	AICC (Smaller is Better)	8284.7
8	1	NN1218-4131	BIC (Smaller is Better)	8289.2

Parameter Code=P9GINBBU Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
9	1	NN1218-4131	-2 Res Log Likelihood	10301.5
10	1	NN1218-4131	AIC (Smaller is Better)	10303.5
11	1	NN1218-4131	AICC (Smaller is Better)	10303.5
12	1	NN1218-4131	BIC (Smaller is Better)	10308.3

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The Mixed procedure
Fit Statistics

Parameter Code=P9PGIN4B Parameter=Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
13	1	NN1218-4131	-2 Res Log Likelihood	3803.0
14	1	NN1218-4131	AIC (Smaller is Better)	3805.0
15	1	NN1218-4131	AICC (Smaller is Better)	3805.0
16	1	NN1218-4131	BIC (Smaller is Better)	3809.6

Parameter Code=P9PGINB4 Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
17	1	NN1218-4131	-2 Res Log Likelihood	4124.7
18	1	NN1218-4131	AIC (Smaller is Better)	4126.7
19	1	NN1218-4131	AICC (Smaller is Better)	4126.7
20	1	NN1218-4131	BIC (Smaller is Better)	4131.3

Parameter Code=P9PGINBB Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
21	1	NN1218-4131	-2 Res Log Likelihood	5119.9
22	1	NN1218-4131	AIC (Smaller is Better)	5121.9
23	1	NN1218-4131	AICC (Smaller is Better)	5121.9
24	1	NN1218-4131	BIC (Smaller is Better)	5126.7

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The Mixed procedure
Solution for Fixed Effects

Parameter Code=P9GIN4BU Parameter=Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1		BOLAD1	
1	1	NN1218-4131	TRTPN	2				
2	1	NN1218-4131	TRTPN	3				
3	1	NN1218-4131	TRTPN	4				
4	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
5	1	NN1218-4131	REGION1	—	EUROPE			
6	1	NN1218-4131	REGION1	—	JAPAN			
7	1	NN1218-4131	REGION1	—	NORTH AMERICA			
8	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
9	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
10	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	-10.7921	5.4213	731	-1.99	0.0469	0.05	-21.4353	-0.1489
2	-13.7342	5.3224	731	-2.58	0.0101	0.05	-24.1832	-3.2852
3	-25.4469	5.3242	731	-4.78	<.0001	0.05	-35.8995	-14.9944
4	27.7640	7.8827	731	3.52	0.0005	0.05	12.2886	43.2395
5	10.9428	5.6694	731	1.93	0.0540	0.05	-0.1875	22.0730
6	14.4381	5.9975	731	2.41	0.0163	0.05	2.6638	26.2124
7	0
8	-8.5002	4.7694	731	-1.78	0.0751	0.05	-17.8635	0.8631
9	0
10	0.1819	0.03059	731	5.95	<.0001	0.05	0.1219	0.2420

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The Mixed procedure
Solution for Fixed Effects

Parameter Code=P9GINB4U Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1			BOLAD1
11	1	NN1218-4131	TRTPN	2				
12	1	NN1218-4131	TRTPN	3				
13	1	NN1218-4131	TRTPN	4				
14	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
15	1	NN1218-4131	REGION1	—	EUROPE			
16	1	NN1218-4131	REGION1	—	JAPAN			
17	1	NN1218-4131	REGION1	—	NORTH AMERICA			
18	1	NN1218-4131	BOLAD1	—				BOLUS INSULIN ALGORITHM (SLIDING SCALE)
19	1	NN1218-4131	BOLAD1	—				CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY
20	1	NN1218-4131	BASE	—				

Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
11	-7.4187	7.0304	718	-1.06	0.2917	0.05	-21.2212	6.3838
12	-17.6800	6.8550	718	-2.58	0.0101	0.05	-31.1382	-4.2218
13	-6.9531	6.9742	718	-1.00	0.3191	0.05	-20.6454	6.7392
14	-7.8419	10.4374	718	-0.75	0.4527	0.05	-28.3333	12.6495
15	3.0592	7.4787	718	0.41	0.6826	0.05	-11.6235	17.7420
16	-5.6068	7.9047	718	-0.71	0.4784	0.05	-21.1259	9.9122
17	0
18	11.7987	6.3054	718	1.87	0.0617	0.05	-0.5804	24.1779
19	0
20	0.09097	0.03360	718	2.71	0.0069	0.05	0.02500	0.1569

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The Mixed procedure
Solution for Fixed Effects

Parameter Code=P9GINBBU Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
21	1	NN1218-4131	TRTPN	2				
22	1	NN1218-4131	TRTPN	3				
23	1	NN1218-4131	TRTPN	4				
24	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
25	1	NN1218-4131	REGION1	—	EUROPE			
26	1	NN1218-4131	REGION1	—	JAPAN			
27	1	NN1218-4131	REGION1	—	NORTH AMERICA			
28	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
29	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
30	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
21	-26.6978	6.1681	895	-4.33	<.0001	0.05	-38.8034	-14.5922
22	-26.8685	6.3322	895	-4.24	<.0001	0.05	-39.2962	-14.4409
23	-27.7425	6.2094	895	-4.47	<.0001	0.05	-39.9292	-15.5558
24	5.5197	9.2088	895	0.60	0.5491	0.05	-12.5537	23.5932
25	12.9010	6.4902	895	1.99	0.0471	0.05	0.1633	25.6387
26	-0.4513	7.0974	895	-0.06	0.9493	0.05	-14.3807	13.4782
27	0
28	5.4938	5.5378	895	0.99	0.3214	0.05	-5.3748	16.3623
29	0
30	0.07452	0.02891	895	2.58	0.0101	0.05	0.01778	0.1313

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The Mixed procedure
Solution for Fixed Effects

Parameter Code=P9PGIN4B Parameter=Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1			BOLAD1
31	1	NN1218-4131	TRTPN	2				
32	1	NN1218-4131	TRTPN	3				
33	1	NN1218-4131	TRTPN	4				
34	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
35	1	NN1218-4131	REGION1	—	EUROPE			
36	1	NN1218-4131	REGION1	—	JAPAN			
37	1	NN1218-4131	REGION1	—	NORTH AMERICA			
38	1	NN1218-4131	BOLAD1	—				BOLUS INSULIN ALGORITHM (SLIDING SCALE)
39	1	NN1218-4131	BOLAD1	—				CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY
40	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
31	-0.5989	0.3009	731	-1.99	0.0469	0.05	-1.1895	-0.00826
32	-0.7622	0.2954	731	-2.58	0.0101	0.05	-1.3420	-0.1823
33	-1.4121	0.2955	731	-4.78	<.0001	0.05	-1.9922	-0.8321
34	1.5407	0.4374	731	3.52	0.0005	0.05	0.6819	2.3995
35	0.6073	0.3146	731	1.93	0.0540	0.05	-0.01040	1.2249
36	0.8012	0.3328	731	2.41	0.0163	0.05	0.1478	1.4546
37	0
38	-0.4717	0.2647	731	-1.78	0.0751	0.05	-0.9913	0.04790
39	0
40	0.1819	0.03059	731	5.95	<.0001	0.05	0.1219	0.2420

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The Mixed procedure
Solution for Fixed Effects

Parameter Code=P9PGINB4 Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
41	1	NN1218-4131	TRTPN	2				
42	1	NN1218-4131	TRTPN	3				
43	1	NN1218-4131	TRTPN	4				
44	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
45	1	NN1218-4131	REGION1	—	EUROPE			
46	1	NN1218-4131	REGION1	—	JAPAN			
47	1	NN1218-4131	REGION1	—	NORTH AMERICA			
48	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
49	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
50	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
41	-0.4117	0.3901	718	-1.06	0.2917	0.05	-1.1776	0.3543
42	-0.9811	0.3804	718	-2.58	0.0101	0.05	-1.7280	-0.2343
43	-0.3859	0.3870	718	-1.00	0.3191	0.05	-1.1457	0.3740
44	-0.4352	0.5792	718	-0.75	0.4527	0.05	-1.5723	0.7020
45	0.1698	0.4150	718	0.41	0.6826	0.05	-0.6450	0.9846
46	-0.3111	0.4387	718	-0.71	0.4784	0.05	-1.1724	0.5501
47	0
48	0.6548	0.3499	718	1.87	0.0617	0.05	-0.03221	1.3417
49	0
50	0.09097	0.03360	718	2.71	0.0069	0.05	0.02500	0.1569

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The Mixed procedure
Solution for Fixed Effects

Parameter Code=P9PGINBB Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
51	1	NN1218-4131	TRTPN	2				
52	1	NN1218-4131	TRTPN	3				
53	1	NN1218-4131	TRTPN	4				
54	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
55	1	NN1218-4131	REGION1	—	EUROPE			
56	1	NN1218-4131	REGION1	—	JAPAN			
57	1	NN1218-4131	REGION1	—	NORTH AMERICA			
58	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
59	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
60	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
51	-1.4816	0.3423	895	-4.33	<.0001	0.05	-2.1534	-0.8098
52	-1.4910	0.3514	895	-4.24	<.0001	0.05	-2.1807	-0.8014
53	-1.5395	0.3446	895	-4.47	<.0001	0.05	-2.2158	-0.8632
54	0.3063	0.5110	895	0.60	0.5491	0.05	-0.6967	1.3093
55	0.7159	0.3602	895	1.99	0.0471	0.05	0.009061	1.4228
56	-0.02504	0.3939	895	-0.06	0.9493	0.05	-0.7980	0.7480
57	0
58	0.3049	0.3073	895	0.99	0.3214	0.05	-0.2983	0.9080
59	0
60	0.07452	0.02891	895	2.58	0.0101	0.05	0.01778	0.1313

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The Mixed procedure
Least Squares Means

Obs	_Imputation_	PARAMCD	PARAM	STUDYID
1	1	P9GIN4BU	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	NN1218-4131
20001	1	P9GIN4BU	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	NN1218-4131
40001	1	P9GINBBU	Nocturnal increment (bedtime to breakfast) (SMPG) (mg/dL)	NN1218-4131
60001	1	P9PGIN4B	Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)	NN1218-4131
80001	1	P9PGINB4	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	NN1218-4131
100001	1	P9PGINBB	Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)	NN1218-4131
120001	1	P9GIN4BU	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	NN1218-4131
140001	1	P9GINB4U	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	NN1218-4131
160001	1	P9GINBBU	Nocturnal increment (bedtime to breakfast) (SMPG) (mg/dL)	NN1218-4131
180001	1	P9PGIN4B	Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)	NN1218-4131
200001	1	P9PGINB4	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	NN1218-4131
220001	1	P9PGINBB	Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)	NN1218-4131
240001	1	P9GIN4BU	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	NN1218-4131
260001	1	P9GINB4U	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	NN1218-4131

Obs	Effect	TRTPN	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	TRTPN	2	WORK.IMPUTE	16.8212	3.7330	731	4.51	<.0001	0.05	9.4926	24.1499
20001	TRTPN	2	WORK.IMPUTE	9.1783	4.8907	718	1.88	0.0610	0.05	-0.4236	18.7801
40001	TRTPN	2	WORK.IMPUTE	14.2903	4.2816	895	3.34	0.0009	0.05	5.8872	22.6935
60001	TRTPN	2	WORK.IMPUTE	0.9335	0.2072	731	4.51	<.0001	0.05	0.5268	1.3402
80001	TRTPN	2	WORK.IMPUTE	0.5093	0.2714	718	1.88	0.0610	0.05	-0.02350	1.0422
100001	TRTPN	2	WORK.IMPUTE	0.7930	0.2376	895	3.34	0.0009	0.05	0.3267	1.2593
120001	TRTPN	3	WORK.IMPUTE	13.8791	3.5261	731	3.94	<.0001	0.05	6.9566	20.8016
140001	TRTPN	3	WORK.IMPUTE	-1.0830	4.6569	718	-0.23	0.8162	0.05	-10.2258	8.0598
160001	TRTPN	3	WORK.IMPUTE	14.1196	4.2975	895	3.29	0.0011	0.05	5.6852	22.5540
180001	TRTPN	3	WORK.IMPUTE	0.7702	0.1957	731	3.94	<.0001	0.05	0.3861	1.1544
200001	TRTPN	3	WORK.IMPUTE	-0.06010	0.2584	718	-0.23	0.8162	0.05	-0.5675	0.4473
220001	TRTPN	3	WORK.IMPUTE	0.7836	0.2385	895	3.29	0.0011	0.05	0.3155	1.2516
240001	TRTPN	4	WORK.IMPUTE	2.1664	3.6655	731	0.59	0.5547	0.05	-5.0297	9.3625
260001	TRTPN	4	WORK.IMPUTE	9.6440	4.8919	718	1.97	0.0491	0.05	0.03991	19.2480

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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Least Squares Means

Obs	_Imputation_	PARAMCD	PARAM							STUDYID	
280001	1	P9GINBBU	Nocturnal increment (bedtime to breakfast) (SMPG) (mg/dL)							NN1218-4131	
300001	1	P9PGIN4B	Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)							NN1218-4131	
320001	1	P9PGINB4	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)							NN1218-4131	
340001	1	P9PGINBB	Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)							NN1218-4131	
Obs	Effect	TRTPN	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
280001	TRTPN	4	WORK.IMPUTE	13.2456	4.2677	895	3.10	0.0020	0.05	4.8697	21.6216
300001	TRTPN	4	WORK.IMPUTE	0.1202	0.2034	731	0.59	0.5547	0.05	-0.2791	0.5196
320001	TRTPN	4	WORK.IMPUTE	0.5352	0.2715	718	1.97	0.0491	0.05	0.002215	1.0681
340001	TRTPN	4	WORK.IMPUTE	0.7351	0.2368	895	3.10	0.0020	0.05	0.2702	1.1999

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Least Squares Means Estimate

Parameter Code=P9GIN4BU Parameter=Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label				
1	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)				
20001	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)				

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	WORK.IMPUTE	14.6549	5.2389	731	2.80	0.0053	0.05	4.3697	24.9400
20001	WORK.IMPUTE	11.7127	5.0911	731	2.30	0.0217	0.05	1.7178	21.7077

Parameter Code=P9GINB4U Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label				
40001	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)				
60001	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)				

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
40001	WORK.IMPUTE	-0.4657	6.9234	718	-0.07	0.9464	0.05	-14.0581	13.1268
60001	WORK.IMPUTE	-10.7269	6.7594	718	-1.59	0.1130	0.05	-23.9975	2.5437

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Least Squares Means Estimate

Parameter Code=P9GINBBU Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label				
80001	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)				
100001	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)				

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
80001	WORK.IMPUTE	1.0447	6.0481	895	0.17	0.8629	0.05	-10.8254	12.9148
100001	WORK.IMPUTE	0.8740	6.0617	895	0.14	0.8854	0.05	-11.0228	12.7707

Parameter Code=P9PGIN4B Parameter=Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label				
120001	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)				
140001	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)				

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
120001	WORK.IMPUTE	0.8133	0.2907	731	2.80	0.0053	0.05	0.2425	1.3840
140001	WORK.IMPUTE	0.6500	0.2825	731	2.30	0.0217	0.05	0.09532	1.2046

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Least Squares Means Estimate

Parameter Code=P9PGINB4 Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
160001	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
180001	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
160001	WORK.IMPUTE	-0.02584	0.3842	718	-0.07	0.9464	0.05	-0.7801	0.7285
180001	WORK.IMPUTE	-0.5953	0.3751	718	-1.59	0.1130	0.05	-1.3317	0.1412

Parameter Code=P9PGINBB Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
200001	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
220001	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
200001	WORK.IMPUTE	0.05798	0.3356	895	0.17	0.8629	0.05	-0.6007	0.7167
220001	WORK.IMPUTE	0.04850	0.3364	895	0.14	0.8854	0.05	-0.6117	0.7087

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2923 of 4425	Novo Nordisk
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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9GIN4BU Parameter=Nocturnal increment (04:00 to breakfast) (SMPG) (mg/d

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	5.651343	13.857421	19.509046	238305	0.407841	0.289699	0.999986

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-11.581255	4.416905	-20.2383	-2.92424	238305	-21.970782	-0.487418

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-2.62	0.0087

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Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2924 of 4425	Novo Nordisk
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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9GINB4U Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	7.524085	23.745478	31.269940	345391	0.316880	0.240634	0.999988

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-8.712390	5.591953	-19.6725	2.247675	345391	-19.964630	1.760866

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-1.56	0.1192

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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9GINBBU Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mg

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	2.205188	18.035563	20.240861	1.68E6	0.122275	0.108954	0.999995

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-21.598549	4.498984	-30.4164	-12.7807	1.68E6	-28.286661	-15.369544

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-4.80	<.0001

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2926 of 4425	Novo Nordisk
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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9PGIN4B Parameter=Nocturnal increment (04:00 to breakfast) (SMPG) (mmol

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.017404	0.042675	0.060080	238305	0.407841	0.289699	0.999986

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.642689	0.245111	-1.12310	-0.16228	238305	-1.219244	-0.027049

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-2.62	0.0087

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2927 of 4425	Novo Nordisk
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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9PGINB4 Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.023171	0.073126	0.096298	345391	0.316880	0.240634	0.999988

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.483484	0.310319	-1.09170	0.124732	345391	-1.107915	0.097717

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-1.56	0.1192

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Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2928 of 4425	Novo Nordisk
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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9PGINBB Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mm

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.006791	0.055542	0.062333	1.68E6	0.122275	0.108954	0.999995

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-1.198588	0.249666	-1.68792	-0.70925	1.68E6	-1.569737	-0.852916

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-4.80	<.0001

nn1218/nn1218-4131/ctr_20180214_er
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Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2929 of 4425	Novo Nordisk
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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9GIN4BU Parameter=Nocturnal increment (04:00 to breakfast) (SMPG) (mg/d

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	3.434011	12.364030	15.798213	423231	0.277756	0.217382	0.999989

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-10.107880	3.974697	-17.8982	-2.31760	423231	-17.264941	-2.910955

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-2.54	0.0110

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2930 of 4425	Novo Nordisk
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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9GINB4U Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	6.093679	21.529352	27.623336	410921	0.283055	0.220614	0.999989

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-13.061199	5.255791	-23.3624	-2.76001	410921	-22.259804	-2.547291

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-2.49	0.0130

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2931 of 4425	Novo Nordisk
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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9GINBBU Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mg

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	1.908237	18.170109	20.078442	2.21E6	0.105026	0.095045	0.999995

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-22.745576	4.480897	-31.5280	-13.9632	2.21E6	-28.812533	-17.659645

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-5.08	<.0001

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Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2932 of 4425	Novo Nordisk
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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9PGIN4B Parameter=Nocturnal increment (04:00 to breakfast) (SMPG) (mmol

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.010575	0.038076	0.048652	423231	0.277756	0.217382	0.999989

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.560926	0.220571	-0.99324	-0.12861	423231	-0.958099	-0.161540

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-2.54	0.0110

nn1218/nn1218-4131/ctr_20180214_er
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Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2933 of 4425	Novo Nordisk
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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9PGINB4 Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.018766	0.066301	0.085068	410921	0.283055	0.220614	0.999989

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.724817	0.291664	-1.29647	-0.15316	410921	-1.235283	-0.141359

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-2.49	0.0130

nn1218/nn1218-4131/ctr_20180214_er
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Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2934 of 4425	Novo Nordisk
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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9PGINBB Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mm

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.005877	0.055956	0.061833	2.21E6	0.105026	0.095045	0.999995

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-1.262241	0.248662	-1.74961	-0.77487	2.21E6	-1.598920	-0.980003

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-5.08	<.0001

nn1218/nn1218-4131/ctr_20180214_er
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Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2935 of 4425	Novo Nordisk
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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9GIN4BU Parameter=Nocturnal increment (04:00 to breakfast) (SMPG) (mg/d

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	3.847070	13.360793	17.208056	400100	0.287952	0.223577	0.999989

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-22.749512	4.148259	-30.8800	-14.6190	400100	-31.041061	-13.325097

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-5.48	<.0001

nn1218/nn1218-4131/ctr_20180214_er
10FEB2018:06:42:09 - a_797pp_stat_diff.sas/a_9pp_noct_stat_in_fas_app.txt

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 2936 of 4425	Novo Nordisk
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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9GINB4U Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	7.238869	23.756358	30.995589	366626	0.304728	0.233561	0.999988

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-1.182340	5.567368	-12.0942	9.729537	366626	-12.192618	9.516821

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-0.21	0.8318

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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9GINBBU Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mg

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	2.061874	17.918991	19.980968	1.88E6	0.115072	0.103198	0.999995

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-21.346583	4.470008	-30.1076	-12.5855	1.88E6	-26.548508	-14.955768

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-4.78	<.0001

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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9PGIN4B Parameter=Nocturnal increment (04:00 to breakfast) (SMPG) (mmol

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.011847	0.041146	0.052993	400100	0.287952	0.223577	0.999989

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-1.262459	0.230203	-1.71365	-0.81127	400100	-1.722589	-0.739462

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-5.48	<.0001

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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9PGINB4 Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.022293	0.073159	0.095453	366626	0.304728	0.233561	0.999988

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.065613	0.308955	-0.67116	0.539930	366626	-0.676616	0.528125

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-0.21	0.8318

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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9PGINBB Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mm

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.006350	0.055183	0.061533	1.88E6	0.115072	0.103198	0.999995

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-1.184605	0.248058	-1.67079	-0.69842	1.88E6	-1.473280	-0.829954

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-4.78	<.0001

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The MI Procedure with MCMC
Model Information

Parameter Code=P9GIN4BU Planned Treatment for Period 30 (N)=2

Obs	PARAM				Description	Value
1	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mg/dL)	Data Set	WORK.ENDPOINT_PARAM
2	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mg/dL)	Method	Monotone-data_MCMC
3	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mg/dL)	Multiple Imputation Chain	Multiple Chains
4	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
5	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mg/dL)	Start	Starting Value
6	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mg/dL)	Prior	Jeffreys
7	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mg/dL)	Number of Imputations	20000
8	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mg/dL)	Number of Burn-in Iterations	200
9	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mg/dL)	Seed for random number generator	1234

Parameter Code=P9GIN4BU Planned Treatment for Period 30 (N)=3

Obs	PARAM				Description	Value
10	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mg/dL)	Data Set	WORK.ENDPOINT_PARAM
11	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mg/dL)	Method	Monotone-data_MCMC
12	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mg/dL)	Multiple Imputation Chain	Multiple Chains
13	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
14	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mg/dL)	Start	Starting Value
15	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mg/dL)	Prior	Jeffreys
16	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mg/dL)	Number of Imputations	20000
17	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mg/dL)	Number of Burn-in Iterations	200
18	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mg/dL)	Seed for random number generator	321548787

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=P9GIN4BU Planned Treatment for Period 30 (N)=4

Obs	PARAM				Description	Value
19	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mg/dL)	Data Set	WORK.ENDPOINT_PARAM
20	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mg/dL)	Method	Monotone-data_MCMC
21	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mg/dL)	Multiple Imputation Chain	Multiple Chains
22	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
23	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mg/dL)	Start	Starting Value
24	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mg/dL)	Prior	Jeffreys
25	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mg/dL)	Number of Imputations	20000
26	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mg/dL)	Number of Burn-in Iterations	200
27	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mg/dL)	Seed for random number generator	996518491

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The MI Procedure with MCMC
Missing data pattern

Parameter Code=P9GIN4BU Planned Treatment for Period 30 (N)=2

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss
1	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	1	X	X
2	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	2	X	X
3	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	3	X	.
4	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	4	X	O

Obs	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
1	X	143	61.11	-23.426699	12.929622	10.539315
2	O	29	12.39	-35.839241	35.845379	.
3	X	29	12.39	-38.166345	.	31.582483
4	O	33	14.10	-37.021576	.	.

Parameter Code=P9GIN4BU Planned Treatment for Period 30 (N)=3

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss
5	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	1	X	X
6	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	2	X	X

Obs	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
5	X	168	64.12	-31.176595	21.847607	21.606298
6	O	25	9.54	-24.185040	14.459040	.

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC
Missing data pattern

Parameter Code=P9GIN4BU Planned Treatment for Period 30 (N)=3

(continued)

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss
7	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	3	X	.
8	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	4	X	0

Obs	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
7	X	37	14.12	-20.415892	.	3.706973
8	0	32	12.21	-32.478188	.	.

Parameter Code=P9GIN4BU Planned Treatment for Period 30 (N)=4

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss
9	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	1	X	X
10	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	2	X	X
11	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	3	X	.

Obs	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
9	X	152	62.55	-16.906053	-2.908013	-5.853184
10	0	33	13.58	-34.535273	-5.649576	.
11	X	32	13.17	-23.953875	.	18.157125

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC
Missing data pattern

Parameter Code=P9GIN4BU Planned Treatment for Period 30 (N)=4

(continued)

Obs	PARAM				Group	BASE_ Miss	visit2200_ Miss
12	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)				4	X	O
Obs	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600	
12	O	26	10.70	-5.609000	.	.	

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=P9GIN4BU Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM					Group	REGION1_ Miss	BOLAD1_ Miss
1	1	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mg/dL)		1	X	X
2	1	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mg/dL)		2	X	X
3	1	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mg/dL)		3	X	X

Obs	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
1	X	X	X	172	73.50	-25.911872	13.908692	14.087291
2	X	X	.	29	12.39	-35.839241	35.845379	.
3	X	.	.	33	14.10	-37.021576	.	.

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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9GIN4BU Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	Intercept	
2	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	REGION1	EUROPE
4	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	REGION1	JAPAN
5	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	BOLAD1	
6	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	BASE	

Obs	BOLAD1	ObsVal	_1
1		0.01653	0.051379
2		0.02852	0.055242
3		-0.04311	-0.187964
4		0.11835	0.080129
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.01858	-0.073219
6		-0.72144	-0.742532

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9GIN4BU Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

Imputed									
Observations									
		P		E		R	B	O	
		A		f		E	O	b	
		R		f		G	L	s	
		A		e		O	A	V	
		A		c		N	D	a	
		M		t		1	1	1	\bar{I}
7	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	Intercept					0.05196	0.118373
8	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	REGION1 ASIA (EXCLUDING JAPAN)					0.10193	0.252526
9	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	REGION1 EUROPE					0.01668	-0.184401

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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9GIN4BU Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM	Effect
10	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	REGION1
11	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	BOLAD1
12	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	BASE
13	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	visit2200

Obs	REGION1	BOLAD1	ObsVal	_1
10	JAPAN		-0.00485	0.046694
11		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.10314	-0.118912
12			-0.60758	-0.693021
13			0.19491	0.067883

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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9GIN4BU Planned Treatment for Period 30 (N)=3

	O	b	s	I	m	p	u	t	a	t	i	o	n	—	P	A	R	A	M	D	e	s	c	r	i	p	t	i	o	n	V	a	l	u	e
1	1			Nocturnal	increment	(04:00	to	breakfast)	(SMPG)	(mg/dL)	Data Set			WORK.MONO_SORT_TRT																					
2	1			Nocturnal	increment	(04:00	to	breakfast)	(SMPG)	(mg/dL)	Method			Monotone																					
3	1			Nocturnal	increment	(04:00	to	breakfast)	(SMPG)	(mg/dL)	Number of Imputations			1																					
4	1			Nocturnal	increment	(04:00	to	breakfast)	(SMPG)	(mg/dL)	Seed for random number generator			4322																					

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=P9GIN4BU Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM					Group	REGION1_ Miss	BOLAD1_ Miss
1	1	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mg/dL)		1	X	X
2	1	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mg/dL)		2	X	X
3	1	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mg/dL)		3	X	X

Obs	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
1	X	X	X	205	78.24	-29.234420	20.767430	18.375688
2	X	X	.	25	9.54	-24.185040	14.459040	.
3	X	.	.	32	12.21	-32.478188	.	.

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9GIN4BU Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	Intercept	
2	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	REGION1	EUROPE
4	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	REGION1	JAPAN
5	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	BOLAD1	
6	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	BASE	

Obs	BOLAD1	ObsVal	_1
1		0.01146	0.124509
2		0.03337	0.192347
3		-0.01034	-0.007644
4		-0.03938	-0.152150
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.01143	0.044205
6		-0.60485	-0.659900

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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9GIN4BU Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM	Effect
10	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	REGION1
11	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	BOLAD1
12	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	BASE
13	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	visit2200

Obs	REGION1	BOLAD1	ObsVal	_1
10	JAPAN		-0.00159	-0.024036
11		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.03949	0.022495
12			-0.63416	-0.640067
13			0.10248	0.133951

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression Model Information

Parameter Code=P9GIN4BU Planned Treatment for Period 30 (N)=4

O b s	I m p u t a t i o n —							P A R A M	D e s c r i p t i o n	V a l u e
1	1	Nocturnal	increment	(04:00	to breakfast)	(SMPG)	(mg/dL)	Data Set		WORK.MONO_SORT_TRT
2	1	Nocturnal	increment	(04:00	to breakfast)	(SMPG)	(mg/dL)	Method		Monotone
3	1	Nocturnal	increment	(04:00	to breakfast)	(SMPG)	(mg/dL)	Number of Imputations		1
4	1	Nocturnal	increment	(04:00	to breakfast)	(SMPG)	(mg/dL)	Seed for random number generator		4323

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=P9GIN4BU Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM					Group	REGION1_ Miss	BOLAD1_ Miss
1	1	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mg/dL)		1	X	X
2	1	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mg/dL)		2	X	X
3	1	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mg/dL)		3	X	X

Obs	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
1	X	X	X	184	75.72	-18.131761	0.776824	-1.677478
2	X	X	.	33	13.58	-34.535273	-5.649576	.
3	X	.	.	26	10.70	-5.609000	.	.

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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9GIN4BU Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	Intercept	
2	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	REGION1	EUROPE
4	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	REGION1	JAPAN
5	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	BOLAD1	
6	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	BASE	

Obs	BOLAD1	ObsVal	_1
1		-0.01464	-0.062642
2		0.0009858	0.057792
3		-0.07316	-0.201019
4		-0.02555	0.028251
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.05800	0.038635
6		-0.69765	-0.772518

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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9GIN4BU Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM				Effect
10	1	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mg/dL)	REGION1
11	1	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mg/dL)	BOLAD1
12	1	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mg/dL)	BASE
13	1	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mg/dL)	visit2200
Obs	REGION1	BOLAD1			ObsVal	_1
10	JAPAN				0.11172	0.018220
11		BOLUS INSULIN ALGORITHM (SLIDING SCALE)			-0.08498	-0.121662
12					-0.67911	-0.697890
13					0.02649	-0.013596

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=P9PGIN4B Planned Treatment for Period 30 (N)=2

Obs	PARAM					Description	Value
1	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)		Data Set	WORK.ENDPOINT_PARAM
2	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)		Method	Monotone-data_MCMC
3	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)		Multiple Imputation Chain	Multiple Chains
4	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)		Initial Estimates for MCMC	EM Posterior Mode
5	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)		Start	Starting Value
6	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)		Prior	Jeffreys
7	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)		Number of Imputations	20000
8	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)		Number of Burn-in Iterations	200
9	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)		Seed for random number generator	1234

Parameter Code=P9PGIN4B Planned Treatment for Period 30 (N)=3

Obs	PARAM					Description	Value
10	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)		Data Set	WORK.ENDPOINT_PARAM
11	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)		Method	Monotone-data_MCMC
12	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)		Multiple Imputation Chain	Multiple Chains
13	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)		Initial Estimates for MCMC	EM Posterior Mode
14	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)		Start	Starting Value
15	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)		Prior	Jeffreys
16	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)		Number of Imputations	20000
17	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)		Number of Burn-in Iterations	200
18	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)		Seed for random number generator	321548787

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=P9PGIN4B Planned Treatment for Period 30 (N)=4

Obs	PARAM					Description	Value
19	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)		Data Set	WORK.ENDPOINT_PARAM
20	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)		Method	Monotone-data_MCMC
21	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)		Multiple Imputation Chain	Multiple Chains
22	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)		Initial Estimates for MCMC	EM Posterior Mode
23	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)		Start	Starting Value
24	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)		Prior	Jeffreys
25	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)		Number of Imputations	20000
26	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)		Number of Burn-in Iterations	200
27	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)		Seed for random number generator	996518491

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The MI Procedure with MCMC
Missing data pattern

Parameter Code=P9PGIN4B Planned Treatment for Period 30 (N)=2

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss
1	Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)	1	X	X
2	Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)	2	X	X
3	Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)	3	X	.
4	Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)	4	X	O

Obs	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
1	X	143	61.11	-1.300039	0.717515	0.584868
2	O	29	12.39	-1.988859	1.989200	.
3	X	29	12.39	-2.117999	.	1.752635
4	O	33	14.10	-2.054471	.	.

Parameter Code=P9PGIN4B Planned Treatment for Period 30 (N)=3

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss
5	Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)	1	X	X
6	Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)	2	X	X

Obs	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
5	X	168	64.12	-1.730111	1.212409	1.199018
6	O	25	9.54	-1.342122	0.802388	.

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The MI Procedure with MCMC
Missing data pattern

Parameter Code=P9PGIN4B Planned Treatment for Period 30 (N)=3

(continued)

Obs	PARAM				Group	BASE_ Miss	visit2200_ Miss
7	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)	3	X	.
8	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)	4	X	O
Obs	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600	
7	X	37	14.12	-1.132957	.	0.205714	
8	O	32	12.21	-1.802341	.	.	

Parameter Code=P9PGIN4B Planned Treatment for Period 30 (N)=4

Obs	PARAM				Group	BASE_ Miss	visit2200_ Miss
9	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)	1	X	X
10	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)	2	X	X
11	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)	3	X	.
Obs	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600	
9	X	152	62.55	-0.938183	-0.161377	-0.324816	
10	O	33	13.58	-1.916497	-0.313517	.	
11	X	32	13.17	-1.329294	.	1.007610	

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC
Missing data pattern

Parameter Code=P9PGIN4B Planned Treatment for Period 30 (N)=4

(continued)

Obs	PARAM				Group	BASE_ Miss	visit2200_ Miss
12	Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)				4	X	O
Obs	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600	
12	O	26	10.70	-0.311265	.	.	

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PGIN4B Planned Treatment for Period 30 (N)=2

Obs	Imputation							Description	Value
1	1	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)	Data Set		WORK.MONO_SORT_TRT	
2	1	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)	Method		Monotone	
3	1	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)	Number of Imputations		1	
4	1	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)	Seed for random number generator		4321	

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The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=P9PGIN4B Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM					Group	REGION1_ Miss	BOLAD1_ Miss
1	1	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)		1	X	X
2	1	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)		2	X	X
3	1	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)		3	X	X

Obs	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
1	X	X	X	172	73.50	-1.437951	0.771847	0.781759
2	X	X	.	29	12.39	-1.988859	1.989200	.
3	X	.	.	33	14.10	-2.054471	.	.

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGIN4B Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)	Intercept	
2	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)	REGION1	EUROPE
4	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)	REGION1	JAPAN
5	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)	BOLAD1	
6	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)	BASE	

Obs	BOLAD1	ObsVal	_1
1		0.01653	0.051379
2		0.02852	0.055242
3		-0.04311	-0.187964
4		0.11835	0.080129
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.01858	-0.073219
6		-0.72144	-0.742532

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGIN4B Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM	Effect
10	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)	REGION1
11	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)	BOLAD1
12	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)	BASE
13	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)	visit2200

Obs	REGION1	BOLAD1	ObsVal	_1
10	JAPAN		-0.00485	0.046694
11		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.10314	-0.118912
12			-0.60758	-0.693021
13			0.19491	0.067883

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression Model Information

Parameter Code=P9PGIN4B Planned Treatment for Period 30 (N)=3

O b s	I m p u t a t i o n —			P A R A M				D e s c r i p t i o n	V a l u e
1	1	Nocturnal	increment	(04:00 to breakfast)	(SMPG)	(mmol/L)	Data Set		WORK.MONO_SORT_TRT
2	1	Nocturnal	increment	(04:00 to breakfast)	(SMPG)	(mmol/L)	Method		Monotone
3	1	Nocturnal	increment	(04:00 to breakfast)	(SMPG)	(mmol/L)	Number of Imputations		1
4	1	Nocturnal	increment	(04:00 to breakfast)	(SMPG)	(mmol/L)	Seed for random number generator		4322

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=P9PGIN4B Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM					Group	REGION1_ Miss	BOLAD1_ Miss
1	1	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)		1	X	X
2	1	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)		2	X	X
3	1	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)		3	X	X

Obs	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
1	X	X	X	205	78.24	-1.622332	1.152466	1.019739
2	X	X	.	25	9.54	-1.342122	0.802388	.
3	X	.	.	32	12.21	-1.802341	.	.

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGIN4B Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)	Intercept	
2	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)	REGION1	EUROPE
4	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)	REGION1	JAPAN
5	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)	BOLAD1	
6	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)	BASE	

Obs	BOLAD1	ObsVal	_1
1		0.01146	0.124509
2		0.03337	0.192347
3		-0.01034	-0.007644
4		-0.03938	-0.152150
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.01143	0.044205
6		-0.60485	-0.659900

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGIN4B Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM	Effect
10	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)	REGION1
11	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)	BOLAD1
12	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)	BASE
13	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)	visit2200

Obs	REGION1	BOLAD1	ObsVal	_1
10	JAPAN		-0.00159	-0.024036
11		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.03949	0.022495
12			-0.63416	-0.640067
13			0.10248	0.133951

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression Model Information

Parameter Code=P9PGIN4B Planned Treatment for Period 30 (N)=4

O b s	I m p u t a t i o n —			P A R A M				D e s c r i p t i o n	V a l u e
1	1	Nocturnal	increment	(04:00 to breakfast)	(SMPG)	(mmol/L)	Data Set		WORK.MONO_SORT_TRT
2	1	Nocturnal	increment	(04:00 to breakfast)	(SMPG)	(mmol/L)	Method		Monotone
3	1	Nocturnal	increment	(04:00 to breakfast)	(SMPG)	(mmol/L)	Number of Imputations		1
4	1	Nocturnal	increment	(04:00 to breakfast)	(SMPG)	(mmol/L)	Seed for random number generator		4323

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=P9PGIN4B Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM					Group	REGION1_ Miss	BOLAD1_ Miss
1	1	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)		1	X	X
2	1	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)		2	X	X
3	1	Nocturnal increment	(04:00 to breakfast)	(SMPG)	(mmol/L)		3	X	X

Obs	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
1	X	X	X	184	75.72	-1.006202	0.043109	-0.093090
2	X	X	.	33	13.58	-1.916497	-0.313517	.
3	X	.	.	26	10.70	-0.311265	.	.

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGIN4B Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)	Intercept	
2	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)	REGION1	EUROPE
4	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)	REGION1	JAPAN
5	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)	BOLAD1	
6	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)	BASE	

Obs	BOLAD1	ObsVal	_1
1		-0.01464	-0.062642
2		0.0009858	0.057792
3		-0.07316	-0.201019
4		-0.02555	0.028251
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.05800	0.038635
6		-0.69765	-0.772518

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The MI Procedure with Monotone Regression Regression Information

Parameter Code=P9PGIN4B Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

O o b s _		P A R A M		E f f e c t		R E G I O N 1		B O L D 1		O b s V a l		I	
7	1	Nocturnal	increment	(04:00 to breakfast)	(SMPG)	(mmol/L)	Intercept				0.03159	0.023368	
8	1	Nocturnal	increment	(04:00 to breakfast)	(SMPG)	(mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)			0.27941	0.409581	
9	1	Nocturnal	increment	(04:00 to breakfast)	(SMPG)	(mmol/L)	REGION1	EUROPE			-0.09369	-0.087423	

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGIN4B Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

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Obs	_Imputation_	PARAM	Effect
10	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)	REGION1
11	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)	BOLAD1
12	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)	BASE
13	1	Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)	visit2200

Obs	REGION1	BOLAD1	ObsVal	_1
10	JAPAN		0.11172	0.018220
11		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.08498	-0.121662
12			-0.67911	-0.697890
13			0.02649	-0.013596

Fast-acting insulin aspart
NN1218-4131

Clinical Trial Report
Statistical document

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1.0

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Novo Nordisk

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=P9GINB4U Planned Treatment for Period 30 (N)=2

Obs	PARAM	Description	Value
1	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	Data Set	WORK.ENDPOINT_PARAM
2	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	Method	Monotone-data MCMC
3	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	Multiple Imputation Chain	Multiple Chains
4	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
5	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	Start	Starting Value
6	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	Prior	Jeffreys
7	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	Number of Imputations	20000
8	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	Number of Burn-in Iterations	200
9	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	Seed for random number generator	1234

Parameter Code=P9GINB4U Planned Treatment for Period 30 (N)=3

Obs	PARAM	Description	Value
10	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	Data Set	WORK.ENDPOINT_PARAM
11	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	Method	Monotone-data MCMC
12	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	Multiple Imputation Chain	Multiple Chains
13	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
14	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	Start	Starting Value
15	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	Prior	Jeffreys
16	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	Number of Imputations	20000
17	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	Number of Burn-in Iterations	200
18	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	Seed for random number generator	903043636

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=P9GINB4U Planned Treatment for Period 30 (N)=4

Obs	PARAM				Description	Value
19	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mg/dL)	Data Set	WORK.ENDPOINT_PARAM
20	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mg/dL)	Method	Monotone-data MCMC
21	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mg/dL)	Multiple Imputation Chain	Multiple Chains
22	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
23	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mg/dL)	Start	Starting Value
24	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mg/dL)	Prior	Jeffreys
25	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mg/dL)	Number of Imputations	20000
26	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mg/dL)	Number of Burn-in Iterations	200
27	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mg/dL)	Seed for random number generator	907994776

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC
Missing data pattern

Parameter Code=P9GINB4U Planned Treatment for Period 30 (N)=2

				v v i i s s i i t t B 2 3 A 2 6 S 0 0 E 0 0						v i s i t 2 2 0 0			v i s i t 3 6 0 0		
				P A R A M			G r o u p			F r e q			B A S E		
				\bar{M} \bar{M} \bar{M}			i i i			s s s			s s s		
				1 X X X			139			59.40			-11.937194		
1 Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)				2 X X O			27			11.54			-19.310667		
2 Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)				3 X . X			34			14.53			1.520412		
3 Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)				4 X O O			34			14.53			-10.795059		
4 Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)															

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC
Missing data pattern

Parameter Code=P9GINB4U Planned Treatment for Period 30 (N)=3

				v v i i s s i i t t B 2 3 A 2 6 S 0 0 E 0 0						v i s i t 2 2 0 0			v i s i t 3 6 0 0		
				P A R A M			G r o u p			F r e q			P e r c e n t B A S E		
				\bar{M} \bar{M} \bar{M} i i i s s s s s s											
5	Nocturnal increment	(bedtime to 04:00)	(SMPG) (mg/dL)	1	X	X	X	169	65.50	-8.442592	1.607456	-6.663373			
6	Nocturnal increment	(bedtime to 04:00)	(SMPG) (mg/dL)	2	X	X	O	25	9.69	-12.031600	11.819760	.			
7	Nocturnal increment	(bedtime to 04:00)	(SMPG) (mg/dL)	3	X	.	X	36	13.95	-51.204333	.	45.345611			
8	Nocturnal increment	(bedtime to 04:00)	(SMPG) (mg/dL)	4	X	O	O	28	10.85	-12.124214	.	.			

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC
Missing data pattern

Parameter Code=P9GINB4U Planned Treatment for Period 30 (N)=4

				v v i i s s i i t t B 2 3 A 2 6 S 0 0 E 0 0						v i s i t 2 2 0 0			v i s i t 3 6 0 0		
				P A R A M			G r o u p			F r e q			B A S E		
				M M M i i i s s s s s s											
9	Nocturnal increment	(bedtime to 04:00)	(SMPG) (mg/dL)	1	X	X	X	151	64.53	-12.288225	-2.607801	3.731881			
10	Nocturnal increment	(bedtime to 04:00)	(SMPG) (mg/dL)	2	X	X	O	27	11.54	-15.312444	49.832444	.			
11	Nocturnal increment	(bedtime to 04:00)	(SMPG) (mg/dL)	3	X	.	X	32	13.68	-10.916125	.	31.613500			
12	Nocturnal increment	(bedtime to 04:00)	(SMPG) (mg/dL)	4	X	O	O	24	10.26	-14.195167	.	.			

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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9GINB4U Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM	Description	Value
1	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	Method	Monotone
3	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	Number of Imputations	1
4	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	Seed for random number generator	4321

nn1218/nn1218-4131/ctr_20180214_er
10FEB2018:19:32:14 - a_797pp_stat_diff.sas/a_9pp_noct_stat_on_fas_app.txt

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=P9GINB4U Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM				Group	REGION1_	BOLAD1_
							Miss	Miss
1	1	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mg/dL)	1	X	X
2	1	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mg/dL)	2	X	X
3	1	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mg/dL)	3	X	X

Obs	BASE_	visit2200_	visit3600_	Freq	Percent	BASE	visit2200	visit3600
	Miss	Miss	Miss					
1	X	X	X	173	73.93	-9.292347	10.391968	2.208624
2	X	X	.	27	11.54	-19.310667	22.221185	.
3	X	.	.	34	14.53	-10.795059	.	.

Fast-acting insulin aspart
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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9GINB4U Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	Intercept	
2	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	REGION1	EUROPE
4	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	REGION1	JAPAN
5	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	BOLAD1	
6	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	BASE	

Obs	BOLAD1	ObsVal	_1
1		-0.02759	0.010137
2		-0.13289	-0.103937
3		0.13451	-0.023259
4		-0.06551	-0.105787
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.07577	0.015156
6		-0.63773	-0.660173

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10FEB2018:19:32:14 - a_797pp_stat_diff.sas/a_9pp_noct_stat_on_fas_app.txt

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9GINB4U Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|

Fast-acting insulin aspart
NN1218-4131

Clinical Trial Report
Statistical document

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Novo Nordisk

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9GINB4U Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM	Effect
10	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	REGION1
11	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	BOLAD1
12	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	BASE
13	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	visit2200

Obs	REGION1	BOLAD1	ObsVal	_1
10	JAPAN		0.07700	0.005221
11		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.02146	-0.060999
12			-0.63767	-0.610416
13			0.17280	0.205175

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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9GINB4U Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM	Description	Value
1	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	Method	Monotone
3	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	Number of Imputations	1
4	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	Seed for random number generator	4322

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10FEB2018:19:32:14 - a_797pp_stat_diff.sas/a_9pp_noct_stat_on_fas_app.txt

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=P9GINB4U Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM				Group	REGION1_	BOLAD1_
							Miss	Miss
1	1	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mg/dL)	1	X	X
2	1	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mg/dL)	2	X	X
3	1	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mg/dL)	3	X	X

Obs	BASE_	visit2200_	visit3600_	Freq	Percent	BASE	visit2200	visit3600
	Miss	Miss	Miss					
1	X	X	X	205	79.46	-15.951971	2.217471	2.469912
2	X	X	.	25	9.69	-12.031600	11.819760	.
3	X	.	.	28	10.85	-12.124214	.	.

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9GINB4U Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2200

Obs	_Imputation_	PARAM				Effect	REGION1
1	1	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mg/dL)	Intercept	
2	1	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mg/dL)	REGION1	EUROPE
4	1	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mg/dL)	REGION1	JAPAN
5	1	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mg/dL)	BOLAD1	
6	1	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mg/dL)	BASE	
Obs		BOLAD1		ObsVal		_1	
1				-0.07898		0.031581	
2				-0.38069		-0.223467	
3				0.01881		0.020727	
4				0.18307		0.072486	
5		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.09671		0.130982	
6				-0.59699		-0.634258	

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9GINB4U Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

O b s		I m p u t a t i o n s		P A R A M E T E R S		E f f e c t		R E G I O N		B O D Y		O b s		I	
7		1		Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)		Intercept		REGION1		ASIA (EXCLUDING JAPAN)		-0.04619		0.034692	
8		1		Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)		REGION1		ASIA (EXCLUDING JAPAN)		-0.19728		-0.047711		-0.047711	
9		1		Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)		REGION1		EUROPE		0.07369		-0.055486		-0.055486	

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9GINB4U Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM	Effect
10	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	REGION1
11	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	BOLAD1
12	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	BASE
13	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	visit2200

Obs	REGION1	BOLAD1	ObsVal	_1
10	JAPAN		0.01302	-0.097841
11		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.09557	0.152556
12			-0.65381	-0.656830
13			0.12600	0.090503

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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9GINB4U Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM	Description	Value
1	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	Method	Monotone
3	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	Number of Imputations	1
4	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	Seed for random number generator	4323

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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=P9GINB4U Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM				Group	REGION1_	BOLAD1_
							Miss	Miss
1	1	Nocturnal increment (bedtime to 04:00)	(SMPG)	(mg/dL)		1	X	X
2	1	Nocturnal increment (bedtime to 04:00)	(SMPG)	(mg/dL)		2	X	X
3	1	Nocturnal increment (bedtime to 04:00)	(SMPG)	(mg/dL)		3	X	X

Obs	BASE_	visit2200_	visit3600_			BASE	visit2200	visit3600
	Miss	Miss	Miss	Freq	Percent			
1	X	X	X	183	78.21	-12.048295	2.913803	8.607355
2	X	X	.	27	11.54	-15.312444	49.832444	.
3	X	.	.	24	10.26	-14.195167	.	.

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9GINB4U Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	Intercept	
2	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	REGION1	EUROPE
4	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	REGION1	JAPAN
5	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	BOLAD1	
6	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	BASE	

Obs	BOLAD1	ObsVal	_1
1		0.00641	-0.039309
2		0.03657	0.094348
3		0.08255	-0.045519
4		-0.05436	-0.001752
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.00991	-0.029000
6		-0.73666	-0.804528

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The MI Procedure with Monotone Regression Regression Information

Parameter Code=P9GINB4U Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

	Obs	Treatment	PAM	Efficacy	R-EGION	BOLD	ObsVal	
7	1	Nocturnal increment (bedtime to 04:00) (SMPG)	(mg/dL)	Intercept			0.02045	0.043256
8	1	Nocturnal increment (bedtime to 04:00) (SMPG)	(mg/dL)	REGION1 ASIA (EXCLUDING JAPAN)			-0.03224	0.061463
9	1	Nocturnal increment (bedtime to 04:00) (SMPG)	(mg/dL)	REGION1 EUROPE			0.02169	-0.022661

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9GINB4U Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM	Effect
10	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	REGION1
11	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	BOLAD1
12	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	BASE
13	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	visit2200

Obs	REGION1	BOLAD1	ObsVal	_1
10	JAPAN		-0.09899	-0.015692
11		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.04605	0.032939
12			-0.40940	-0.461186
13			0.33768	0.266911

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=P9PGINB4 Planned Treatment for Period 30 (N)=2

Obs	PARAM				Description	Value
1	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mmol/L)	Data Set	WORK.ENDPOINT_PARAM
2	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mmol/L)	Method	Monotone-data_MCMC
3	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mmol/L)	Multiple Imputation Chain	Multiple Chains
4	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
5	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mmol/L)	Start	Starting Value
6	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mmol/L)	Prior	Jeffreys
7	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mmol/L)	Number of Imputations	20000
8	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mmol/L)	Number of Burn-in Iterations	200
9	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mmol/L)	Seed for random number generator	1234

Parameter Code=P9PGINB4 Planned Treatment for Period 30 (N)=3

Obs	PARAM				Description	Value
10	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mmol/L)	Data Set	WORK.ENDPOINT_PARAM
11	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mmol/L)	Method	Monotone-data_MCMC
12	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mmol/L)	Multiple Imputation Chain	Multiple Chains
13	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
14	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mmol/L)	Start	Starting Value
15	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mmol/L)	Prior	Jeffreys
16	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mmol/L)	Number of Imputations	20000
17	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mmol/L)	Number of Burn-in Iterations	200
18	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mmol/L)	Seed for random number generator	903043636

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=P9PGINB4 Planned Treatment for Period 30 (N)=4

Obs	PARAM				Description	Value
19	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mmol/L)	Data Set	WORK.ENDPOINT_PARAM
20	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mmol/L)	Method	Monotone-data MCMC
21	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mmol/L)	Multiple Imputation Chain	Multiple Chains
22	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
23	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mmol/L)	Start	Starting Value
24	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mmol/L)	Prior	Jeffreys
25	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mmol/L)	Number of Imputations	20000
26	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mmol/L)	Number of Burn-in Iterations	200
27	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mmol/L)	Seed for random number generator	907994776

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC

Missing data pattern

Parameter Code=P9PGINB4 Planned Treatment for Period 30 (N)=4

O b s							v i s i t t B A S E			P e r c e n t			v i s i t 2 2 0 0	v i s i t 3 6 0 0			
							G r o u p	M̄ i s s	M̄ i s s	M̄ i s s	F r e q	B A S E					
9	Nocturnal	increment	(bedtime to 04:00)	(SMPG)	(mmol/L)		1	X	X	X	151	64.53	-0.681921	-0.144717	0.207097		
10	Nocturnal	increment	(bedtime to 04:00)	(SMPG)	(mmol/L)		2	X	X	O	27	11.54	-0.849747	2.765396	.		
11	Nocturnal	increment	(bedtime to 04:00)	(SMPG)	(mmol/L)		3	X	.	X	32	13.68	-0.605778	.	1.754356		
12	Nocturnal	increment	(bedtime to 04:00)	(SMPG)	(mmol/L)		4	X	O	O	24	10.26	-0.787745	.	.		

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The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PGINB4 Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM	Description	Value
1	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	Method	Monotone
3	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	Number of Imputations	1
4	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	Seed for random number generator	4321

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The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=P9PGINB4 Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM				Group	REGION1_ Miss	BOLAD1_ Miss
1	1	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mmol/L)	1	X	X
2	1	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mmol/L)	2	X	X
3	1	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mmol/L)	3	X	X

Obs	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
1	X	X	X	173	73.93	-0.515669	0.576691	0.122565
2	X	X	.	27	11.54	-1.071624	1.233140	.
3	X	.	.	34	14.53	-0.599060	.	.

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGINB4 Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	Intercept	
2	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	REGION1	EUROPE
4	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	REGION1	JAPAN
5	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	BOLAD1	
6	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	BASE	

Obs	BOLAD1	ObsVal	_1
1		-0.02759	0.010137
2		-0.13289	-0.103937
3		0.13451	-0.023259
4		-0.06551	-0.105787
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.07577	0.015156
6		-0.63773	-0.660173

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGINB4 Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

Obs	No	Variable	Description	Unit	Estimate	Standard Error	t-Statistic	p-Value	Confidence Limits
7	1	Nocturnal increment	(bedtime to 04:00) (SMPG)	(mmol/L)	Intercept			0.01000	-0.095506
8	1	Nocturnal increment	(bedtime to 04:00) (SMPG)	(mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)		-0.00252	-0.034525
9	1	Nocturnal increment	(bedtime to 04:00) (SMPG)	(mmol/L)	REGION1	EUROPE		0.01129	0.069588

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGINB4 Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM	Effect
10	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	REGION1
11	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	BOLAD1
12	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	BASE
13	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	visit2200

Obs	REGION1	BOLAD1	ObsVal	_1
10	JAPAN		0.07700	0.005221
11		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.02146	-0.060999
12			-0.63767	-0.610416
13			0.17280	0.205175

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PGINB4 Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM	Description	Value
1	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	Method	Monotone
3	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	Number of Imputations	1
4	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	Seed for random number generator	4322

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=P9PGINB4 Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM				Group	REGION1_ Miss	BOLAD1_ Miss
1	1	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mmol/L)	1	X	X
2	1	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mmol/L)	2	X	X
3	1	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mmol/L)	3	X	X

Obs	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
1	X	X	X	205	79.46	-0.885237	0.123056	0.137065
2	X	X	.	25	9.69	-0.667680	0.655925	.
3	X	.	.	28	10.85	-0.672820	.	.

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGINB4 Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	Intercept	
2	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	REGION1	EUROPE
4	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	REGION1	JAPAN
5	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	BOLAD1	
6	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	BASE	

Obs	BOLAD1	ObsVal	_1
1		-0.07898	0.031581
2		-0.38069	-0.223467
3		0.01881	0.020727
4		0.18307	0.072486
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.09671	0.130982
6		-0.59699	-0.634258

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGINB4 Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

Obs	N	Imputed	P	A	R	M	E	f	f	e	c	t	R	E	G	I	O	N	1	B	O	L	A	D	1	O	b	s	V	a	l	I
7	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	Intercept																													
8	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)																												
9	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	REGION1	EUROPE																												

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGINB4 Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM	Effect
10	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	REGION1
11	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	BOLAD1
12	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	BASE
13	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	visit2200

Obs	REGION1	BOLAD1	ObsVal	_1
10	JAPAN		0.01302	-0.097841
11		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.09557	0.152556
12			-0.65381	-0.656830
13			0.12600	0.090503

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The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9PGINB4 Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM	Description	Value
1	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	Method	Monotone
3	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	Number of Imputations	1
4	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	Seed for random number generator	4323

nn1218/nn1218-4131/ctr_20180214_er
10FEB2018:19:32:14 - a_797pp_stat_diff.sas/a_9pp_noct_stat_on_fas_app.txt

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=P9PGINB4 Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM				Group	REGION1_ Miss -	BOLAD1_ Miss -
1	1	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mmol/L)	1	X	X
2	1	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mmol/L)	2	X	X
3	1	Nocturnal increment	(bedtime to 04:00)	(SMPG)	(mmol/L)	3	X	X

Obs	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
1	X	X	X	183	78.21	-0.668607	0.161698	0.477656
2	X	X	.	27	11.54	-0.849747	2.765396	.
3	X	.	.	24	10.26	-0.787745	.	.

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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGINB4 Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	Intercept	
2	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	REGION1	EUROPE
4	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	REGION1	JAPAN
5	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	BOLAD1	
6	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	BASE	

Obs	BOLAD1	ObsVal	_1
1		0.00641	-0.039309
2		0.03657	0.094348
3		0.08255	-0.045519
4		-0.05436	-0.001752
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.00991	-0.029000
6		-0.73666	-0.804528

nn1218/nn1218-4131/ctr_20180214_er
10FEB2018:19:32:14 - a_797pp_stat_diff.sas/a_9pp_noct_stat_on_fas_app.txt

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGINB4 Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

Imputed		Observations		Region		Treatment		Outcome		Mean	
Obs	N	Variable	Value	Region	Value	Treatment	Value	Outcome	Value	Mean	Value
7	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	Intercept						0.02045	0.043256	
8	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)					-0.03224	0.061463	
9	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	REGION1	EUROPE					0.02169	-0.022661	

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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGINB4 Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM	Effect
10	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	REGION1
11	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	BOLAD1
12	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	BASE
13	1	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	visit2200

Obs	REGION1	BOLAD1	ObsVal	_1
10	JAPAN		-0.09899	-0.015692
11		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.04605	0.032939
12			-0.40940	-0.461186
13			0.33768	0.266911

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=P9GINBBU Planned Treatment for Period 30 (N)=2

Obs	PARAM				Description	Value
1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	Data Set	WORK.ENDPOINT_PARAM
2	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	Method	Monotone-data_MCMC
3	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	Multiple Imputation Chain	Multiple Chains
4	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
5	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	Start	Starting Value
6	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	Prior	Jeffreys
7	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	Number of Imputations	20000
8	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	Number of Burn-in Iterations	200
9	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	Seed for random number generator	1234

Parameter Code=P9GINBBU Planned Treatment for Period 30 (N)=3

Obs	PARAM				Description	Value
10	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	Data Set	WORK.ENDPOINT_PARAM
11	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	Method	Monotone-data_MCMC
12	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	Multiple Imputation Chain	Multiple Chains
13	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
14	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	Start	Starting Value
15	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	Prior	Jeffreys
16	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	Number of Imputations	20000
17	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	Number of Burn-in Iterations	200
18	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	Seed for random number generator	275848675

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=P9GINBBU Planned Treatment for Period 30 (N)=4

Obs	PARAM				Description	Value
19	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	Data Set	WORK.ENDPOINT_PARAM
20	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	Method	Monotone-data_MCMC
21	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	Multiple Imputation Chain	Multiple Chains
22	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
23	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	Start	Starting Value
24	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	Prior	Jeffreys
25	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	Number of Imputations	20000
26	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	Number of Burn-in Iterations	200
27	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	Seed for random number generator	192502820

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC
Missing data pattern

Parameter Code=P9GINBBU Planned Treatment for Period 30 (N)=2

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss
1	Nocturnal increment (bedtime to breakfast) (SMPG) (mg/dL)	1	X	X
2	Nocturnal increment (bedtime to breakfast) (SMPG) (mg/dL)	2	X	X
3	Nocturnal increment (bedtime to breakfast) (SMPG) (mg/dL)	3	X	.
4	Nocturnal increment (bedtime to breakfast) (SMPG) (mg/dL)	4	X	0

Obs	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
1	X	247	82.06	-37.135215	23.198340	18.330397
2	0	17	5.65	-35.201059	3.993647	.
3	X	22	7.31	-33.723273	.	-9.998182
4	0	15	4.98	-10.295600	.	.

Parameter Code=P9GINBBU Planned Treatment for Period 30 (N)=3

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss
5	Nocturnal increment (bedtime to breakfast) (SMPG) (mg/dL)	1	X	X
6	Nocturnal increment (bedtime to breakfast) (SMPG) (mg/dL)	2	X	X

Obs	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
5	X	246	82.27	-38.819707	20.026398	14.015195
6	0	16	5.35	-45.471625	8.280750	.

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC
Missing data pattern

Parameter Code=P9GINBBU Planned Treatment for Period 30 (N)=3

(continued)

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss
7	Nocturnal increment (bedtime to breakfast) (SMPG) (mg/dL)	3	X	.
8	Nocturnal increment (bedtime to breakfast) (SMPG) (mg/dL)	4	X	0

Obs	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
7	X	26	8.70	-54.662385	.	49.195154
8	0	11	3.68	-31.987455	.	.

Parameter Code=P9GINBBU Planned Treatment for Period 30 (N)=4

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss
9	Nocturnal increment (bedtime to breakfast) (SMPG) (mg/dL)	1	X	X
10	Nocturnal increment (bedtime to breakfast) (SMPG) (mg/dL)	2	X	X
11	Nocturnal increment (bedtime to breakfast) (SMPG) (mg/dL)	3	X	.

Obs	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
9	X	248	81.85	-29.268524	-0.695185	7.380145
10	0	19	6.27	-81.583684	77.483053	.
11	X	22	7.26	6.794364	.	-20.034182

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC
Missing data pattern

Parameter Code=P9GINBBU Planned Treatment for Period 30 (N)=4

(continued)

Obs	PARAM				Group	BASE_ Miss	visit2200_ Miss
12	Nocturnal increment (bedtime to breakfast) (SMPG) (mg/dL)				4	X	O
Obs	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600	
12	O	14	4.62	-45.900429	.	.	

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression Model Information

Parameter Code=P9GINBBU Planned Treatment for Period 30 (N)=2

O b s	I m p u t a t i o n —							P A R A M	D e s c r i p t i o n	V a l u e
1	1	Nocturnal	increment	(bedtime	to	breakfast)	(SMPG)	(mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	Nocturnal	increment	(bedtime	to	breakfast)	(SMPG)	(mg/dL)	Method	Monotone
3	1	Nocturnal	increment	(bedtime	to	breakfast)	(SMPG)	(mg/dL)	Number of Imputations	1
4	1	Nocturnal	increment	(bedtime	to	breakfast)	(SMPG)	(mg/dL)	Seed for random number generator	4321

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=P9GINBBU Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM					Group	REGION1_ Miss	BOLAD1_ Miss
1	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)		1	X	X
2	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)		2	X	X
3	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)		3	X	X

Obs	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
1	X	X	X	269	89.37	-36.856171	23.350364	16.013561
2	X	X	.	17	5.65	-35.201059	3.993647	.
3	X	.	.	15	4.98	-10.295600	.	.

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9GINBBU Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2200

Obs	_Imputation_	PARAM				Effect	REGION1
1	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	Intercept	
2	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	REGION1	EUROPE
4	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	REGION1	JAPAN
5	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	BOLAD1	
6	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	BASE	
Obs		BOLAD1		ObsVal	_1		
1				-0.01492	0.016991		
2				0.04604	0.075675		
3				0.00518	-0.121069		
4				-0.03689	-0.060263		
5		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.06884	0.021228		
6				-0.64515	-0.661800		

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression Regression Information

Parameter Code=P9GINBBU Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

O b s	I m p u t a t i o n s							E f f e c t	R E G I O N 1	B O L D 1	O b s V a l	\bar{I}	
		P A R A M											
7	1	Nocturnal increment (bedtime to breakfast) (SMPG) (mg/dL)	Intercept								-0.00121	-0.011634	
8	1	Nocturnal increment (bedtime to breakfast) (SMPG) (mg/dL)	REGION1 ASIA (EXCLUDING JAPAN)								0.02931	0.092490	
9	1	Nocturnal increment (bedtime to breakfast) (SMPG) (mg/dL)	REGION1 EUROPE								0.07785	0.054138	

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9GINBBU Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM				Effect
10	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	REGION1
11	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	BOLAD1
12	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	BASE
13	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	visit2200
Obs	REGION1	BOLAD1			ObsVal	_1
10	JAPAN				0.07434	0.083490
11		BOLUS INSULIN ALGORITHM (SLIDING SCALE)			-0.05965	-0.092421
12					-0.72953	-0.767483
13					-0.00164	-0.090951

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=P9GINBBU Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM				Group	REGION1_ Miss	BOLAD1_ Miss
1	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	1	X	X
2	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	2	X	X
3	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	3	X	X

Obs	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
1	X	X	X	272	90.97	-40.334081	18.274759	17.377985
2	X	X	.	16	5.35	-45.471625	8.280750	.
3	X	.	.	11	3.68	-31.987455	.	.

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9GINBBU Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2200

Obs	_Imputation_	PARAM				Effect	REGION1
1	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	Intercept	
2	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	REGION1	EUROPE
4	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	REGION1	JAPAN
5	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	BOLAD1	
6	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	BASE	
Obs		BOLAD1		ObsVal	_1		
1				-0.07904	0.014678		
2				-0.34841	-0.218623		
3				0.13082	0.130473		
4				0.12320	0.034945		
5		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.09045	0.114427		
6				-0.65357	-0.688306		

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9GINBBU Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

Imputed										
Obs										
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I										
7	1	Nocturnal increment (bedtime to breakfast)	(SMPG)	(mg/dL)	Intercept				-0.02718	0.002146
8	1	Nocturnal increment (bedtime to breakfast)	(SMPG)	(mg/dL)	REGION1 ASIA (EXCLUDING JAPAN)				-0.08841	-0.179245
9	1	Nocturnal increment (bedtime to breakfast)	(SMPG)	(mg/dL)	REGION1 EUROPE				0.02547	0.038544

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9GINBBU Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM				Effect
10	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	REGION1
11	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	BOLAD1
12	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	BASE
13	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	visit2200
Obs	REGION1	BOLAD1			ObsVal	_1
10	JAPAN				-0.06866	0.066871
11		BOLUS INSULIN ALGORITHM (SLIDING SCALE)			0.11297	0.093670
12					-0.63316	-0.660452
13					0.14984	0.118030

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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=P9GINBBU Planned Treatment for Period 30 (N)=4

Obs	Imputation							Description	Value
		P A R A M							
1	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	Data Set	WORK.MONO_SORT_TRT		
2	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	Method	Monotone		
3	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	Number of Imputations	1		
4	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	Seed for random number generator	4323		

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=P9GINBBU Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM					Group	REGION1_ Miss	BOLAD1_ Miss
1	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)		1	X	X
2	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)		2	X	X
3	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)		3	X	X

Obs	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
1	X	X	X	270	89.11	-26.330067	-3.880989	5.146385
2	X	X	.	19	6.27	-81.583684	77.483053	.
3	X	.	.	14	4.62	-45.900429	.	.

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9GINBBU Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2200

Obs	_Imputation_	PARAM				Effect	REGION1
1	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	Intercept	
2	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	REGION1	EUROPE
4	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	REGION1	JAPAN
5	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	BOLAD1	
6	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	BASE	
Obs		BOLAD1		ObsVal	_1		
1				0.01677	-0.022590		
2				0.12713	0.171231		
3				0.06851	-0.030585		
4				-0.03201	0.003569		
5		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.00801	0.003780		
6				-0.73206	-0.788693		

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9GINBBU Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM				Effect
10	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	REGION1
11	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	BOLAD1
12	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	BASE
13	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mg/dL)	visit2200
Obs	REGION1	BOLAD1			ObsVal	_1
10	JAPAN				-0.04298	0.016390
11		BOLUS INSULIN ALGORITHM (SLIDING SCALE)			0.02572	-0.108264
12					-0.62609	-0.659558
13					0.18369	0.057108

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The MI Procedure with MCMC
Model Information

Parameter Code=P9PGINBB Planned Treatment for Period 30 (N)=2

Obs	PARAM	Description	Value
1	Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)	Data Set	WORK.ENDPOINT_PARAM
2	Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)	Method	Monotone-data_MCMC
3	Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)	Multiple Imputation Chain	Multiple Chains
4	Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
5	Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)	Start	Starting Value
6	Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)	Prior	Jeffreys
7	Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)	Number of Imputations	20000
8	Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)	Number of Burn-in Iterations	200
9	Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)	Seed for random number generator	1234

Parameter Code=P9PGINBB Planned Treatment for Period 30 (N)=3

Obs	PARAM	Description	Value
10	Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)	Data Set	WORK.ENDPOINT_PARAM
11	Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)	Method	Monotone-data_MCMC
12	Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)	Multiple Imputation Chain	Multiple Chains
13	Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
14	Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)	Start	Starting Value
15	Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)	Prior	Jeffreys
16	Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)	Number of Imputations	20000
17	Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)	Number of Burn-in Iterations	200
18	Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)	Seed for random number generator	275848675

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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=P9PGINBB Planned Treatment for Period 30 (N)=4

Obs	PARAM				Description	Value
19	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	Data Set	WORK.ENDPOINT_PARAM
20	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	Method	Monotone-data_MCMC
21	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	Multiple Imputation Chain	Multiple Chains
22	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
23	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	Start	Starting Value
24	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	Prior	Jeffreys
25	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	Number of Imputations	20000
26	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	Number of Burn-in Iterations	200
27	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	Seed for random number generator	192502820

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The MI Procedure with MCMC
Missing data pattern

Parameter Code=P9PGINBB Planned Treatment for Period 30 (N)=2

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss
1	Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)	1	X	X
2	Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)	2	X	X
3	Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)	3	X	.
4	Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)	4	X	O

Obs	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
1	X	247	82.06	-2.060778	1.287366	1.017225
2	O	17	5.65	-1.953444	0.221623	.
3	X	22	7.31	-1.871436	.	-0.554838
4	O	15	4.98	-0.571343	.	.

Parameter Code=P9PGINBB Planned Treatment for Period 30 (N)=3

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss
5	Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)	1	X	X
6	Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)	2	X	X

Obs	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
5	X	246	82.27	-2.154257	1.111343	0.777758
6	O	16	5.35	-2.523398	0.459531	.

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC
Missing data pattern

Parameter Code=P9PGINBB Planned Treatment for Period 30 (N)=3

(continued)

Obs	PARAM				Group	BASE_ Miss	visit2200_ Miss
7	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	3	X	.
8	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	4	X	O
Obs	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600	
7	X	26	8.70	-3.033429	.	2.730031	
8	O	11	3.68	-1.775108	.	.	

Parameter Code=P9PGINBB Planned Treatment for Period 30 (N)=4

Obs	PARAM				Group	BASE_ Miss	visit2200_ Miss
9	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	1	X	X
10	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	2	X	X
11	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	3	X	.
Obs	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600	
9	X	248	81.85	-1.624224	-0.038579	0.409553	
10	O	19	6.27	-4.527396	4.299836	.	
11	X	22	7.26	0.377046	.	-1.111775	

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The MI Procedure with MCMC
Missing data pattern

Parameter Code=P9PGINBB Planned Treatment for Period 30 (N)=4

(continued)

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss
12	Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)	4	X	O

Obs	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
12	O	14	4.62	-2.547194	.	.

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=P9PGINBB Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM				Group	REGION1_ Miss	BOLAD1_ Miss
1	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	1	X	X
2	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	2	X	X
3	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	3	X	X

Obs	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
1	X	X	X	269	89.37	-2.045293	1.295803	0.888655
2	X	X	.	17	5.65	-1.953444	0.221623	.
3	X	.	.	15	4.98	-0.571343	.	.

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGINBB Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2200

Obs	_Imputation_	PARAM				Effect	REGION1
1	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	Intercept	
2	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	REGION1	EUROPE
4	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	REGION1	JAPAN
5	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	BOLAD1	
6	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	BASE	
Obs	BOLAD1		ObsVal		_1		
1			-0.01492		0.016991		
2			0.04604		0.075675		
3			0.00518		-0.121069		
4			-0.03689		-0.060263		
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.06884		0.021228		
6			-0.64515		-0.661800		

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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGINBB Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

O b s _	I m p u t a t i o n s	P A R A M E T E R	E f f e c t	R E G I O N	B O D Y	O b s _	I m p u t a t i o n s
7	1	Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L) Intercept				-0.00121	-0.011634
8	1	Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L) REGION1 ASIA (EXCLUDING JAPAN)				0.02931	0.092490
9	1	Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L) REGION1 EUROPE				0.07785	0.054138

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGINBB Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM				Effect
10	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	REGION1
11	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	BOLAD1
12	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	BASE
13	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	visit2200
Obs	REGION1	BOLAD1			ObsVal	_1
10	JAPAN				0.07434	0.083490
11		BOLUS INSULIN ALGORITHM (SLIDING SCALE)			-0.05965	-0.092421
12					-0.72953	-0.767483
13					-0.00164	-0.090951

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression Model Information

Parameter Code=P9PGINBB Planned Treatment for Period 30 (N)=3

O b s	I m p u t a t i o n	P A R A M	D e s c r i p t i o n	V a l u e
1	1	Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)	Method	Monotone
3	1	Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)	Number of Imputations	1
4	1	Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)	Seed for random number generator	4322

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=P9PGINBB Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM				Group	REGION1_ Miss	BOLAD1_ Miss
1	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	1	X	X
2	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	2	X	X
3	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	3	X	X

Obs	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
1	X	X	X	272	90.97	-2.238295	1.014138	0.964372
2	X	X	.	16	5.35	-2.523398	0.459531	.
3	X	.	.	11	3.68	-1.775108	.	.

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGINBB Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)	Intercept	
2	1	Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)	REGION1	EUROPE
4	1	Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)	REGION1	JAPAN
5	1	Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)	BOLAD1	
6	1	Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)	BASE	

Obs	BOLAD1	ObsVal	_1
1		-0.07904	0.014678
2		-0.34841	-0.218623
3		0.13082	0.130473
4		0.12320	0.034945
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.09045	0.114427
6		-0.65357	-0.688306

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The MI Procedure with Monotone Regression Regression Information

Parameter Code=P9PGINBB Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

				P A R A M		E f f e c t	R E G I O N 1	B O L D 1	O b s V a l	\bar{I}
7	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	Intercept			-0.02718	0.002146
8	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)		-0.08841	-0.179245
9	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	REGION1	EUROPE		0.02547	0.038544

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGINBB Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM				Effect
10	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	REGION1
11	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	BOLAD1
12	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	BASE
13	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	visit2200
Obs	REGION1	BOLAD1			ObsVal	_1
10	JAPAN				-0.06866	0.066871
11		BOLUS INSULIN ALGORITHM (SLIDING SCALE)			0.11297	0.093670
12					-0.63316	-0.660452
13					0.14984	0.118030

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression Model Information

Parameter Code=P9PGINBB Planned Treatment for Period 30 (N)=4

O b s	I m p u t a t i o n _	P A R A M	D e s c r i p t i o n	V a l u e
1	1	Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)	Method	Monotone
3	1	Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)	Number of Imputations	1
4	1	Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)	Seed for random number generator	4323

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=P9PGINBB Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM				Group	REGION1_ Miss	BOLAD1_ Miss
1	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	1	X	X
2	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	2	X	X
3	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	3	X	X

Obs	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
1	X	X	X	270	89.11	-1.461158	-0.215371	0.285593
2	X	X	.	19	6.27	-4.527396	4.299836	.
3	X	.	.	14	4.62	-2.547194	.	.

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGINBB Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2200

Obs	_Imputation_	PARAM				Effect	REGION1
1	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	Intercept	
2	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	REGION1	EUROPE
4	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	REGION1	JAPAN
5	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	BOLAD1	
6	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	BASE	
Obs	BOLAD1		ObsVal		_1		
1			0.01677		-0.022590		
2			0.12713		0.171231		
3			0.06851		-0.030585		
4			-0.03201		0.003569		
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.00801		0.003780		
6			-0.73206		-0.788693		

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGINBB Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

O o b n s _	I m p u t a t i o n s _	P A R A M	E f f e c t	R E G I O N	B O D Y	I
7 1	Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)	Intercept				0.03452 0.053986
8 1	Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)	REGION1 ASIA (EXCLUDING JAPAN)				0.00114 0.106871
9 1	Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)	REGION1 EUROPE				0.05057 0.017946

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=P9PGINBB Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM				Effect
10	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	REGION1
11	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	BOLAD1
12	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	BASE
13	1	Nocturnal increment	(bedtime to breakfast)	(SMPG)	(mmol/L)	visit2200
Obs	REGION1	BOLAD1		ObsVal	_1	
10	JAPAN			-0.04298	0.016390	
11		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.02572	-0.108264	
12				-0.62609	-0.659558	
13				0.18369	0.057108	

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Model Information

Parameter Code=P9GIN4BU Parameter=Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Data Set	WORK.IMPUTE
2	1	NN1218-4131	Dependent Variable	eotVisit
3	1	NN1218-4131	Covariance Structure	Diagonal
4	1	NN1218-4131	Estimation Method	REML
5	1	NN1218-4131	Residual Variance Method	Profile
6	1	NN1218-4131	Fixed Effects SE Method	Model-Based
7	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=P9GINB4U Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
8	1	NN1218-4131	Data Set	WORK.IMPUTE
9	1	NN1218-4131	Dependent Variable	eotVisit
10	1	NN1218-4131	Covariance Structure	Diagonal
11	1	NN1218-4131	Estimation Method	REML
12	1	NN1218-4131	Residual Variance Method	Profile
13	1	NN1218-4131	Fixed Effects SE Method	Model-Based
14	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=P9GINBBU Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
15	1	NN1218-4131	Data Set	WORK.IMPUTE
16	1	NN1218-4131	Dependent Variable	eotVisit
17	1	NN1218-4131	Covariance Structure	Diagonal

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The Mixed procedure
Model Information

Parameter Code=P9GINBBU Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mg/dL)

(continued)

Obs	_Imputation_	STUDYID	Descr	Value
18	1	NN1218-4131	Estimation Method	REML
19	1	NN1218-4131	Residual Variance Method	Profile
20	1	NN1218-4131	Fixed Effects SE Method	Model-Based
21	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=P9PGIN4B Parameter=Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
22	1	NN1218-4131	Data Set	WORK.IMPUTE
23	1	NN1218-4131	Dependent Variable	eotVisit
24	1	NN1218-4131	Covariance Structure	Diagonal
25	1	NN1218-4131	Estimation Method	REML
26	1	NN1218-4131	Residual Variance Method	Profile
27	1	NN1218-4131	Fixed Effects SE Method	Model-Based
28	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=P9PGINB4 Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
29	1	NN1218-4131	Data Set	WORK.IMPUTE
30	1	NN1218-4131	Dependent Variable	eotVisit
31	1	NN1218-4131	Covariance Structure	Diagonal
32	1	NN1218-4131	Estimation Method	REML

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Model Information

Parameter Code=P9PGINB4 Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)

(continued)

Obs	_Imputation_	STUDYID	Descr	Value
33	1	NN1218-4131	Residual Variance Method	Profile
34	1	NN1218-4131	Fixed Effects SE Method	Model-Based
35	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=P9PGINBB Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
36	1	NN1218-4131	Data Set	WORK.IMPUTE
37	1	NN1218-4131	Dependent Variable	eotVisit
38	1	NN1218-4131	Covariance Structure	Diagonal
39	1	NN1218-4131	Estimation Method	REML
40	1	NN1218-4131	Residual Variance Method	Profile
41	1	NN1218-4131	Fixed Effects SE Method	Model-Based
42	1	NN1218-4131	Degrees of Freedom Method	Residual

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Class Level Information

Parameter Code=P9GINB4U Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)

Ob- s	—	Input ID	STUDY	Class	Level	Values	Unit
4	1	NN1218-4131	TRTPN		3 2 3 4		5
5	1	NN1218-4131	REGION1		4 ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA		49
6	1	NN1218-4131	BOLAD1		2 BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULI		85

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Class Level Information

Parameter Code=P9GINBBU Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mg/dL)

Ob- s	—	Input ID	STUDY	Class	Level	Values	min
7	1	NN1218-4131	TRTPN		3 2 3 4		5
8	1	NN1218-4131	REGION1		4 ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA		49
9	1	NN1218-4131	BOLAD1		2 BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULI		85

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Class Level Information

Parameter Code=P9PGINB4 Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)

Obs	Input	STUDY ID	Class	Level	Values	min
13	1	NN1218-4131	TRTPN	3 2 3 4		5
14	1	NN1218-4131	REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA	49
15	1	NN1218-4131	BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULI	85

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Class Level Information

Parameter Code=P9PGINBB Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)

Obs	Inpution	STUDY ID	Classs	Level	Values	min
16	1	NN1218-4131	TRTPN	3 2 3 4		5
17	1	NN1218-4131	REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA	49
18	1	NN1218-4131	BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULI	85

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Dimensions

Parameter Code=P9GIN4BU Parameter=Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Covariance Parameters	1
2	1	NN1218-4131	Columns in X	10
3	1	NN1218-4131	Columns in Z	0
4	1	NN1218-4131	Subjects	1
5	1	NN1218-4131	Max Obs per Subject	739

Parameter Code=P9GINB4U Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
6	1	NN1218-4131	Covariance Parameters	1
7	1	NN1218-4131	Columns in X	10
8	1	NN1218-4131	Columns in Z	0
9	1	NN1218-4131	Subjects	1
10	1	NN1218-4131	Max Obs per Subject	726

Parameter Code=P9GINBBU Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
11	1	NN1218-4131	Covariance Parameters	1
12	1	NN1218-4131	Columns in X	10
13	1	NN1218-4131	Columns in Z	0
14	1	NN1218-4131	Subjects	1
15	1	NN1218-4131	Max Obs per Subject	903

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Dimensions

Parameter Code=P9PGIN4B Parameter=Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
16	1	NN1218-4131	Covariance Parameters	1
17	1	NN1218-4131	Columns in X	10
18	1	NN1218-4131	Columns in Z	0
19	1	NN1218-4131	Subjects	1
20	1	NN1218-4131	Max Obs per Subject	739

Parameter Code=P9PGINB4 Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
21	1	NN1218-4131	Covariance Parameters	1
22	1	NN1218-4131	Columns in X	10
23	1	NN1218-4131	Columns in Z	0
24	1	NN1218-4131	Subjects	1
25	1	NN1218-4131	Max Obs per Subject	726

Parameter Code=P9PGINBB Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
26	1	NN1218-4131	Covariance Parameters	1
27	1	NN1218-4131	Columns in X	10
28	1	NN1218-4131	Columns in Z	0
29	1	NN1218-4131	Subjects	1
30	1	NN1218-4131	Max Obs per Subject	903

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Number of Observations

Parameter Code=P9GIN4BU Parameter=Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
1	1	NN1218-4131	Number of Observations Read	739	739	739	739	739
2	1	NN1218-4131	Number of Observations Used	739	739	739	739	739
3	1	NN1218-4131	Number of Observations Not Used	0	739	739	739	739

Parameter Code=P9GINB4U Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
4	1	NN1218-4131	Number of Observations Read	726	726	726	726	726
5	1	NN1218-4131	Number of Observations Used	726	726	726	726	726
6	1	NN1218-4131	Number of Observations Not Used	0	726	726	726	726

Parameter Code=P9GINBBU Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
7	1	NN1218-4131	Number of Observations Read	903	903	903	903	903
8	1	NN1218-4131	Number of Observations Used	903	903	903	903	903
9	1	NN1218-4131	Number of Observations Not Used	0	903	903	903	903

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The Mixed procedure
Number of Observations

Parameter Code=P9PGIN4B Parameter=Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
10	1	NN1218-4131	Number of Observations Read	739	739	739	739	739
11	1	NN1218-4131	Number of Observations Used	739	739	739	739	739
12	1	NN1218-4131	Number of Observations Not Used	0	739	739	739	739

Parameter Code=P9PGINB4 Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
13	1	NN1218-4131	Number of Observations Read	726	726	726	726	726
14	1	NN1218-4131	Number of Observations Used	726	726	726	726	726
15	1	NN1218-4131	Number of Observations Not Used	0	726	726	726	726

Parameter Code=P9PGINBB Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
16	1	NN1218-4131	Number of Observations Read	903	903	903	903	903
17	1	NN1218-4131	Number of Observations Used	903	903	903	903	903
18	1	NN1218-4131	Number of Observations Not Used	0	903	903	903	903

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The Mixed procedure
Covariance Parameter Estimates

Parameter Code=P9GIN4BU Parameter=Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	CovParm	Estimate
1	1	NN1218-4131	Residual	3368.61

Parameter Code=P9GINB4U Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	CovParm	Estimate
20001	1	NN1218-4131	Residual	5783.47

Parameter Code=P9GINBBU Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	CovParm	Estimate
40001	1	NN1218-4131	Residual	5414.71

Parameter Code=P9PGIN4B Parameter=Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	CovParm	Estimate
60001	1	NN1218-4131	Residual	10.3739

Parameter Code=P9PGINB4 Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	CovParm	Estimate
80001	1	NN1218-4131	Residual	17.8106

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The Mixed procedure
Covariance Parameter Estimates

Parameter Code=P9PGINBB Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	CovParm	Estimate
100001	1	NN1218-4131	Residual	16.6750

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The Mixed procedure
Fit Statistics

Parameter Code=P9GIN4BU Parameter=Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	-2 Res Log Likelihood	8062.5
2	1	NN1218-4131	AIC (Smaller is Better)	8064.5
3	1	NN1218-4131	AICC (Smaller is Better)	8064.5
4	1	NN1218-4131	BIC (Smaller is Better)	8069.1

Parameter Code=P9GINB4U Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
5	1	NN1218-4131	-2 Res Log Likelihood	8308.3
6	1	NN1218-4131	AIC (Smaller is Better)	8310.3
7	1	NN1218-4131	AICC (Smaller is Better)	8310.3
8	1	NN1218-4131	BIC (Smaller is Better)	8314.9

Parameter Code=P9GINBBU Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
9	1	NN1218-4131	-2 Res Log Likelihood	10286.8
10	1	NN1218-4131	AIC (Smaller is Better)	10288.8
11	1	NN1218-4131	AICC (Smaller is Better)	10288.8
12	1	NN1218-4131	BIC (Smaller is Better)	10293.6

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The Mixed procedure
Fit Statistics

Parameter Code=P9PGIN4B Parameter=Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
13	1	NN1218-4131	-2 Res Log Likelihood	3829.3
14	1	NN1218-4131	AIC (Smaller is Better)	3831.3
15	1	NN1218-4131	AICC (Smaller is Better)	3831.3
16	1	NN1218-4131	BIC (Smaller is Better)	3835.9

Parameter Code=P9PGINB4 Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
17	1	NN1218-4131	-2 Res Log Likelihood	4150.3
18	1	NN1218-4131	AIC (Smaller is Better)	4152.3
19	1	NN1218-4131	AICC (Smaller is Better)	4152.3
20	1	NN1218-4131	BIC (Smaller is Better)	4156.9

Parameter Code=P9PGINBB Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
21	1	NN1218-4131	-2 Res Log Likelihood	5105.2
22	1	NN1218-4131	AIC (Smaller is Better)	5107.2
23	1	NN1218-4131	AICC (Smaller is Better)	5107.2
24	1	NN1218-4131	BIC (Smaller is Better)	5112.0

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The Mixed procedure
Solution for Fixed Effects

Parameter Code=P9GIN4BU Parameter=Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1		BOLAD1	
1	1	NN1218-4131	TRTPN	2				
2	1	NN1218-4131	TRTPN	3				
3	1	NN1218-4131	TRTPN	4				
4	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
5	1	NN1218-4131	REGION1	—	EUROPE			
6	1	NN1218-4131	REGION1	—	JAPAN			
7	1	NN1218-4131	REGION1	—	NORTH AMERICA			
8	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
9	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
10	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	-8.0995	5.5198	731	-1.47	0.1427	0.05	-18.9361	2.7371
2	-10.0007	5.4191	731	-1.85	0.0654	0.05	-20.6396	0.6382
3	-24.1075	5.4209	731	-4.45	<.0001	0.05	-34.7500	-13.4651
4	30.6959	8.0260	731	3.82	0.0001	0.05	14.9392	46.4526
5	7.8381	5.7724	731	1.36	0.1749	0.05	-3.4944	19.1706
6	13.1640	6.1065	731	2.16	0.0314	0.05	1.1757	25.1523
7	0
8	-9.0263	4.8560	731	-1.86	0.0635	0.05	-18.5598	0.5071
9	0
10	-0.8110	0.03114	731	-26.04	<.0001	0.05	-0.8721	-0.7498

nn1218/nn1218-4131/ctr_20180214_er
10FEB2018:19:32:14 - a_797pp_stat_diff.sas/a_9pp_noct_stat_on_fas_app.txt

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The Mixed procedure
Solution for Fixed Effects

Parameter Code=P9GINB4U Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
11	1	NN1218-4131	TRTPN	2				
12	1	NN1218-4131	TRTPN	3				
13	1	NN1218-4131	TRTPN	4				
14	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
15	1	NN1218-4131	REGION1	—	EUROPE			
16	1	NN1218-4131	REGION1	—	JAPAN			
17	1	NN1218-4131	REGION1	—	NORTH AMERICA			
18	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
19	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
20	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
11	-10.2057	7.1570	718	-1.43	0.1543	0.05	-24.2569	3.8455
12	-14.7187	6.9785	718	-2.11	0.0353	0.05	-28.4194	-1.0181
13	-8.3406	7.0999	718	-1.17	0.2405	0.05	-22.2796	5.5984
14	-4.5214	10.6254	718	-0.43	0.6706	0.05	-25.3821	16.3392
15	5.3612	7.6135	718	0.70	0.4816	0.05	-9.5861	20.3084
16	-5.5934	8.0471	718	-0.70	0.4872	0.05	-21.3920	10.2053
17	0
18	10.0858	6.4190	718	1.57	0.1166	0.05	-2.5164	22.6880
19	0
20	-0.9079	0.03421	718	-26.54	<.0001	0.05	-0.9750	-0.8407

nn1218/nn1218-4131/ctr_20180214_er
10FEB2018:19:32:14 - a_797pp_stat_diff.sas/a_9pp_noct_stat_on_fas_app.txt

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The Mixed procedure
Solution for Fixed Effects

Parameter Code=P9GINBBU Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
21	1	NN1218-4131	TRTPN	2				
22	1	NN1218-4131	TRTPN	3				
23	1	NN1218-4131	TRTPN	4				
24	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
25	1	NN1218-4131	REGION1	—	EUROPE			
26	1	NN1218-4131	REGION1	—	JAPAN			
27	1	NN1218-4131	REGION1	—	NORTH AMERICA			
28	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
29	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
30	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
21	-27.7978	6.1176	895	-4.54	<.0001	0.05	-39.8044	-15.7912
22	-28.8825	6.2804	895	-4.60	<.0001	0.05	-41.2085	-16.5565
23	-29.5887	6.1586	895	-4.80	<.0001	0.05	-41.6758	-17.5017
24	10.7036	9.1335	895	1.17	0.2415	0.05	-7.2220	28.6292
25	18.6442	6.4371	895	2.90	0.0039	0.05	6.0107	31.2777
26	8.8171	7.0393	895	1.25	0.2107	0.05	-4.9983	22.6326
27	0
28	-0.8086	5.4925	895	-0.15	0.8830	0.05	-11.5883	9.9710
29	0
30	-0.9347	0.02868	895	-32.59	<.0001	0.05	-0.9909	-0.8784

nn1218/nn1218-4131/ctr_20180214_er
10FEB2018:19:32:14 - a_797pp_stat_diff.sas/a_9pp_noct_stat_on_fas_app.txt

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The Mixed procedure
Solution for Fixed Effects

Parameter Code=P9PGIN4B Parameter=Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
31	1	NN1218-4131	TRTPN	2				
32	1	NN1218-4131	TRTPN	3				
33	1	NN1218-4131	TRTPN	4				
34	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
35	1	NN1218-4131	REGION1	—	EUROPE			
36	1	NN1218-4131	REGION1	—	JAPAN			
37	1	NN1218-4131	REGION1	—	NORTH AMERICA			
38	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
39	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
40	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
31	-0.4495	0.3063	731	-1.47	0.1427	0.05	-1.0508	0.1519
32	-0.5550	0.3007	731	-1.85	0.0654	0.05	-1.1454	0.03542
33	-1.3378	0.3008	731	-4.45	<.0001	0.05	-1.9284	-0.7472
34	1.7034	0.4454	731	3.82	0.0001	0.05	0.8290	2.5778
35	0.4350	0.3203	731	1.36	0.1749	0.05	-0.1939	1.0639
36	0.7305	0.3389	731	2.16	0.0314	0.05	0.06524	1.3958
37	0
38	-0.5009	0.2695	731	-1.86	0.0635	0.05	-1.0300	0.02814
39	0
40	-0.8110	0.03114	731	-26.04	<.0001	0.05	-0.8721	-0.7498

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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Solution for Fixed Effects

Parameter Code=P9PGINB4 Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
41	1	NN1218-4131	TRTPN	2				
42	1	NN1218-4131	TRTPN	3				
43	1	NN1218-4131	TRTPN	4				
44	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
45	1	NN1218-4131	REGION1	—	EUROPE			
46	1	NN1218-4131	REGION1	—	JAPAN			
47	1	NN1218-4131	REGION1	—	NORTH AMERICA			
48	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
49	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
50	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
41	-0.5664	0.3972	718	-1.43	0.1543	0.05	-1.3461	0.2134
42	-0.8168	0.3873	718	-2.11	0.0353	0.05	-1.5771	-0.05650
43	-0.4629	0.3940	718	-1.17	0.2405	0.05	-1.2364	0.3107
44	-0.2509	0.5896	718	-0.43	0.6706	0.05	-1.4086	0.9067
45	0.2975	0.4225	718	0.70	0.4816	0.05	-0.5320	1.1270
46	-0.3104	0.4466	718	-0.70	0.4872	0.05	-1.1871	0.5663
47	0
48	0.5597	0.3562	718	1.57	0.1166	0.05	-0.1396	1.2590
49	0
50	-0.9079	0.03421	718	-26.54	<.0001	0.05	-0.9750	-0.8407

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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Solution for Fixed Effects

Parameter Code=P9PGINBB Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
51	1	NN1218-4131	TRTPN	2				
52	1	NN1218-4131	TRTPN	3				
53	1	NN1218-4131	TRTPN	4				
54	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
55	1	NN1218-4131	REGION1	—	EUROPE			
56	1	NN1218-4131	REGION1	—	JAPAN			
57	1	NN1218-4131	REGION1	—	NORTH AMERICA			
58	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
59	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
60	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
51	-1.5426	0.3395	895	-4.54	<.0001	0.05	-2.2089	-0.8763
52	-1.6028	0.3485	895	-4.60	<.0001	0.05	-2.2868	-0.9188
53	-1.6420	0.3418	895	-4.80	<.0001	0.05	-2.3128	-0.9712
54	0.5940	0.5069	895	1.17	0.2415	0.05	-0.4008	1.5887
55	1.0346	0.3572	895	2.90	0.0039	0.05	0.3336	1.7357
56	0.4893	0.3906	895	1.25	0.2107	0.05	-0.2774	1.2560
57	0
58	-0.04488	0.3048	895	-0.15	0.8830	0.05	-0.6431	0.5533
59	0
60	-0.9347	0.02868	895	-32.59	<.0001	0.05	-0.9909	-0.8784

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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Least Squares Means

Obs	_Imputation_	PARAMCD	PARAM	STUDYID
1	1	P9GIN4BU	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	NN1218-4131
2	1	P9GIN4BU	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	NN1218-4131
3	1	P9GIN4BU	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	NN1218-4131
4	1	P9GINB4U	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	NN1218-4131
5	1	P9GINB4U	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	NN1218-4131
6	1	P9GINB4U	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	NN1218-4131
7	1	P9GINBBU	Nocturnal increment (bedtime to breakfast) (SMPG) (mg/dL)	NN1218-4131
8	1	P9GINBBU	Nocturnal increment (bedtime to breakfast) (SMPG) (mg/dL)	NN1218-4131
9	1	P9GINBBU	Nocturnal increment (bedtime to breakfast) (SMPG) (mg/dL)	NN1218-4131
10	1	P9PGIN4B	Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)	NN1218-4131
11	1	P9PGIN4B	Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)	NN1218-4131
12	1	P9PGIN4B	Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)	NN1218-4131
13	1	P9PGINB4	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	NN1218-4131
14	1	P9PGINB4	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	NN1218-4131

Obs	Effect	TRTPN	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	TRTPN	2	WORK.IMPUTE	18.0613	3.8008	731	4.75	<.0001	0.05	10.5995	25.5232
2	TRTPN	3	WORK.IMPUTE	16.1602	3.5902	731	4.50	<.0001	0.05	9.1119	23.2084
3	TRTPN	4	WORK.IMPUTE	2.0533	3.7321	731	0.55	0.5824	0.05	-5.2736	9.3802
4	TRTPN	2	WORK.IMPUTE	6.5836	4.9789	718	1.32	0.1865	0.05	-3.1913	16.3584
5	TRTPN	3	WORK.IMPUTE	2.0705	4.7408	718	0.44	0.6624	0.05	-7.2370	11.3781
6	TRTPN	4	WORK.IMPUTE	8.4487	4.9800	718	1.70	0.0902	0.05	-1.3284	18.2258
7	TRTPN	2	WORK.IMPUTE	14.9077	4.2466	895	3.51	0.0005	0.05	6.5733	23.2421
8	TRTPN	3	WORK.IMPUTE	13.8230	4.2624	895	3.24	0.0012	0.05	5.4575	22.1884
9	TRTPN	4	WORK.IMPUTE	13.1167	4.2328	895	3.10	0.0020	0.05	4.8093	21.4241
10	TRTPN	2	WORK.IMPUTE	1.0023	0.2109	731	4.75	<.0001	0.05	0.5882	1.4164
11	TRTPN	3	WORK.IMPUTE	0.8968	0.1992	731	4.50	<.0001	0.05	0.5057	1.2879
12	TRTPN	4	WORK.IMPUTE	0.1139	0.2071	731	0.55	0.5824	0.05	-0.2927	0.5205
13	TRTPN	2	WORK.IMPUTE	0.3653	0.2763	718	1.32	0.1865	0.05	-0.1771	0.9078
14	TRTPN	3	WORK.IMPUTE	0.1149	0.2631	718	0.44	0.6624	0.05	-0.4016	0.6314

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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Least Squares Means

Obs	_Imputation_	PARAMCD	PARAM							STUDYID	
15	1	P9PGINB4	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)							NN1218-4131	
16	1	P9PGINBB	Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)							NN1218-4131	
17	1	P9PGINBB	Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)							NN1218-4131	
18	1	P9PGINBB	Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)							NN1218-4131	
Obs	Effect	TRTPN	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
15	TRTPN	4	WORK.IMPUTE	0.4689	0.2764	718	1.70	0.0902	0.05	-0.07372	1.0114
16	TRTPN	2	WORK.IMPUTE	0.8273	0.2357	895	3.51	0.0005	0.05	0.3648	1.2898
17	TRTPN	3	WORK.IMPUTE	0.7671	0.2365	895	3.24	0.0012	0.05	0.3029	1.2313
18	TRTPN	4	WORK.IMPUTE	0.7279	0.2349	895	3.10	0.0020	0.05	0.2669	1.1889

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Least Squares Means Estimate

Parameter Code=P9GIN4BU Parameter=Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
1	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
2	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	WORK.IMPUTE	16.0080	5.3341	731	3.00	0.0028	0.05	5.5359	26.4801
2	WORK.IMPUTE	14.1068	5.1837	731	2.72	0.0067	0.05	3.9302	24.2835

Parameter Code=P9GINB4U Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
3	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
4	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
3	WORK.IMPUTE	-1.8651	7.0481	718	-0.26	0.7914	0.05	-15.7025	11.9722
4	WORK.IMPUTE	-6.3782	6.8812	718	-0.93	0.3543	0.05	-19.8879	7.1315

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Least Squares Means Estimate

Parameter Code=P9GINBBU Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
5	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
6	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
5	WORK.IMPUTE	1.7909	5.9986	895	0.30	0.7653	0.05	-9.9821	13.5640
6	WORK.IMPUTE	0.7062	6.0121	895	0.12	0.9065	0.05	-11.0932	12.5057

Parameter Code=P9PGIN4B Parameter=Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
7	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
8	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
7	WORK.IMPUTE	0.8883	0.2960	731	3.00	0.0028	0.05	0.3072	1.4695
8	WORK.IMPUTE	0.7828	0.2877	731	2.72	0.0067	0.05	0.2181	1.3476

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Least Squares Means Estimate

Parameter Code=P9PGINB4 Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
9	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
10	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
9	WORK.IMPUTE	-0.1035	0.3911	718	-0.26	0.7914	0.05	-0.8714	0.6644
10	WORK.IMPUTE	-0.3539	0.3819	718	-0.93	0.3543	0.05	-1.1037	0.3958

Parameter Code=P9PGINBB Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
11	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
12	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
11	WORK.IMPUTE	0.09939	0.3329	895	0.30	0.7653	0.05	-0.5539	0.7527
12	WORK.IMPUTE	0.03919	0.3336	895	0.12	0.9065	0.05	-0.6156	0.6940

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Planned Treatment for Period 30 (N)=2 Parameter Code=P9GIN4BU Parameter=Nocturnal increment (04:00 to breakfast) (SMPG) (mg/d

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	5.742754	13.926991	19.670032	234604	0.412368	0.291975	0.999985

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits	DF	Minimum	Maximum
Estimate	13.751106	4.435091	5.058442 22.44377	234604	4.234502	23.011104

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	3.10	0.0019

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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9GINB4U Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	7.502586	23.643829	31.146790	344643	0.317333	0.240895	0.999988

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	4.810862	5.580931	-6.12760	15.74932	344643	-6.078483	16.093520

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	0.86	0.3887

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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9GINBBU Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mg

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	2.274314	18.040717	20.315144	1.6E6	0.126072	0.111958	0.999994

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits	DF	Minimum	Maximum
Estimate	14.112362	4.507232	5.278342 22.94638	1.6E6	8.309414	20.396293

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	3.13	0.0017

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9PGIN4B Parameter=Nocturnal increment (04:00 to breakfast) (SMPG) (mmol

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.017685	0.042889	0.060575	234604	0.412368	0.291975	0.999985

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits	DF	Minimum	Maximum
Estimate	0.763102	0.246120	0.280713 1.245492	234604	0.234989	1.276976

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	3.10	0.0019

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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9PGINB4 Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.023105	0.072813	0.095919	344643	0.317333	0.240895	0.999988

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.266973	0.309708	-0.34004	0.873991	344643	-0.337319	0.893092

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	0.86	0.3887

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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9PGINBB Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mm

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.007004	0.055558	0.062562	1.6E6	0.126072	0.111958	0.999994

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits	DF	Minimum	Maximum
Estimate	0.783150	0.250124	0.292916 1.273384	1.6E6	0.461122	1.131870

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	3.13	0.0017

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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9GIN4BU Parameter=Nocturnal increment (04:00 to breakfast) (SMPG) (mg/d

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	3.488388	12.426103	15.914666	416208	0.280745	0.219208	0.999989

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits	DF	Minimum	Maximum
Estimate	15.676601	3.989319	7.857656 23.49554	416208	8.633906	23.022201

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	3.93	<.0001

nn1218/nn1218-4131/ctr_20180214_er
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Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 3096 of 4425	Novo Nordisk
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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9GINB4U Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	6.218992	21.437189	27.656491	395475	0.290117	0.224881	0.999989

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.060358	5.258944	-10.3677	10.24701	395475	-10.952360	11.271025

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-0.01	0.9908

nn1218/nn1218-4131/ctr_20180214_er
10FEB2018:19:32:14 - a_797pp_stat_diff.sas/a_9pp_noct_stat_on_fas_app.txt

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 3097 of 4425	Novo Nordisk
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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9GINBBU Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mg

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	1.898795	18.175302	20.074192	2.24E6	0.104476	0.094594	0.999995

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits	DF	Minimum	Maximum
Estimate	12.771103	4.480423	3.989630 21.55258	2.24E6	7.623989	18.010385

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	2.85	0.0044

nn1218/nn1218-4131/ctr_20180214_er
10FEB2018:19:32:14 - a_797pp_stat_diff.sas/a_9pp_noct_stat_on_fas_app.txt

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9PGIN4B Parameter=Nocturnal increment (04:00 to breakfast) (SMPG) (mmol

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.010743	0.038267	0.049010	416208	0.280745	0.219208	0.999989

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits	DF	Minimum	Maximum
Estimate	0.869956	0.221383	0.436052 1.303859	416208	0.479129	1.277592

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	3.93	<.0001

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 3099 of 4425	Novo Nordisk
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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9PGINB4 Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.019152	0.066017	0.085170	395475	0.290117	0.224881	0.999989

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.003350	0.291839	-0.57535	0.568647	395475	-0.607789	0.625473

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-0.01	0.9908

nn1218/nn1218-4131/ctr_20180214_er
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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9PGINBB Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mm

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.005847	0.055972	0.061820	2.24E6	0.104476	0.094594	0.999995

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits	DF	Minimum	Maximum
Estimate	0.708718	0.248636	0.221400 1.196036	2.24E6	0.423085	0.999466

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	2.85	0.0044

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9GIN4BU Parameter=Nocturnal increment (04:00 to breakfast) (SMPG) (mg/d

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	3.982133	13.427870	17.410202	382244	0.296572	0.228740	0.999989

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	3.000486	4.172553	-5.17759	11.17857	382244	-4.384167	10.965629

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	0.72	0.4721

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9GINB4U Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	7.510807	23.654662	31.165844	344310	0.317535	0.241011	0.999988

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits	DF	Minimum	Maximum
Estimate	11.627021	5.582638	0.685214 22.56883	344310	0.986634	23.355248

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	2.08	0.0373

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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9GINBBU Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mg

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	2.093051	17.924112	20.017268	1.83E6	0.116779	0.104568	0.999995

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits	DF	Minimum	Maximum
Estimate	14.100952	4.474066	5.331937 22.86997	1.83E6	8.270296	19.794739

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	3.15	0.0016

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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9PGIN4B Parameter=Nocturnal increment (04:00 to breakfast) (SMPG) (mmol

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.012263	0.041352	0.053616	382244	0.296572	0.228740	0.999989

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.166509	0.231551	-0.28732	0.620342	382244	-0.243295	0.608525

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	0.72	0.4721

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 3105 of 4425	Novo Nordisk
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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9PGINB4 Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.023130	0.072846	0.095977	344310	0.317535	0.241011	0.999988

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits	DF	Minimum	Maximum
Estimate	0.645229	0.309802	0.038025 1.252432	344310	0.054752	1.296074

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	2.08	0.0373

nn1218/nn1218-4131/ctr_20180214_er
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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9PGINBB Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mm

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.006446	0.055199	0.061645	1.83E6	0.116779	0.104568	0.999995

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits	DF	Minimum	Maximum
Estimate	0.782517	0.248283	0.295890 1.269144	1.83E6	0.458951	1.098487

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	3.15	0.0016

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 3107 of 4425	Novo Nordisk
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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=P9GIN4BU Label=Faster aspart (meal) - NovoRapid (meal) Parameter=Nocturnal increment (04:00 to breakfast) (SMP

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	9.719305	27.430331	37.150121	292156	0.354345	0.261641	0.999987

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	10.750619	6.095090	-1.19559	22.69683	292156	-0.794118	24.485471

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	1.76	0.0778

nn1218/nn1218-4131/ctr_20180214_er
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Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 3108 of 4425	Novo Nordisk
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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=P9GIN4BU Label=Faster aspart (post) - NovoRapid (meal) Parameter=Nocturnal increment (04:00 to breakfast) (SMP

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	7.490904	25.904419	33.395697	397445	0.289189	0.224323	0.999989

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	12.676114	5.778901	1.349642	24.00259	397445	2.115410	23.679647

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	2.19	0.0283

nn1218/nn1218-4131/ctr_20180214_er
10FEB2018:19:32:14 - a_797pp_stat_diff.sas/a_9pp_noct_stat_on_fas_app.txt

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 3109 of 4425	Novo Nordisk
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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=P9GINB4U Label=Faster aspart (meal) - NovoRapid (meal) Parameter=Nocturnal increment (bedtime to 04:00) (SMPG)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	14.706390	47.380836	62.087961	356424	0.310402	0.236880	0.999988

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-6.816159	7.879591	-22.2599	8.627609	356424	-20.887916	8.770051

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-0.87	0.3870

nn1218/nn1218-4131/ctr_20180214_er
10FEB2018:19:32:14 - a_797pp_stat_diff.sas/a_9pp_noct_stat_on_fas_app.txt

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 3110 of 4425	Novo Nordisk
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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=P9GINB4U Label=Faster aspart (post) - NovoRapid (meal) Parameter=Nocturnal increment (bedtime to 04:00) (SMPG)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	13.684036	45.163636	58.848357	369833	0.303003	0.232546	0.999988

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-11.687379	7.671268	-26.7228	3.348079	369833	-26.850138	2.945398

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-1.52	0.1276

nn1218/nn1218-4131/ctr_20180214_er
10FEB2018:19:32:14 - a_797pp_stat_diff.sas/a_9pp_noct_stat_on_fas_app.txt

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 3111 of 4425	Novo Nordisk
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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=P9GINBBU Label=Faster aspart (meal) - NovoRapid (meal) Parameter=Nocturnal increment (bedtime to breakfast) (S

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	4.417291	35.998249	40.415761	1.67E6	0.122715	0.109303	0.999995

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.011410	6.357339	-12.4488	12.47157	1.67E6	-8.646612	8.572876

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	0.00	0.9986

nn1218/nn1218-4131/ctr_20180214_er
10FEB2018:19:32:14 - a_797pp_stat_diff.sas/a_9pp_noct_stat_on_fas_app.txt

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 3112 of 4425	Novo Nordisk
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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=P9GINBBU Label=Faster aspart (post) - NovoRapid (meal) Parameter=Nocturnal increment (bedtime to breakfast) (S

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	4.013067	36.159925	40.173192	2E6	0.110987	0.099900	0.999995

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-1.329849	6.338233	-13.7526	11.09287	2E6	-8.750531	6.969718

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-0.21	0.8338

nn1218/nn1218-4131/ctr_20180214_er
10FEB2018:19:32:14 - a_797pp_stat_diff.sas/a_9pp_noct_stat_on_fas_app.txt

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 3113 of 4425	Novo Nordisk
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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=P9PGIN4B Label=Faster aspart (meal) - NovoRapid (meal) Parameter=Nocturnal increment (04:00 to breakfast) (SMP

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.029931	0.084474	0.114406	292156	0.354345	0.261641	0.999987

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits	DF	Minimum	Maximum
Estimate	0.596594	0.338240	-0.06635 1.259535	292156	-0.044069	1.358794

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	1.76	0.0778

nn1218/nn1218-4131/ctr_20180214_er
10FEB2018:19:32:14 - a_797pp_stat_diff.sas/a_9pp_noct_stat_on_fas_app.txt

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 3114 of 4425	Novo Nordisk
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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=P9PGIN4B Label=Faster aspart (post) - NovoRapid (meal) Parameter=Nocturnal increment (04:00 to breakfast) (SMP

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.023069	0.079775	0.102844	397445	0.289189	0.224323	0.999989

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits	DF	Minimum	Maximum
Estimate	0.703447	0.320694	0.074897 1.331997	397445	0.117392	1.314076

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	2.19	0.0283

nn1218/nn1218-4131/ctr_20180214_er
10FEB2018:19:32:14 - a_797pp_stat_diff.sas/a_9pp_noct_stat_on_fas_app.txt

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 3115 of 4425	Novo Nordisk
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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=P9PGINB4 Label=Faster aspart (meal) - NovoRapid (meal) Parameter=Nocturnal increment (bedtime to 04:00) (SMPG)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.045289	0.145913	0.191204	356424	0.310402	0.236880	0.999988

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.378255	0.437269	-1.23529	0.478780	356424	-1.159152	0.486684

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-0.87	0.3870

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 3116 of 4425	Novo Nordisk
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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=P9PGINB4 Label=Faster aspart (post) - NovoRapid (meal) Parameter=Nocturnal increment (bedtime to 04:00) (SMPG)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.042141	0.139085	0.181228	369833	0.303003	0.232546	0.999988

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.648578	0.425709	-1.48295	0.185798	369833	-1.490019	0.163452

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-1.52	0.1276

nn1218/nn1218-4131/ctr_20180214_er
10FEB2018:19:32:14 - a_797pp_stat_diff.sas/a_9pp_noct_stat_on_fas_app.txt

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=P9PGINBB Label=Faster aspart (meal) - NovoRapid (meal) Parameter=Nocturnal increment (bedtime to breakfast) (S

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.013603	0.110859	0.124463	1.67E6	0.122715	0.109303	0.999995

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.000633	0.352794	-0.69083	0.692096	1.67E6	-0.479834	0.475742

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	0.00	0.9986

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 3118 of 4425	Novo Nordisk
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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=P9PGINBB Label=Faster aspart (post) - NovoRapid (meal) Parameter=Nocturnal increment (bedtime to breakfast) (S

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.012359	0.111357	0.123716	2E6	0.110987	0.099900	0.999995

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.073799	0.351733	-0.76318	0.615586	2E6	-0.485601	0.386777

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-0.21	0.8338

nn1218/nn1218-4131/ctr_20180214_er
10FEB2018:19:32:14 - a_797pp_stat_diff.sas/a_9pp_noct_stat_on_fas_app.txt

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Model Information

Parameter Code=P9GIN4BU Parameter=Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Data Set	WORK.IMPUTE_ABS
2	1	NN1218-4131	Dependent Variable	eotVisitAbs
3	1	NN1218-4131	Covariance Structure	Diagonal
4	1	NN1218-4131	Estimation Method	REML
5	1	NN1218-4131	Residual Variance Method	Profile
6	1	NN1218-4131	Fixed Effects SE Method	Model-Based
7	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=P9GINB4U Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
8	1	NN1218-4131	Data Set	WORK.IMPUTE_ABS
9	1	NN1218-4131	Dependent Variable	eotVisitAbs
10	1	NN1218-4131	Covariance Structure	Diagonal
11	1	NN1218-4131	Estimation Method	REML
12	1	NN1218-4131	Residual Variance Method	Profile
13	1	NN1218-4131	Fixed Effects SE Method	Model-Based
14	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=P9GINBBU Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
15	1	NN1218-4131	Data Set	WORK.IMPUTE_ABS
16	1	NN1218-4131	Dependent Variable	eotVisitAbs
17	1	NN1218-4131	Covariance Structure	Diagonal

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Model Information

Parameter Code=P9GINBBU Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mg/dL)

(continued)

Obs	_Imputation_	STUDYID	Descr	Value
18	1	NN1218-4131	Estimation Method	REML
19	1	NN1218-4131	Residual Variance Method	Profile
20	1	NN1218-4131	Fixed Effects SE Method	Model-Based
21	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=P9PGIN4B Parameter=Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
22	1	NN1218-4131	Data Set	WORK.IMPUTE_ABS
23	1	NN1218-4131	Dependent Variable	eotVisitAbs
24	1	NN1218-4131	Covariance Structure	Diagonal
25	1	NN1218-4131	Estimation Method	REML
26	1	NN1218-4131	Residual Variance Method	Profile
27	1	NN1218-4131	Fixed Effects SE Method	Model-Based
28	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=P9PGINB4 Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
29	1	NN1218-4131	Data Set	WORK.IMPUTE_ABS
30	1	NN1218-4131	Dependent Variable	eotVisitAbs
31	1	NN1218-4131	Covariance Structure	Diagonal
32	1	NN1218-4131	Estimation Method	REML

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Model Information

Parameter Code=P9PGINB4 Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)

(continued)

Obs	_Imputation_	STUDYID	Descr	Value
33	1	NN1218-4131	Residual Variance Method	Profile
34	1	NN1218-4131	Fixed Effects SE Method	Model-Based
35	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=P9PGINBB Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
36	1	NN1218-4131	Data Set	WORK.IMPUTE_ABS
37	1	NN1218-4131	Dependent Variable	eotVisitAbs
38	1	NN1218-4131	Covariance Structure	Diagonal
39	1	NN1218-4131	Estimation Method	REML
40	1	NN1218-4131	Residual Variance Method	Profile
41	1	NN1218-4131	Fixed Effects SE Method	Model-Based
42	1	NN1218-4131	Degrees of Freedom Method	Residual

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nn1218/nn1218-4131/ctr_20180214_er
10FEB2018:19:32:14 - a 797pp stat diff.sas/a 9pp noct stat on_fas app.txt
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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Class Level Information

Parameter Code=P9GINB4U Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)

Ob- s	—	Input ID	STUDY	Class	Level	Values	min
4	1	NN1218-4131	TRTPN		3 2 3 4		5
5	1	NN1218-4131	REGION1		4 ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA		49
6	1	NN1218-4131	BOLAD1		2 BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULI		85

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Class Level Information

Parameter Code=P9GINBBU Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mg/dL)

Ob- s-	Input ion	STUD ID	Class s	Lev- els	Val- ues	min in - T e g t h
7 1	NN1218-4131	TRTPN		3 2 3 4		5
8 1	NN1218-4131	REGION1		4 ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA		49
9 1	NN1218-4131	BOLAD1		2 BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULI		85

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Class Level Information

Parameter Code=P9PGINB4 Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)

Obs	Inpution	STUDY ID	Classes	Levels	Values	min
13	1	NN1218-4131	TRTPN	3 2 3 4		5
14	1	NN1218-4131	REGION1	4 ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA		49
15	1	NN1218-4131	BOLAD1	2 BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULI		85

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Class Level Information

Parameter Code=P9PGINBB Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)

Obs	Input	STUDY ID	Class	Level	Values	min
16	1	NN1218-4131	TRTPN	3 2 3 4		5
17	1	NN1218-4131	REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA	49
18	1	NN1218-4131	BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULI	85

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Dimensions

Parameter Code=P9GIN4BU Parameter=Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Covariance Parameters	1
2	1	NN1218-4131	Columns in X	10
3	1	NN1218-4131	Columns in Z	0
4	1	NN1218-4131	Subjects	1
5	1	NN1218-4131	Max Obs per Subject	739

Parameter Code=P9GINB4U Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
6	1	NN1218-4131	Covariance Parameters	1
7	1	NN1218-4131	Columns in X	10
8	1	NN1218-4131	Columns in Z	0
9	1	NN1218-4131	Subjects	1
10	1	NN1218-4131	Max Obs per Subject	726

Parameter Code=P9GINBBU Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
11	1	NN1218-4131	Covariance Parameters	1
12	1	NN1218-4131	Columns in X	10
13	1	NN1218-4131	Columns in Z	0
14	1	NN1218-4131	Subjects	1
15	1	NN1218-4131	Max Obs per Subject	903

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Dimensions

Parameter Code=P9PGIN4B Parameter=Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
16	1	NN1218-4131	Covariance Parameters	1
17	1	NN1218-4131	Columns in X	10
18	1	NN1218-4131	Columns in Z	0
19	1	NN1218-4131	Subjects	1
20	1	NN1218-4131	Max Obs per Subject	739

Parameter Code=P9PGINB4 Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
21	1	NN1218-4131	Covariance Parameters	1
22	1	NN1218-4131	Columns in X	10
23	1	NN1218-4131	Columns in Z	0
24	1	NN1218-4131	Subjects	1
25	1	NN1218-4131	Max Obs per Subject	726

Parameter Code=P9PGINBB Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
26	1	NN1218-4131	Covariance Parameters	1
27	1	NN1218-4131	Columns in X	10
28	1	NN1218-4131	Columns in Z	0
29	1	NN1218-4131	Subjects	1
30	1	NN1218-4131	Max Obs per Subject	903

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Number of Observations

Parameter Code=P9GIN4BU Parameter=Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
1	1	NN1218-4131	Number of Observations Read	739	739	739	739	739
2	1	NN1218-4131	Number of Observations Used	739	739	739	739	739
3	1	NN1218-4131	Number of Observations Not Used	0	739	739	739	739

Parameter Code=P9GINB4U Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
4	1	NN1218-4131	Number of Observations Read	726	726	726	726	726
5	1	NN1218-4131	Number of Observations Used	726	726	726	726	726
6	1	NN1218-4131	Number of Observations Not Used	0	726	726	726	726

Parameter Code=P9GINBBU Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
7	1	NN1218-4131	Number of Observations Read	903	903	903	903	903
8	1	NN1218-4131	Number of Observations Used	903	903	903	903	903
9	1	NN1218-4131	Number of Observations Not Used	0	903	903	903	903

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Number of Observations

Parameter Code=P9PGIN4B Parameter=Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
10	1	NN1218-4131	Number of Observations Read	739	739	739	739	739
11	1	NN1218-4131	Number of Observations Used	739	739	739	739	739
12	1	NN1218-4131	Number of Observations Not Used	0	739	739	739	739

Parameter Code=P9PGINB4 Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
13	1	NN1218-4131	Number of Observations Read	726	726	726	726	726
14	1	NN1218-4131	Number of Observations Used	726	726	726	726	726
15	1	NN1218-4131	Number of Observations Not Used	0	726	726	726	726

Parameter Code=P9PGINBB Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
16	1	NN1218-4131	Number of Observations Read	903	903	903	903	903
17	1	NN1218-4131	Number of Observations Used	903	903	903	903	903
18	1	NN1218-4131	Number of Observations Not Used	0	903	903	903	903

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Covariance Parameter Estimates

Parameter Code=P9GIN4BU Parameter=Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	CovParm	Estimate
1	1	NN1218-4131	Residual	3368.61

Parameter Code=P9GINB4U Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	CovParm	Estimate
20001	1	NN1218-4131	Residual	5783.47

Parameter Code=P9GINBBU Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	CovParm	Estimate
40001	1	NN1218-4131	Residual	5414.71

Parameter Code=P9PGIN4B Parameter=Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	CovParm	Estimate
60001	1	NN1218-4131	Residual	10.3739

Parameter Code=P9PGINB4 Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	CovParm	Estimate
80001	1	NN1218-4131	Residual	17.8106

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Covariance Parameter Estimates

Parameter Code=P9PGINBB Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	CovParm	Estimate
100001	1	NN1218-4131	Residual	16.6750

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Fit Statistics

Parameter Code=P9GIN4BU Parameter=Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	-2 Res Log Likelihood	8062.5
2	1	NN1218-4131	AIC (Smaller is Better)	8064.5
3	1	NN1218-4131	AICC (Smaller is Better)	8064.5
4	1	NN1218-4131	BIC (Smaller is Better)	8069.1

Parameter Code=P9GINB4U Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
5	1	NN1218-4131	-2 Res Log Likelihood	8308.3
6	1	NN1218-4131	AIC (Smaller is Better)	8310.3
7	1	NN1218-4131	AICC (Smaller is Better)	8310.3
8	1	NN1218-4131	BIC (Smaller is Better)	8314.9

Parameter Code=P9GINBBU Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
9	1	NN1218-4131	-2 Res Log Likelihood	10286.8
10	1	NN1218-4131	AIC (Smaller is Better)	10288.8
11	1	NN1218-4131	AICC (Smaller is Better)	10288.8
12	1	NN1218-4131	BIC (Smaller is Better)	10293.6

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Fit Statistics

Parameter Code=P9PGIN4B Parameter=Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
13	1	NN1218-4131	-2 Res Log Likelihood	3829.3
14	1	NN1218-4131	AIC (Smaller is Better)	3831.3
15	1	NN1218-4131	AICC (Smaller is Better)	3831.3
16	1	NN1218-4131	BIC (Smaller is Better)	3835.9

Parameter Code=P9PGINB4 Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
17	1	NN1218-4131	-2 Res Log Likelihood	4150.3
18	1	NN1218-4131	AIC (Smaller is Better)	4152.3
19	1	NN1218-4131	AICC (Smaller is Better)	4152.3
20	1	NN1218-4131	BIC (Smaller is Better)	4156.9

Parameter Code=P9PGINBB Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
21	1	NN1218-4131	-2 Res Log Likelihood	5105.2
22	1	NN1218-4131	AIC (Smaller is Better)	5107.2
23	1	NN1218-4131	AICC (Smaller is Better)	5107.2
24	1	NN1218-4131	BIC (Smaller is Better)	5112.0

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NN1218-4131

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Novo Nordisk

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Solution for Fixed Effects

Parameter Code=P9GIN4BU Parameter=Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1		BOLAD1	
1	1	NN1218-4131	TRTPN	2				
2	1	NN1218-4131	TRTPN	3				
3	1	NN1218-4131	TRTPN	4				
4	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
5	1	NN1218-4131	REGION1	—	EUROPE			
6	1	NN1218-4131	REGION1	—	JAPAN			
7	1	NN1218-4131	REGION1	—	NORTH AMERICA			
8	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
9	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
10	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	-8.0995	5.5198	731	-1.47	0.1427	0.05	-18.9361	2.7371
2	-10.0007	5.4191	731	-1.85	0.0654	0.05	-20.6396	0.6382
3	-24.1075	5.4209	731	-4.45	<.0001	0.05	-34.7500	-13.4651
4	30.6959	8.0260	731	3.82	0.0001	0.05	14.9392	46.4526
5	7.8381	5.7724	731	1.36	0.1749	0.05	-3.4944	19.1706
6	13.1640	6.1065	731	2.16	0.0314	0.05	1.1757	25.1523
7	0
8	-9.0263	4.8560	731	-1.86	0.0635	0.05	-18.5598	0.5071
9	0
10	0.1890	0.03114	731	6.07	<.0001	0.05	0.1279	0.2502

nn1218/nn1218-4131/ctr_20180214_er
10FEB2018:19:32:14 - a_797pp_stat_diff.sas/a_9pp_noct_stat_on_fas_app.txt

Fast-acting insulin aspart
NN1218-4131

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Novo Nordisk

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Solution for Fixed Effects

Parameter Code=P9GINB4U Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1		BOLAD1	
11	1	NN1218-4131	TRTPN	2				
12	1	NN1218-4131	TRTPN	3				
13	1	NN1218-4131	TRTPN	4				
14	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
15	1	NN1218-4131	REGION1	—	EUROPE			
16	1	NN1218-4131	REGION1	—	JAPAN			
17	1	NN1218-4131	REGION1	—	NORTH AMERICA			
18	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
19	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
20	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
11	-10.2057	7.1570	718	-1.43	0.1543	0.05	-24.2569	3.8455
12	-14.7187	6.9785	718	-2.11	0.0353	0.05	-28.4194	-1.0181
13	-8.3406	7.0999	718	-1.17	0.2405	0.05	-22.2796	5.5984
14	-4.5214	10.6254	718	-0.43	0.6706	0.05	-25.3821	16.3392
15	5.3612	7.6135	718	0.70	0.4816	0.05	-9.5861	20.3084
16	-5.5934	8.0471	718	-0.70	0.4872	0.05	-21.3920	10.2053
17	0
18	10.0858	6.4190	718	1.57	0.1166	0.05	-2.5164	22.6880
19	0
20	0.09212	0.03421	718	2.69	0.0072	0.05	0.02496	0.1593

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The Mixed procedure
Solution for Fixed Effects

Parameter Code=P9GINBBU Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
21	1	NN1218-4131	TRTPN	2				
22	1	NN1218-4131	TRTPN	3				
23	1	NN1218-4131	TRTPN	4				
24	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
25	1	NN1218-4131	REGION1	—	EUROPE			
26	1	NN1218-4131	REGION1	—	JAPAN			
27	1	NN1218-4131	REGION1	—	NORTH AMERICA			
28	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
29	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
30	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
21	-27.7978	6.1176	895	-4.54	<.0001	0.05	-39.8044	-15.7912
22	-28.8825	6.2804	895	-4.60	<.0001	0.05	-41.2085	-16.5565
23	-29.5887	6.1586	895	-4.80	<.0001	0.05	-41.6758	-17.5017
24	10.7036	9.1335	895	1.17	0.2415	0.05	-7.2220	28.6292
25	18.6442	6.4371	895	2.90	0.0039	0.05	6.0107	31.2777
26	8.8171	7.0393	895	1.25	0.2107	0.05	-4.9983	22.6326
27	0
28	-0.8086	5.4925	895	-0.15	0.8830	0.05	-11.5883	9.9710
29	0
30	0.06534	0.02868	895	2.28	0.0229	0.05	0.009059	0.1216

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Parameter Code=P9PGIN4B Parameter=Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
31	1	NN1218-4131	TRTPN	2				
32	1	NN1218-4131	TRTPN	3				
33	1	NN1218-4131	TRTPN	4				
34	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
35	1	NN1218-4131	REGION1	—	EUROPE			
36	1	NN1218-4131	REGION1	—	JAPAN			
37	1	NN1218-4131	REGION1	—	NORTH AMERICA			
38	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
39	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
40	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
31	-0.4495	0.3063	731	-1.47	0.1427	0.05	-1.0508	0.1519
32	-0.5550	0.3007	731	-1.85	0.0654	0.05	-1.1454	0.03542
33	-1.3378	0.3008	731	-4.45	<.0001	0.05	-1.9284	-0.7472
34	1.7034	0.4454	731	3.82	0.0001	0.05	0.8290	2.5778
35	0.4350	0.3203	731	1.36	0.1749	0.05	-0.1939	1.0639
36	0.7305	0.3389	731	2.16	0.0314	0.05	0.06524	1.3958
37	0
38	-0.5009	0.2695	731	-1.86	0.0635	0.05	-1.0300	0.02814
39	0
40	0.1890	0.03114	731	6.07	<.0001	0.05	0.1279	0.2502

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The Mixed procedure
Solution for Fixed Effects

Parameter Code=P9PGINB4 Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1		BOLAD1	
41	1	NN1218-4131	TRTPN	2				
42	1	NN1218-4131	TRTPN	3				
43	1	NN1218-4131	TRTPN	4				
44	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
45	1	NN1218-4131	REGION1	—	EUROPE			
46	1	NN1218-4131	REGION1	—	JAPAN			
47	1	NN1218-4131	REGION1	—	NORTH AMERICA			
48	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
49	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
50	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
41	-0.5664	0.3972	718	-1.43	0.1543	0.05	-1.3461	0.2134
42	-0.8168	0.3873	718	-2.11	0.0353	0.05	-1.5771	-0.05650
43	-0.4629	0.3940	718	-1.17	0.2405	0.05	-1.2364	0.3107
44	-0.2509	0.5896	718	-0.43	0.6706	0.05	-1.4086	0.9067
45	0.2975	0.4225	718	0.70	0.4816	0.05	-0.5320	1.1270
46	-0.3104	0.4466	718	-0.70	0.4872	0.05	-1.1871	0.5663
47	0
48	0.5597	0.3562	718	1.57	0.1166	0.05	-0.1396	1.2590
49	0
50	0.09212	0.03421	718	2.69	0.0072	0.05	0.02496	0.1593

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The Mixed procedure
Solution for Fixed Effects

Parameter Code=P9PGINBB Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
51	1	NN1218-4131	TRTPN	2				
52	1	NN1218-4131	TRTPN	3				
53	1	NN1218-4131	TRTPN	4				
54	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
55	1	NN1218-4131	REGION1	—	EUROPE			
56	1	NN1218-4131	REGION1	—	JAPAN			
57	1	NN1218-4131	REGION1	—	NORTH AMERICA			
58	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
59	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
60	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
51	-1.5426	0.3395	895	-4.54	<.0001	0.05	-2.2089	-0.8763
52	-1.6028	0.3485	895	-4.60	<.0001	0.05	-2.2868	-0.9188
53	-1.6420	0.3418	895	-4.80	<.0001	0.05	-2.3128	-0.9712
54	0.5940	0.5069	895	1.17	0.2415	0.05	-0.4008	1.5887
55	1.0346	0.3572	895	2.90	0.0039	0.05	0.3336	1.7357
56	0.4893	0.3906	895	1.25	0.2107	0.05	-0.2774	1.2560
57	0
58	-0.04488	0.3048	895	-0.15	0.8830	0.05	-0.6431	0.5533
59	0
60	0.06534	0.02868	895	2.28	0.0229	0.05	0.009059	0.1216

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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Least Squares Means

Obs	_Imputation_	PARAMCD	PARAM	STUDYID
1	1	P9GIN4BU	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	NN1218-4131
20001	1	P9GIN4BU	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	NN1218-4131
40001	1	P9GINBBU	Nocturnal increment (bedtime to breakfast) (SMPG) (mg/dL)	NN1218-4131
60001	1	P9PGIN4B	Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)	NN1218-4131
80001	1	P9PGINB4	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	NN1218-4131
100001	1	P9PGINBB	Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)	NN1218-4131
120001	1	P9GIN4BU	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	NN1218-4131
140001	1	P9GINB4U	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	NN1218-4131
160001	1	P9GINBBU	Nocturnal increment (bedtime to breakfast) (SMPG) (mg/dL)	NN1218-4131
180001	1	P9PGIN4B	Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)	NN1218-4131
200001	1	P9PGINB4	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)	NN1218-4131
220001	1	P9PGINBB	Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)	NN1218-4131
240001	1	P9GIN4BU	Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)	NN1218-4131
260001	1	P9GINB4U	Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)	NN1218-4131

Obs	Effect	TRTPN	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	TRTPN	2	WORK.IMPUTE	18.0613	3.8008	731	4.75	<.0001	0.05	10.5995	25.5232
20001	TRTPN	2	WORK.IMPUTE	6.5836	4.9789	718	1.32	0.1865	0.05	-3.1913	16.3584
40001	TRTPN	2	WORK.IMPUTE	14.9077	4.2466	895	3.51	0.0005	0.05	6.5733	23.2421
60001	TRTPN	2	WORK.IMPUTE	1.0023	0.2109	731	4.75	<.0001	0.05	0.5882	1.4164
80001	TRTPN	2	WORK.IMPUTE	0.3653	0.2763	718	1.32	0.1865	0.05	-0.1771	0.9078
100001	TRTPN	2	WORK.IMPUTE	0.8273	0.2357	895	3.51	0.0005	0.05	0.3648	1.2898
120001	TRTPN	3	WORK.IMPUTE	16.1602	3.5902	731	4.50	<.0001	0.05	9.1119	23.2084
140001	TRTPN	3	WORK.IMPUTE	2.0705	4.7408	718	0.44	0.6624	0.05	-7.2370	11.3781
160001	TRTPN	3	WORK.IMPUTE	13.8230	4.2624	895	3.24	0.0012	0.05	5.4575	22.1884
180001	TRTPN	3	WORK.IMPUTE	0.8968	0.1992	731	4.50	<.0001	0.05	0.5057	1.2879
200001	TRTPN	3	WORK.IMPUTE	0.1149	0.2631	718	0.44	0.6624	0.05	-0.4016	0.6314
220001	TRTPN	3	WORK.IMPUTE	0.7671	0.2365	895	3.24	0.0012	0.05	0.3029	1.2313
240001	TRTPN	4	WORK.IMPUTE	2.0533	3.7321	731	0.55	0.5824	0.05	-5.2736	9.3802
260001	TRTPN	4	WORK.IMPUTE	8.4487	4.9800	718	1.70	0.0902	0.05	-1.3284	18.2258

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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Least Squares Means

Obs	_Imputation_	PARAMCD	PARAM							STUDYID	
280001	1	P9GINBBU	Nocturnal increment (bedtime to breakfast) (SMPG) (mg/dL)							NN1218-4131	
300001	1	P9PGIN4B	Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)							NN1218-4131	
320001	1	P9PGINB4	Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)							NN1218-4131	
340001	1	P9PGINBB	Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)							NN1218-4131	

Obs	Effect	TRTPN	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
280001	TRTPN	4	WORK.IMPUTE	13.1167	4.2328	895	3.10	0.0020	0.05	4.8093	21.4241
300001	TRTPN	4	WORK.IMPUTE	0.1139	0.2071	731	0.55	0.5824	0.05	-0.2927	0.5205
320001	TRTPN	4	WORK.IMPUTE	0.4689	0.2764	718	1.70	0.0902	0.05	-0.07372	1.0114
340001	TRTPN	4	WORK.IMPUTE	0.7279	0.2349	895	3.10	0.0020	0.05	0.2669	1.1889

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Least Squares Means Estimate

Parameter Code=P9GIN4BU Parameter=Nocturnal increment (04:00 to breakfast) (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
1	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
20001	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	WORK.IMPUTE	16.0080	5.3341	731	3.00	0.0028	0.05	5.5359	26.4801
20001	WORK.IMPUTE	14.1068	5.1837	731	2.72	0.0067	0.05	3.9302	24.2835

Parameter Code=P9GINB4U Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
40001	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
60001	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
40001	WORK.IMPUTE	-1.8651	7.0481	718	-0.26	0.7914	0.05	-15.7025	11.9722
60001	WORK.IMPUTE	-6.3782	6.8812	718	-0.93	0.3543	0.05	-19.8879	7.1315

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Least Squares Means Estimate

Parameter Code=P9GINBBU Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mg/dL)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label					
80001	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)					
100001	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)					
Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper	
80001	WORK.IMPUTE	1.7909	5.9986	895	0.30	0.7653	0.05	-9.9821	13.5640	
100001	WORK.IMPUTE	0.7062	6.0121	895	0.12	0.9065	0.05	-11.0932	12.5057	

Parameter Code=P9PGIN4B Parameter=Nocturnal increment (04:00 to breakfast) (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label					
120001	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)					
140001	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)					
Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper	
120001	WORK.IMPUTE	0.8883	0.2960	731	3.00	0.0028	0.05	0.3072	1.4695	
140001	WORK.IMPUTE	0.7828	0.2877	731	2.72	0.0067	0.05	0.2181	1.3476	

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Least Squares Means Estimate

Parameter Code=P9PGINB4 Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
160001	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
180001	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
160001	WORK.IMPUTE	-0.1035	0.3911	718	-0.26	0.7914	0.05	-0.8714	0.6644
180001	WORK.IMPUTE	-0.3539	0.3819	718	-0.93	0.3543	0.05	-1.1037	0.3958

Parameter Code=P9PGINBB Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mmol/L)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
200001	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
220001	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
200001	WORK.IMPUTE	0.09939	0.3329	895	0.30	0.7653	0.05	-0.5539	0.7527
220001	WORK.IMPUTE	0.03919	0.3336	895	0.12	0.9065	0.05	-0.6156	0.6940

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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9GIN4BU Parameter=Nocturnal increment (04:00 to breakfast) (SMPG) (mg/d

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	5.742754	13.926991	19.670032	234604	0.412368	0.291975	0.999985

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-11.927674	4.435091	-20.6203	-3.23501	234604	-21.444278	-2.667676

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-2.69	0.0072

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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9GINB4U Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	7.502586	23.643829	31.146790	344643	0.317333	0.240895	0.999988

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-8.089105	5.580931	-19.0276	2.849357	344643	-18.978450	3.193554

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-1.45	0.1472

nn1218/nn1218-4131/ctr_20180214_er
10FEB2018:19:32:14 - a_797pp_stat_diff.sas/a_9pp_noct_stat_on_fas_app.txt

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 3149 of 4425	Novo Nordisk
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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9GINBBU Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mg

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	2.274314	18.040717	20.315144	1.6E6	0.126072	0.111958	0.999994

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-21.346391	4.507232	-30.1804	-12.5124	1.6E6	-27.149339	-15.062460

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-4.74	<.0001

nn1218/nn1218-4131/ctr_20180214_er
10FEB2018:19:32:14 - a_797pp_stat_diff.sas/a_9pp_noct_stat_on_fas_app.txt

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 3150 of 4425	Novo Nordisk
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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9PGIN4B Parameter=Nocturnal increment (04:00 to breakfast) (SMPG) (mmol

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.017685	0.042889	0.060575	234604	0.412368	0.291975	0.999985

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.661913	0.246120	-1.14430	-0.17952	234604	-1.190027	-0.148040

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-2.69	0.0072

nn1218/nn1218-4131/ctr_20180214_er
10FEB2018:19:32:14 - a_797pp_stat_diff.sas/a_9pp_noct_stat_on_fas_app.txt

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 3151 of 4425	Novo Nordisk
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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9PGINB4 Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.023105	0.072813	0.095919	344643	0.317333	0.240895	0.999988

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.448896	0.309708	-1.05591	0.158122	344643	-1.053188	0.177223

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-1.45	0.1472

nn1218/nn1218-4131/ctr_20180214_er
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Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 3152 of 4425	Novo Nordisk
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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=P9PGINBB Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mm

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.007004	0.055558	0.062562	1.6E6	0.126072	0.111958	0.999994

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-1.184594	0.250124	-1.67483	-0.69436	1.6E6	-1.506623	-0.835875

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-4.74	<.0001

nn1218/nn1218-4131/ctr_20180214_er
10FEB2018:19:32:14 - a_797pp_stat_diff.sas/a_9pp_noct_stat_on_fas_app.txt

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 3153 of 4425	Novo Nordisk
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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9GIN4BU Parameter=Nocturnal increment (04:00 to breakfast) (SMPG) (mg/d

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	3.488388	12.426103	15.914666	416208	0.280745	0.219208	0.999989

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-10.002179	3.989319	-17.8211	-2.18323	416208	-17.044874	-2.656579

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-2.51	0.0122

nn1218/nn1218-4131/ctr_20180214_er
10FEB2018:19:32:14 - a_797pp_stat_diff.sas/a_9pp_noct_stat_on_fas_app.txt

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 3154 of 4425	Novo Nordisk
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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9GINB4U Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	6.218992	21.437189	27.656491	395475	0.290117	0.224881	0.999989

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-12.960325	5.258944	-23.2677	-2.65295	395475	-23.852327	-1.628942

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-2.46	0.0137

nn1218/nn1218-4131/ctr_20180214_er
10FEB2018:19:32:14 - a_797pp_stat_diff.sas/a_9pp_noct_stat_on_fas_app.txt

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 3155 of 4425	Novo Nordisk
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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9GINBBU Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mg

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	1.898795	18.175302	20.074192	2.24E6	0.104476	0.094594	0.999995

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-22.687650	4.480423	-31.4691	-13.9062	2.24E6	-27.834764	-17.448368

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-5.06	<.0001

nn1218/nn1218-4131/ctr_20180214_er
10FEB2018:19:32:14 - a_797pp_stat_diff.sas/a_9pp_noct_stat_on_fas_app.txt

Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9PGIN4B Parameter=Nocturnal increment (04:00 to breakfast) (SMPG) (mmol

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.010743	0.038267	0.049010	416208	0.280745	0.219208	0.999989

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.555060	0.221383	-0.98896	-0.12116	416208	-0.945886	-0.147424

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-2.51	0.0122

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 3157 of 4425	Novo Nordisk
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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9PGINB4 Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.019152	0.066017	0.085170	395475	0.290117	0.224881	0.999989

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.719219	0.291839	-1.29122	-0.14722	395475	-1.323659	-0.090396

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-2.46	0.0137

nn1218/nn1218-4131/ctr_20180214_er
10FEB2018:19:32:14 - a_797pp_stat_diff.sas/a_9pp_noct_stat_on_fas_app.txt

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 3158 of 4425	Novo Nordisk
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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=P9PGINBB Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mm

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.005847	0.055972	0.061820	2.24E6	0.104476	0.094594	0.999995

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-1.259026	0.248636	-1.74634	-0.77171	2.24E6	-1.544660	-0.968278

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-5.06	<.0001

nn1218/nn1218-4131/ctr_20180214_er
10FEB2018:19:32:14 - a_797pp_stat_diff.sas/a_9pp_noct_stat_on_fas_app.txt

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 3159 of 4425	Novo Nordisk
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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9GIN4BU Parameter=Nocturnal increment (04:00 to breakfast) (SMPG) (mg/d

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	3.982133	13.427870	17.410202	382244	0.296572	0.228740	0.999989

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-22.678293	4.172553	-30.8564	-14.5002	382244	-30.062947	-14.713150

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-5.44	<.0001

nn1218/nn1218-4131/ctr_20180214_er
10FEB2018:19:32:14 - a_797pp_stat_diff.sas/a_9pp_noct_stat_on_fas_app.txt

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 3160 of 4425	Novo Nordisk
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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9GINB4U Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	7.510807	23.654662	31.165844	344310	0.317535	0.241011	0.999988

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-1.272946	5.582638	-12.2148	9.668862	344310	-11.913333	10.455281

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-0.23	0.8196

nn1218/nn1218-4131/ctr_20180214_er
10FEB2018:19:32:14 - a_797pp_stat_diff.sas/a_9pp_noct_stat_on_fas_app.txt

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 3161 of 4425	Novo Nordisk
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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9GINBBU Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mg

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	2.093051	17.924112	20.017268	1.83E6	0.116779	0.104568	0.999995

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-21.357801	4.474066	-30.1268	-12.5888	1.83E6	-27.188457	-15.664014

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-4.77	<.0001

nn1218/nn1218-4131/ctr_20180214_er
10FEB2018:19:32:14 - a_797pp_stat_diff.sas/a_9pp_noct_stat_on_fas_app.txt

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 3162 of 4425	Novo Nordisk
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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9PGIN4B Parameter=Nocturnal increment (04:00 to breakfast) (SMPG) (mmol

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.012263	0.041352	0.053616	382244	0.296572	0.228740	0.999989

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-1.258507	0.231551	-1.71234	-0.80467	382244	-1.668310	-0.816490

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-5.44	<.0001

nn1218/nn1218-4131/ctr_20180214_er
10FEB2018:19:32:14 - a_797pp_stat_diff.sas/a_9pp_noct_stat_on_fas_app.txt

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 3163 of 4425	Novo Nordisk
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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9PGINB4 Parameter=Nocturnal increment (bedtime to 04:00) (SMPG) (mmol/L

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.023130	0.072846	0.095977	344310	0.317535	0.241011	0.999988

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.070641	0.309802	-0.67784	0.536563	344310	-0.661117	0.580204

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-0.23	0.8196

nn1218/nn1218-4131/ctr_20180214_er
10FEB2018:19:32:14 - a_797pp_stat_diff.sas/a_9pp_noct_stat_on_fas_app.txt

Fast-acting insulin aspart NN1218-4131	Clinical Trial Report Statistical document	Date: Version:	14 February 2018 1.0	Status: Page:	Final 3164 of 4425	Novo Nordisk
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Nocturnal increments in 9-point self-measured plasma glucose profile 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=P9PGINBB Parameter=Nocturnal increment (bedtime to breakfast) (SMPG) (mm

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.006446	0.055199	0.061645	1.83E6	0.116779	0.104568	0.999995

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-1.185228	0.248283	-1.67185	-0.69860	1.83E6	-1.508793	-0.869257

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-4.77	<.0001

nn1218/nn1218-4131/ctr_20180214_er
10FEB2018:19:32:14 - a_797pp_stat_diff.sas/a_9pp_noct_stat_on_fas_app.txt

28: Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG78 Parameter=PPG <=7.8 mmol/L (SMPG) Study Identifier=NN1218-4131

The GENMOD Procedure

Model Information

Data Set	WORK.ENDPOINT
Distribution	Binomial
Link Function	Logit
Dependent Variable	aval

Number of Observations Read	977
Number of Observations Used	977
Number of Events	227
Number of Trials	977

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Response Profile

Ordered Value	aval	Total Frequency
1	0	227
2	1	750

nn1218/nn1218-4131/ctr_20180214_er
09FEB2018:20:27:17 - a_stat_resp.sas/a_ppg_resp_stat_in_fas_app.txt

Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG78 Parameter=PPG <=7.8 mmol/L (SMPG) Study Identifier=NN1218-4131

The GENMOD Procedure

PROC GENMOD is modeling the probability that aval='0'. One way to change this to model the probability that aval='1' is to specify the DESCENDING option in the PROC statement.

Parameter Information					
Parameter	Effect	TRTPN	REGION1	BOLAD1	
Prm1	Intercept				
Prm2	TRTPN	2			
Prm3	TRTPN	3			
Prm4	TRTPN	4			
Prm5	REGION1		ASIA (EXCLUDING JAPAN)		
Prm6	REGION1		EUROPE		
Prm7	REGION1		JAPAN		
Prm8	REGION1		NORTH AMERICA		
Prm9	BOLAD1			BOLUS INSULIN ALGORITHM (SLIDING SCALE)	
Prm10	BOLAD1			CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY	
Prm11	P9PPRABL				

Criteria For Assessing Goodness Of Fit

Criterion	DF	Value	Value/DF
Log Likelihood		-464.4212	
Full Log Likelihood		-464.4212	
AIC (smaller is better)		944.8425	
AICC (smaller is better)		944.9912	
BIC (smaller is better)		983.9184	

Fast-acting insulin aspart
NN1218-4131

Clinical Trial Report
Statistical document

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG78 Parameter=PPG <=7.8 mmol/L (SMPG) Study Identifier=NN1218-4131

The GENMOD Procedure

Algorithm converged.

Analysis Of Maximum Likelihood Parameter Estimates

Parameter		DF	Estimate	Standard Error	Wald 95% Confidence Limits		Wald Chi-Square
Intercept		1	1.3963	0.4481	0.5180	2.2745	9.71
TRTPN	2	1	0.4326	0.1964	0.0478	0.8175	4.85
TRTPN	3	1	-0.0188	0.2058	-0.4223	0.3846	0.01
TRTPN	4	0	0.0000	0.0000	0.0000	0.0000	.
REGION1	ASIA (EXCLUDING JAPAN)	1	0.3604	0.2832	-0.1946	0.9154	1.62
REGION1	EUROPE	1	0.5802	0.2068	0.1748	0.9856	7.87
REGION1	JAPAN	1	-0.4808	0.2710	-1.0119	0.0504	3.15
REGION1	NORTH AMERICA	0	0.0000	0.0000	0.0000	0.0000	.
BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	1	0.4380	0.1857	0.0741	0.8019	5.57

Analysis Of Maximum Likelihood Parameter Estimates

Parameter		Pr > ChiSq
Intercept		0.0018
TRTPN	2	0.0276
TRTPN	3	0.9271
TRTPN	4	.
REGION1	ASIA (EXCLUDING JAPAN)	0.2031
REGION1	EUROPE	0.0050
REGION1	JAPAN	0.0760
REGION1	NORTH AMERICA	.
BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.0183

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Analysis Of Maximum Likelihood Parameter Estimates

Parameter	DF	Estimate	Standard Error	Wald 95% Confidence Limits	Wald Chi-Square
BOLAD1 CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY	0	0.0000	0.0000	0.0000 0.0000	.
P9PPRABL	1	-0.3498	0.0446	-0.4372 -0.2624	61.55
Scale	0	1.0000	0.0000	1.0000 1.0000	

Analysis Of Maximum Likelihood Parameter Estimates

Parameter	Pr > ChiSq
BOLAD1 CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY	.
P9PPRABL	<.0001
Scale	

NOTE: The scale parameter was held fixed.

Coefficients for TRTPN Least Squares Means Using WORK.ENDPOINT Margins

Parameter	Geographic Region Grouping Method 1
Intercept	
Planned Treatment (N) 2	
Planned Treatment (N) 3	
Planned Treatment (N) 4	
Geographic Region Grouping Method 1 ASIA (EXCLUDING JAPAN)	ASIA (EXCLUDING JAPAN)
Geographic Region Grouping Method 1 EUROPE	EUROPE
Geographic Region Grouping Method 1 JAPAN	JAPAN

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Coefficients for TRTPN Least Squares Means Using WORK.ENDPOINT Margins

Parameter	Geographic Region Grouping Method 1
Geographic Region Grouping Method 1 NORTH AMERICA	NORTH AMERICA
Bolus Adjustment Method at Timepoint 1 BOLUS INSULIN ALGORITHM (SLIDING SCALE)	
Bolus Adjustment Method at Timepoint 1 CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY	
PPG all meals (SMPG) (mmol/L) at Baseline	

Coefficients for TRTPN Least Squares Means Using WORK.ENDPOINT Margins

	Planned Treatment (N)	Row1	Row2	Row3
Bolus Adjustment Method at Timepoint 1				
	1	1	1	
	2	1		
	3		1	
	4			1
		0.1351	0.1351	0.1351
		0.3367	0.3367	0.3367
		0.2467	0.2467	0.2467
		0.2815	0.2815	0.2815
BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.5793	0.5793	0.5793
CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0.4207	0.4207	0.4207
		9.5719	9.5719	9.5719

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TRTPN Least Squares Means

Planned Treatment (N)	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
2	WORK.ENDPOINT	-1.1399	0.1386	-8.22	<.0001	0.05	-1.4115	-0.8682
3	WORK.ENDPOINT	-1.5914	0.1539	-10.34	<.0001	0.05	-1.8929	-1.2898
4	WORK.ENDPOINT	-1.5725	0.1505	-10.45	<.0001	0.05	-1.8675	-1.2776

Differences of TRTPN Least Squares Means

Planned Treatment (N)	Planned Treatment (N)	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
2	4	WORK.ENDPOINT	0.4326	0.1964	2.20	0.0276	0.05	0.04779	0.8175
3	4	WORK.ENDPOINT	-0.01884	0.2058	-0.09	0.9271	0.05	-0.4223	0.3846

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) / NovoRapid (meal)	WORK.ENDPOINT	0.4326	0.1964	2.20	0.0276	0.05	0.04779	0.8175

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Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
TRTPN	Faster aspart (post) / NovoRapid (meal)	WORK.ENDPOINT	-0.01884	0.2058	-0.09	0.9271	0.05	-0.4223	0.3846

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
1	1	0.1632	-1.634609	0.2762527	0.1365658
2	1	0.1063577	-2.128497	0.2740134	0.0950458
3	1	0.0539653	-2.863938	0.2965425	0.051053
4	1	0.0211111	-3.836618	0.3632241	0.0206654
5	1	0.0629717	-2.700028	0.2890512	0.0590063
6	1	0.4613503	-0.154908	0.283867	0.2485062
7	1	0.0443806	-3.069557	0.29188	0.042411
8	1	0.0304743	-3.459923	0.3111989	0.0295456
9	1	0.1839054	-1.490109	0.2795975	0.1500842
10	1	0.205878	-1.349954	0.2441735	0.1634922
11	1	0.1470985	-1.757542	0.27435	0.1254605
12	1	0.0266501	-3.597953	0.3196082	0.0259398
13	1	0.1705944	-1.581421	0.2935933	0.1414919
14	1	0.1959799	-1.411612	0.2975405	0.1575718
15	1	0.1637899	-1.630295	0.2763353	0.1369628

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Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
16	1	0.3181168	-0.76244	0.3385247	0.2169185
17	1	0.097527	-2.225009	0.2505738	0.0880155
18	1	0.1745434	-1.553763	0.2402027	0.144078
19	1	0.0848796	-2.377822	0.2740234	0.077675
20	1	0.0199024	-3.896814	0.3992262	0.0195063
21	1	0.0174477	-4.030947	0.3499174	0.0171433
22	1	0.0426748	-3.110534	0.2935717	0.0408537
23	0	0.0821323	-2.413722	0.2572596	0.0753866
24	1	0.0110398	-4.495147	0.3895119	0.0109179
25	1	0.0388812	-3.207587	0.2979055	0.0373695
26	1	0.0429399	-3.104064	0.293299	0.0410961
27	1	0.0318472	-3.414439	0.3217541	0.030833
28	1	0.1103158	-2.08752	0.2736495	0.0981462
29	0	0.0943906	-2.261167	0.2479804	0.085481
30	1	0.088526	-2.331767	0.2540981	0.0806891
31	1	0.0271205	-3.579969	0.3425461	0.026385
32	1	0.050204	-2.940153	0.2870967	0.0476835
33	0	0.1912955	-1.441614	0.242051	0.1547015
34	1	0.1774131	-1.533973	0.2956565	0.1459377
35	1	0.0379834	-3.231882	0.2974314	0.0365407
36	1	0.0641781	-2.679763	0.2776858	0.0600593
37	1	0.0082389	-4.790618	0.416857	0.008171
38	1	0.0528382	-2.886235	0.2853615	0.0500463
39	1	0.0270445	-3.582856	0.3186519	0.0263131

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Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
40	0	0.2277168	-1.221249	0.3118582	0.1758618
41	1	0.1864275	-1.473393	0.2464695	0.1516723
42	0	0.3657908	-0.550317	0.288717	0.2319879
43	1	0.0387865	-3.210123	0.303521	0.0372821
44	1	0.1728729	-1.565402	0.2384466	0.1429879
45	1	0.1103346	-2.087327	0.253899	0.0981609
46	1	0.2027588	-1.36914	0.2372467	0.1616477
47	1	0.1681938	-1.598482	0.2445678	0.1399047
48	1	0.0835637	-2.394884	0.2530599	0.0765808
49	0	0.5205712	0.0823313	0.3015323	0.2495768
50	0	0.1188657	-2.003215	0.2502805	0.1047367
51	1	0.13364	-1.869151	0.2439944	0.1157804
52	0	0.2100574	-1.324579	0.2500407	0.1659333
53	1	0.1127705	-2.062749	0.2424633	0.1000533
54	1	0.0397026	-3.185827	0.3035242	0.0381263
55	1	0.1676931	-1.602066	0.2389606	0.1395721
56	1	0.0388079	-3.209551	0.3053373	0.0373018
57	1	0.0646581	-2.671798	0.2889473	0.0604775
58	1	0.0422211	-3.121698	0.296706	0.0404384
59	1	0.1420973	-1.797979	0.2436724	0.1219056
60	0	0.3626618	-0.56383	0.2822818	0.2311382
61	1	0.1057625	-2.134775	0.2561157	0.0945768
62	1	0.047022	-3.008976	0.2906441	0.0448109
63	1	0.0546838	-2.849951	0.2775857	0.0516935

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
64	1	0.0730356	-2.540968	0.2629166	0.06777014
65	1	0.0778479	-2.471953	0.259738	0.0717876
66	1	0.1385847	-1.827095	0.2437634	0.119379
67	1	0.0814036	-2.423427	0.2576595	0.0747771
68	0	0.2861672	-0.914073	0.2444957	0.2042755
69	1	0.1794453	-1.52011	0.2379369	0.1472447
70	0	0.3604732	-0.573311	0.2584552	0.2305323
71	1	0.2965849	-0.863614	0.2639387	0.2086223
72	1	0.0752563	-2.508618	0.2613946	0.0695927
73	1	0.1228519	-1.965697	0.2406883	0.1077593
74	0	0.0744109	-2.520828	0.2784112	0.0688739
75	1	0.0812803	-2.425078	0.254351	0.0746738
76	1	0.0505226	-2.933491	0.2855118	0.0479701
77	1	0.2750215	-0.969293	0.2585107	0.1993847
78	1	0.0631743	-2.6966	0.2907635	0.0591833
79	1	0.144437	-1.778917	0.2426916	0.1235749
80	1	0.1242531	-1.952756	0.2404988	0.1088143
81	1	0.1750423	-1.550305	0.2382613	0.1444025
82	1	0.1016329	-2.179212	0.2454009	0.0913036
83	1	0.2361001	-1.174181	0.2497269	0.1803568
84	0	0.3374504	-0.674677	0.2536067	0.2235776
85	1	0.1224493	-1.969438	0.2450181	0.1074554
86	1	0.1509518	-1.727155	0.2413878	0.1281653
87	1	0.0764658	-2.491364	0.2606059	0.0706188

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Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
88	0	0.1491355	-1.741398	0.2389978	0.1268941
89	1	0.1014883	-2.180796	0.2493173	0.0911884
90	1	0.2841432	-0.924002	0.2607656	0.2034059
91	1	0.1394197	-1.820118	0.2392036	0.1199818
92	1	0.1416338	-1.801786	0.2391181	0.1215737
93	1	0.0376764	-3.240317	0.3059083	0.0362569
94	1	0.1829651	-1.496387	0.2377254	0.1494889
95	1	0.0580085	-2.787406	0.2736169	0.0546435
96	1	0.128362	-1.91552	0.2443851	0.1118852
97	1	0.0943741	-2.261359	0.2740459	0.0854677
98	1	0.0179043	-4.00465	0.4103623	0.0175837
99	1	0.1245294	-1.95022	0.2814986	0.1090218
100	1	0.1827705	-1.497689	0.2410227	0.1493654
101	1	0.0978596	-2.221236	0.2752015	0.0882831
102	1	0.1030547	-2.163735	0.2779112	0.0924344
103	0	0.0842267	-2.386257	0.2527006	0.0771326
104	1	0.05859	-2.776815	0.2799786	0.0551572
105	1	0.0962336	-2.239792	0.2741383	0.0869727
106	1	0.0796843	-2.446645	0.2553047	0.0733347
107	1	0.0499054	-2.946432	0.2863752	0.0474149
108	1	0.2781567	-0.953624	0.2647129	0.2007855
109	1	0.1011445	-2.184572	0.2746716	0.0909143
110	1	0.1618486	-1.644538	0.2872542	0.1356536
111	0	0.0502796	-2.938569	0.2849548	0.0477515

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Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
112	0	0.0964214	-2.237635	0.274149	0.0871243
113	1	0.0304574	-3.460495	0.3099474	0.0295298
114	1	0.0223016	-3.780543	0.3585532	0.0218042
115	1	0.0129806	-4.331237	0.3751142	0.0128121
116	1	0.1223672	-1.970202	0.2775971	0.1073934
117	1	0.1640855	-1.628138	0.2763771	0.1371615
118	1	0.2092161	-1.329657	0.3017717	0.1654447
119	0	0.0982411	-2.216923	0.2751351	0.0885898
120	1	0.0452796	-3.048561	0.2891305	0.0432294
121	0	0.1874928	-1.466385	0.2802586	0.1523392
122	1	0.046437	-3.022109	0.2900264	0.0442806
123	1	0.0414354	-3.1413	0.2931264	0.0397185
124	1	0.0471429	-3.006282	0.3040648	0.0449204
125	1	0.100297	-2.193929	0.2776156	0.0902375
126	1	0.0254465	-3.6454	0.3226698	0.024799
127	1	0.1322506	-1.881205	0.2832083	0.1147604
128	1	0.0831131	-2.400782	0.2567348	0.0762053
129	1	0.3383725	-0.670556	0.3186792	0.2238765
130	1	0.0520877	-2.901333	0.2858318	0.0493746
131	1	0.0672584	-2.629586	0.2792812	0.0627347
132	0	0.1320833	-1.882663	0.2396666	0.1146373
133	1	0.0208188	-3.850861	0.3361157	0.0203854
134	1	0.1097658	-2.093135	0.2754941	0.0977173
135	1	0.076681	-2.488321	0.2775275	0.070801

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Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
136	1	0.0979521	-2.220189	0.2466387	0.0883575
137	1	0.0809611	-2.429359	0.2796741	0.0744064
138	0	0.1954707	-1.414847	0.2973798	0.1572619
139	1	0.1054717	-2.137854	0.2782068	0.0943474
140	1	0.0737559	-2.530377	0.2779289	0.068316
141	1	0.1675114	-1.603368	0.2396528	0.1394513
142	1	0.1213731	-1.979492	0.2493337	0.1066416
143	1	0.1996392	-1.388551	0.2372481	0.1597834
144	1	0.1624607	-1.640032	0.2393529	0.1360672
145	1	0.1528024	-1.712789	0.2437308	0.1294538
146	1	0.1288454	-1.911207	0.2443428	0.1122442
147	1	0.0778068	-2.472525	0.2564833	0.0717529
148	1	0.2646558	-1.021909	0.2415414	0.1946131
149	1	0.2021186	-1.373105	0.2487229	0.1612667
150	1	0.0373648	-3.248944	0.3065959	0.0359687
151	1	0.0738774	-2.5286	0.2591628	0.0684195
152	1	0.0335523	-3.360521	0.3173079	0.0324266
153	1	0.1733039	-1.56239	0.2400952	0.1432697
154	1	0.3221974	-0.743692	0.2506332	0.2183862
155	0	0.2899983	-0.895392	0.2677023	0.2058993
156	1	0.0488927	-2.967999	0.2878295	0.0465022
157	0	0.1597221	-1.660297	0.2399618	0.134211
158	1	0.0710658	-2.570432	0.2817716	0.0660154
159	0	0.062098	-2.714932	0.2921207	0.0582418

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG78 Parameter=PPG ≤ 7.8 mmol/L (SMPG) Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
160	1	0.1812502	-1.5079	0.2458431	0.1483985
161	1	0.0346895	-3.326014	0.3145081	0.0334861
162	1	0.1335152	-1.870229	0.2440018	0.1156889
163	1	0.0958758	-2.243913	0.2474029	0.0866836
164	1	0.0745092	-2.519401	0.2618957	0.0689576
165	1	0.08456	-2.381943	0.2525225	0.0774096
166	1	0.0680507	-2.617026	0.2637266	0.0634198
167	1	0.0188533	-3.952034	0.3693969	0.0184978
168	1	0.1146405	-2.044193	0.2519929	0.101498
169	1	0.0562962	-2.819185	0.2781936	0.0531269
170	1	0.1842582	-1.48776	0.237658	0.1503071
171	1	0.1826429	-1.498543	0.2377431	0.1492845
172	1	0.2295515	-1.210845	0.248412	0.1768576
173	1	0.06683	-2.636436	0.2647821	0.0623637
174	1	0.0942064	-2.263324	0.2480539	0.0853315
175	1	0.0522038	-2.898984	0.2832435	0.0494786
176	0	0.0194037	-3.922695	0.4018841	0.0190272
177	1	0.1426239	-1.793666	0.2436637	0.1222823
178	1	0.0738774	-2.5286	0.2591628	0.0684195
179	1	0.0579618	-2.788261	0.2976709	0.0546023
180	0	0.0728511	-2.543697	0.259913	0.0675438
181	1	0.1028733	-2.165699	0.248916	0.0922903
182	1	0.0978121	-2.221774	0.2504778	0.0882449
183	1	0.0710176	-2.571163	0.2643872	0.0659741

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
184	1	0.0947599	-2.256854	0.2478343	0.0857805
185	0	0.2912604	-0.88927	0.2452791	0.2064278
186	1	0.0793061	-2.451813	0.2739102	0.0730166
187	1	0.0236944	-3.718537	0.3483105	0.023133
188	1	0.0579618	-2.788261	0.2976709	0.0546023
189	1	0.0535699	-2.87171	0.2827263	0.0507001
190	1	0.1261428	-1.935503	0.2402634	0.1102308
191	1	0.0905191	-2.307313	0.2651849	0.0823254
192	1	0.1731495	-1.563469	0.2400821	0.1431687
193	1	0.0516728	-2.909767	0.283947	0.0490028
194	1	0.0267473	-3.594211	0.3182781	0.0260319
195	1	0.0345262	-3.330899	0.3132451	0.0333342
196	1	0.0832339	-2.399197	0.2532412	0.0763061
197	1	0.2244818	-1.239737	0.2378957	0.1740897
198	1	0.078897	-2.457428	0.2557913	0.0726723
199	1	0.4067847	-0.377274	0.2956218	0.2413109
200	1	0.0775388	-2.476267	0.2599291	0.0715265
201	1	0.1849074	-1.483446	0.2376262	0.1507167
202	1	0.0664631	-2.642334	0.2680405	0.0620457
203	1	0.1055587	-2.136932	0.2562194	0.0944161
204	1	0.1353569	-1.854402	0.2448995	0.1170354
205	1	0.2412989	-1.145572	0.2561379	0.1830737
206	1	0.1148595	-2.042036	0.2519003	0.1016668
207	0	0.2231316	-1.247509	0.2471785	0.1733439

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
208	1	0.012983	-4.331045	0.4077783	0.0128145
209	1	0.1069229	-2.122565	0.2478482	0.0954904
210	1	0.1780435	-1.52966	0.2958495	0.146344
211	1	0.1675912	-1.602796	0.2445205	0.1395044
212	1	0.0647118	-2.670912	0.2878588	0.0605241
213	1	0.0462212	-3.026994	0.2882627	0.0440848
214	1	0.0245188	-3.683491	0.3506663	0.0239176
215	1	0.0453729	-3.046405	0.2890427	0.0433142
216	1	0.0375134	-3.244823	0.2980778	0.0361061
217	1	0.2447645	-1.126733	0.2515471	0.1848548
218	1	0.245804	-1.121118	0.239489	0.1853844
219	1	0.0441151	-3.075835	0.2953772	0.042169
220	1	0.2460686	-1.119691	0.2571751	0.1855188
221	1	0.2510387	-1.09308	0.2400033	0.1880183
222	0	0.297307	-0.860155	0.2462474	0.2089156
223	1	0.0734748	-2.534498	0.2626077	0.0680763
224	1	0.0895291	-2.319398	0.2500624	0.0815136
225	1	0.0357323	-3.295314	0.3103323	0.0344555
226	1	0.1678923	-1.600639	0.244544	0.1397045
227	1	0.0233477	-3.733634	0.3496883	0.0228026
228	1	0.1624607	-1.640032	0.2393529	0.1360672
229	1	0.03286	-3.382089	0.3190761	0.0317802
230	1	0.0567954	-2.809828	0.2993393	0.0535697
231	1	0.0773847	-2.478424	0.260025	0.0713963

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
232	1	0.128362	-1.91552	0.2443851	0.1118852
233	1	0.0682239	-2.614297	0.2665704	0.0635694
234	1	0.134701	-1.860017	0.2394684	0.1165567
235	1	0.0241476	-3.699126	0.3465467	0.0235645
236	1	0.0505576	-2.932761	0.309144	0.0480016
237	1	0.1243949	-1.951454	0.2482577	0.1089208
238	1	0.2073288	-1.341103	0.2372902	0.1643435
239	1	0.1868317	-1.47073	0.2414912	0.1519256
240	1	0.2117569	-1.314368	0.2451427	0.1669159
241	1	0.055049	-2.842909	0.2796658	0.0520186
242	1	0.0472883	-3.00305	0.352712	0.0450521
243	1	0.326645	-0.723399	0.2315557	0.2199481
244	1	0.255392	-1.070058	0.2403879	0.1901669
245	0	0.3671667	-0.544391	0.2349683	0.2323553
246	1	0.0407865	-3.157762	0.371528	0.039123
247	1	0.305668	-0.820451	0.2306299	0.2122351
248	1	0.1308807	-1.893194	0.2882004	0.1137509
249	1	0.1497601	-1.736484	0.260794	0.127332
250	0	0.4045894	-0.386378	0.2495817	0.2408968
251	1	0.5855209	0.3454793	0.2574345	0.2426862
252	0	0.1730811	-1.563947	0.2529451	0.143124
253	1	0.340356	-0.661708	0.2316749	0.2245138
254	1	0.1446168	-1.777462	0.2628941	0.1237028
255	0	0.3523968	-0.60852	0.2432315	0.2282133

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Parameter Code=PPG78 Parameter=PPG ≤ 7.8 mmol/L (SMPG) Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
256	0	0.1362871	-1.846477	0.2666252	0.1177129
257	1	0.3238053	-0.736339	0.2313942	0.2189554
258	1	0.2549821	-1.072215	0.2404083	0.1899662
259	0	0.1296589	-1.903978	0.2890233	0.1128475
260	1	0.2008167	-1.381198	0.2381404	0.1604894
261	1	0.151065	-1.726273	0.2528949	0.1282444
262	1	0.001143	-6.772994	0.7823105	0.0011416
263	1	0.1030222	-2.164086	0.2805651	0.0924086
264	1	0.0990077	-2.208299	0.2838197	0.0892052
265	0	0.1258143	-1.938486	0.2916843	0.1099851
266	1	0.0818098	-2.418007	0.3056106	0.075117
267	0	0.4720928	-0.111745	0.237629	0.2492212
268	1	0.0581594	-2.784649	0.3365972	0.0547768
269	1	0.0455009	-3.043456	0.3605198	0.0434305
270	0	0.2196433	-1.267746	0.2489506	0.1714001
271	0	0.3503003	-0.617719	0.2333067	0.22759
272	1	0.2476778	-1.111036	0.2408294	0.1863335
273	0	0.4719108	-0.112475	0.2614518	0.249211
274	1	0.2541636	-1.076528	0.2404501	0.1895644
275	1	0.3175117	-0.765231	0.2329086	0.216698
276	0	0.4812386	-0.075081	0.2387536	0.249648
277	1	0.1096326	-2.094499	0.2818981	0.0976133
278	0	0.4299327	-0.282126	0.2335618	0.2450906
279	0	0.6236516	0.5050764	0.2670102	0.2347103

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Parameter Code=PPG78 Parameter=PPG ≤ 7.8 mmol/L (SMPG) Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
280	0	0.3821237	-0.480544	0.2313184	0.2361052
281	0	0.3855215	-0.466177	0.2469459	0.2368947
282	1	0.4723058	-0.11089	0.2517529	0.249233
283	0	0.3737053	-0.516354	0.2356985	0.2340496
284	1	0.392048	-0.438712	0.2379891	0.2383464
285	1	0.347361	-0.63066	0.2330512	0.2267013
286	1	0.3454078	-0.639286	0.2328872	0.2261013
287	1	0.3706816	-0.529294	0.235355	0.2332768
288	1	0.3978538	-0.414416	0.2486114	0.2395661
289	1	0.4941704	-0.02332	0.2404869	0.249966
290	1	0.3956521	-0.423615	0.2384796	0.2391115
291	1	0.2086342	-1.333178	0.2451533	0.165106
292	1	0.2903305	-0.893779	0.230369	0.2060387
293	1	0.2096097	-1.32728	0.2364917	0.1656735
294	0	0.6789899	0.7491338	0.3214568	0.2179626
295	1	0.3243267	-0.733958	0.2324576	0.2191389
296	1	0.1698148	-1.58694	0.2667355	0.1409777
297	1	0.3951365	-0.425771	0.2384086	0.2390037
298	1	0.1782336	-1.528361	0.2515351	0.1464664
299	1	0.3281958	-0.716356	0.2412894	0.2204833
300	1	0.2142926	-1.299242	0.235709	0.1683713
301	1	0.3142493	-0.780328	0.2331503	0.2154967
302	0	0.3505968	-0.616417	0.2313699	0.2276787
303	1	0.1290265	-1.909594	0.2633981	0.1123787

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
304	1	0.3704823	-0.530148	0.2311869	0.2332252
305	0	0.3413251	-0.657395	0.2316397	0.2248223
306	0	0.5329432	0.1319641	0.2466746	0.2489147
307	0	0.2860238	-0.914774	0.2397423	0.2042142
308	1	0.1445461	-1.778034	0.2556879	0.1236525
309	1	0.0756697	-2.502691	0.3072526	0.0699438
310	1	0.2820765	-0.934185	0.2397338	0.2025093
311	1	0.3704823	-0.530148	0.2311869	0.2332252
312	0	0.3498096	-0.619876	0.2332633	0.2274429
313	1	0.3196942	-0.755177	0.2407785	0.2174898
314	1	0.2646613	-1.02188	0.2391007	0.1946157
315	1	0.2213713	-1.257693	0.2433233	0.1723661
316	1	0.1862155	-1.474791	0.2599003	0.1515393
317	0	0.3671667	-0.544391	0.2349683	0.2323553
318	0	0.4019944	-0.397162	0.2492029	0.2403949
319	0	0.1282056	-1.916918	0.2900162	0.1117689
320	1	0.1475044	-1.75431	0.2543904	0.1257469
321	1	0.2062721	-1.347545	0.252901	0.1637239
322	0	0.1347304	-1.859765	0.2856765	0.1165781
323	0	0.2295565	-1.210817	0.2335819	0.1768603
324	0	0.301564	-0.839861	0.230524	0.2106232
325	1	0.1202071	-1.990471	0.2685481	0.1057573
326	0	0.5536294	0.215346	0.2807527	0.2471239
327	1	0.0801621	-2.440146	0.3020364	0.0737362

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
328	0	0.4887802	-0.044887	0.2397441	0.2498741
329	1	0.2803327	-0.942812	0.2397381	0.2017463
330	1	0.2059192	-1.349701	0.2530126	0.1635165
331	0	0.2580004	-1.056388	0.240261	0.1914362
332	1	0.5470834	0.1888934	0.2694449	0.2477832
333	1	0.1789407	-1.523541	0.2433733	0.1469209
334	0	0.5670915	0.2699941	0.2533488	0.2454987
335	1	0.3176969	-0.764376	0.2310845	0.2167656
336	1	0.4719108	-0.112475	0.2614518	0.249211
337	1	0.5949098	0.3843002	0.2596496	0.2409921
338	1	0.3572029	-0.587525	0.2339471	0.229609
339	1	0.3851836	-0.467604	0.2313811	0.2368172
340	1	0.3552245	-0.596152	0.2337578	0.2290401
341	0	0.688706	0.7940767	0.2872185	0.21439
342	1	0.2476778	-1.111036	0.2408294	0.1863335
343	0	0.245568	-1.122391	0.2319834	0.1852643
344	1	0.4753189	-0.098805	0.238016	0.2493908
345	0	0.3631107	-0.561888	0.1885929	0.2312613
346	1	0.3732086	-0.518476	0.1853772	0.2339239
347	0	0.6214896	0.4958756	0.1975821	0.2352403
348	0	0.4263029	-0.296951	0.1803663	0.2445687
349	0	0.4704902	-0.118177	0.1794871	0.2491292
350	1	0.5177432	0.0710026	0.2035903	0.2496852
351	1	0.2878274	-0.905959	0.1978474	0.2049828

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
352	1	0.3325322	-0.696754	0.2096756	0.2219545
353	1	0.2947892	-0.872236	0.2066552	0.2078885
354	1	0.1206404	-1.98638	0.2532934	0.1060863
355	1	0.3333954	-0.692868	0.2098041	0.2222429
356	1	0.109944	-2.091313	0.261931	0.0978563
357	1	0.1184629	-2.007067	0.2351557	0.1044295
358	0	0.2375157	-1.166348	0.204213	0.181102
359	1	0.4218398	-0.315225	0.2037303	0.243891
360	1	0.2475096	-1.111939	0.2024502	0.1862486
361	0	0.4322996	-0.272475	0.2052243	0.2454167
362	1	0.2765533	-0.961624	0.2053775	0.2000716
363	0	0.2991079	-0.851549	0.197198	0.2096424
364	1	0.2612751	-1.039352	0.2047759	0.1930104
365	0	0.4030065	-0.392953	0.2013637	0.2405923
366	1	0.313834	-0.782255	0.2071289	0.2153422
367	1	0.0628472	-2.70214	0.2856925	0.0588974
368	1	0.4402613	-0.240102	0.2316365	0.2464313
369	1	0.3420879	-0.654004	0.2111485	0.2250638
370	1	0.1378185	-1.833528	0.2219622	0.1188246
371	0	0.2423562	-1.139805	0.2025764	0.1836197
372	1	0.0843972	-2.384048	0.2621844	0.0772743
373	1	0.2110547	-1.318579	0.2041137	0.1665106
374	1	0.327377	-0.720073	0.2089277	0.2202013
375	0	0.4783664	-0.086588	0.241734	0.249532

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Parameter Code=PPG78 Parameter=PPG ≤ 7.8 mmol/L (SMPG) Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
376	0	0.3543007	-0.600188	0.2142572	0.2287717
377	1	0.5335594	0.1344398	0.183137	0.2488738
378	0	0.3543007	-0.600188	0.2142572	0.2287717
379	0	0.2481108	-1.108713	0.2025697	0.1865518
380	1	0.1227171	-1.966948	0.2517394	0.1076576
381	1	0.1106419	-2.084201	0.2368276	0.0984002
382	1	0.2283709	-1.217533	0.2029321	0.1762176
383	1	0.2395132	-1.15535	0.2026088	0.1821466
384	1	0.1681222	-1.598994	0.214364	0.1398571
385	0	0.3662622	-0.548286	0.1885764	0.2321142
386	1	0.4204489	-0.320931	0.1906491	0.2436716
387	0	0.5034902	0.0139612	0.1806911	0.2499878
388	1	0.5209668	0.0839165	0.1819576	0.2495604
389	1	0.4462095	-0.215998	0.1930709	0.2471066
390	0	0.3716625	-0.525091	0.198414	0.2335295
391	1	0.4671028	-0.131779	0.1794525	0.2489178
392	1	0.5287203	0.1150078	0.1826574	0.2491751
393	0	0.4685542	-0.125949	0.1794653	0.2490112
394	1	0.6625437	0.6746504	0.2081537	0.2235796
395	1	0.3523957	-0.608525	0.1887704	0.228213
396	1	0.406639	-0.377877	0.1900975	0.2412837
397	1	0.1843946	-1.486853	0.2238195	0.1503932
398	0	0.5238758	0.0955758	0.1822102	0.2494299
399	0	0.3211623	-0.748436	0.1904186	0.2180171

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Parameter Code=PPG78 Parameter=PPG ≤ 7.8 mmol/L (SMPG) Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
400	0	0.5605167	0.2432592	0.186409	0.2463377
401	1	0.3247058	-0.732229	0.1940226	0.2192719
402	1	0.1990215	-1.392421	0.2054841	0.159412
403	1	0.2105182	-1.321805	0.2104311	0.1662003
404	1	0.0750416	-2.511706	0.2691261	0.0694104
405	1	0.2257586	-1.232417	0.2066465	0.1747917
406	0	0.2651587	-1.019326	0.2029819	0.1948496
407	1	0.3740955	-0.514687	0.2177349	0.2341481
408	1	0.1330409	-1.874336	0.224139	0.115341
409	0	0.3217092	-0.745928	0.2095063	0.2182124
410	1	0.1970755	-1.404674	0.2083342	0.1582367
411	0	0.4968134	-0.012747	0.2469965	0.2499898
412	1	0.2395132	-1.15535	0.2026088	0.1821466
413	0	0.614772	0.4674161	0.2271215	0.2368274
414	1	0.3019935	-0.837823	0.1923319	0.2107934
415	0	0.529376	0.1176395	0.2058552	0.2491371
416	0	0.3747345	-0.511958	0.1892626	0.2343086
417	1	0.6625437	0.6746504	0.2081537	0.2235796
418	0	0.6616742	0.6707639	0.207903	0.2238615
419	1	0.0651049	-2.664434	0.3298742	0.0608663
420	0	0.5034902	0.0139612	0.1806911	0.2499878
421	1	0.3196138	-0.755547	0.1951728	0.2174608
422	0	0.0720502	-2.555615	0.3185922	0.066859
423	1	0.4422249	-0.232137	0.1927276	0.246662

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
424	1	0.1945387	-1.420784	0.219398	0.1566934
425	0	0.3620753	-0.566368	0.1893632	0.2309768
426	0	0.6485035	0.6124678	0.2042504	0.2279467
427	1	0.2463383	-1.118238	0.2041587	0.1856557
428	0	0.4692096	-0.123318	0.1958208	0.249052
429	1	0.5582917	0.2342317	0.2121413	0.2466021
430	0	0.3771241	-0.501773	0.198834	0.2349015
431	0	0.4146336	-0.344843	0.1905382	0.2427126
432	1	0.2504163	-1.096393	0.2019874	0.187708
433	1	0.1559888	-1.688382	0.2180284	0.1316563
434	1	0.4225054	-0.312497	0.1805784	0.2439946
435	0	0.2627162	-1.031899	0.2002657	0.1936964
436	0	0.4306412	-0.279236	0.1916848	0.2451894
437	0	0.1263705	-1.933439	0.2615103	0.110401
438	1	0.130111	-1.899978	0.2464991	0.1131821
439	1	0.2248078	-1.237865	0.2068612	0.1742693
440	1	0.1187796	-2.004038	0.2652098	0.104671
441	0	0.3894063	-0.449808	0.2206965	0.237769
442	1	0.2274834	-1.222576	0.2253411	0.1757347
443	1	0.5457171	0.1833806	0.2092931	0.2479099
444	1	0.1266508	-1.930902	0.227319	0.1106104
445	1	0.4070302	-0.376256	0.2018334	0.2413566
446	1	0.147537	-1.754051	0.2180164	0.1257698
447	1	0.166299	-1.612088	0.2351201	0.1386436

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
448	1	0.2735069	-0.976902	0.1990541	0.1987009
449	1	0.2194646	-1.268789	0.2034304	0.1712999
450	1	0.3036668	-0.829897	0.2059465	0.2114533
451	1	0.1348196	-1.859	0.2433847	0.1166433
452	1	0.3014981	-0.840174	0.2072642	0.210597
453	1	0.4065561	-0.378221	0.1817117	0.2412682
454	1	0.2689863	-0.999772	0.2050226	0.1966327
455	1	0.5784932	0.3165908	0.2179667	0.2438388
456	0	0.1317677	-1.885419	0.2548053	0.114405
457	1	0.4413884	-0.235529	0.1925521	0.2465647
458	1	0.4373183	-0.252053	0.1798746	0.246071
459	1	0.3071389	-0.81353	0.1917468	0.2128046
460	1	0.43621	-0.256558	0.2058146	0.2459308
461	1	0.2914512	-0.888346	0.1937016	0.2065074
462	0	0.3208828	-0.749718	0.1948817	0.217917
463	0	0.1502949	-1.73229	0.2445221	0.1277063
464	1	0.2807362	-0.940813	0.1953386	0.2019234
465	0	0.6520389	0.6280135	0.2052045	0.2268842
466	1	0.3427022	-0.651275	0.1890972	0.2252574
467	1	0.1965852	-1.407775	0.2206662	0.1579395
468	1	0.4157213	-0.340363	0.1903005	0.2428971
469	1	0.3085874	-0.806732	0.1915917	0.2133612
470	0	0.4587255	-0.165475	0.1945544	0.2482964
471	0	0.4460628	-0.216591	0.1931115	0.2470908

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Parameter Code=PPG78 Parameter=PPG <=7.8 mmol/L (SMPG) Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
472	1	0.4225054	-0.312497	0.1805784	0.2439946
473	1	0.4157213	-0.340363	0.1903005	0.2428971
474	1	0.2804774	-0.942095	0.205693	0.2018098
475	1	0.5190267	0.0761437	0.1817957	0.249638
476	1	0.2979132	-0.857255	0.1928344	0.2091609
477	0	0.5727601	0.2931214	0.2164819	0.244706
478	1	0.2810088	-0.939463	0.1967511	0.2020429
479	0	0.502205	0.0088201	0.2008046	0.2499951
480	1	0.5325921	0.1305534	0.1830385	0.2489378
481	0	0.3459223	-0.637012	0.1897374	0.2262601
482	1	0.2253372	-1.23483	0.2101835	0.1745603
483	1	0.4204489	-0.320931	0.1906491	0.2436716
484	1	0.2946719	-0.872801	0.1932583	0.2078404
485	1	0.1631288	-1.63513	0.2368745	0.1365178
486	0	0.4556847	-0.177727	0.1941565	0.2480362
487	1	0.4547209	-0.181614	0.1940466	0.2479498
488	1	0.1513665	-1.723924	0.2414425	0.1284547
489	0	0.3840245	-0.472501	0.1887762	0.2365497
490	0	0.3738244	-0.515845	0.1892613	0.2340797
491	0	0.5486871	0.1953676	0.2099499	0.2476296
492	0	0.4809874	-0.076087	0.1976664	0.2496385
493	1	0.3427022	-0.651275	0.1890972	0.2252574
494	0	0.264177	-1.02437	0.1983838	0.1943875
495	0	0.5488341	0.1959612	0.2106759	0.2476152

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Parameter Code=PPG78 Parameter=PPG <=7.8 mmol/L (SMPG) Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
496	1	0.3308517	-0.704336	0.1907517	0.2213888
497	1	0.2226351	-1.250376	0.2110529	0.1730687
498	0	0.527587	0.1104603	0.2060476	0.249239
499	0	0.4792123	-0.083199	0.179653	0.2495679
500	0	0.6146089	0.4667276	0.1960556	0.2368648
501	0	0.4887529	-0.044996	0.1988904	0.2498735
502	0	0.5555611	0.2231661	0.2122447	0.246913
503	0	0.3018684	-0.838417	0.193628	0.2107439
504	0	0.280344	-0.942756	0.1954034	0.2017512
505	0	0.5605167	0.2432592	0.186409	0.2463377
506	1	0.3575991	-0.5858	0.1894606	0.229722
507	0	0.5119188	0.0476842	0.2025138	0.2498579
508	0	0.3523957	-0.608525	0.1887704	0.228213
509	0	0.6660105	0.690196	0.209165	0.2224405
510	1	0.3561031	-0.592318	0.1879627	0.2292937
511	1	0.2442897	-1.129303	0.2029363	0.1846122
512	1	0.4074108	-0.374679	0.181641	0.2414272
513	1	0.5374262	0.1499855	0.1835438	0.2485993
514	1	0.2560769	-1.06646	0.2138909	0.1905015
515	1	0.2937416	-0.877281	0.1947343	0.2074575
516	0	0.3649102	-0.554115	0.1885815	0.2317507
517	1	0.4780774	-0.087746	0.1972259	0.2495194
518	0	0.2996802	-0.848821	0.2001491	0.209872
519	0	0.3043312	-0.826757	0.1933196	0.2117137

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
520	1	0.3487214	-0.624664	0.1897524	0.2271148
521	1	0.0934262	-2.272501	0.2930089	0.0846977
522	1	0.3561031	-0.592318	0.1879627	0.2292937
523	1	0.106708	-2.124817	0.2789035	0.0953214
524	0	0.4531053	-0.188132	0.1794874	0.2478009
525	1	0.5041481	0.0165929	0.2011378	0.2499828
526	1	0.1955578	-1.414293	0.2409112	0.1573149
527	1	0.2235262	-1.245235	0.2270999	0.1735622
528	1	0.4291568	-0.285292	0.1802212	0.2449812
529	1	0.2038363	-1.362488	0.2156946	0.162287
530	1	0.2730871	-0.979016	0.2080344	0.1985106
531	0	0.3620753	-0.566368	0.1893632	0.2309768
532	1	0.6202795	0.4907345	0.2287781	0.2355329
533	1	0.3289811	-0.712797	0.1930939	0.2207526
534	1	0.4792123	-0.083199	0.179653	0.2495679
535	1	0.5235628	0.0943211	0.2047043	0.2494448
536	1	0.2757957	-0.965413	0.2071625	0.1997324
537	1	0.6458413	0.6008086	0.2035446	0.2287303
538	1	0.2833705	-0.927804	0.1963501	0.2030716
539	1	0.4772727	-0.090972	0.1796066	0.2494835
540	1	0.7227929	0.958358	0.2286189	0.2003633
541	1	0.5544547	0.2186861	0.2112535	0.2470347
542	0	0.3228592	-0.740663	0.1902836	0.2186211
543	1	0.3460781	-0.636323	0.189865	0.2263081

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
544	1	0.2351849	-1.179262	0.2048994	0.1798729
545	1	0.2741143	-0.973847	0.1964792	0.1989757
546	0	0.4992902	-0.002839	0.2003129	0.2499995
547	1	0.3786792	-0.495158	0.1846529	0.2352813
548	0	0.2317076	-1.198694	0.2050392	0.1780192
549	1	0.3322753	-0.697912	0.1896317	0.2218684
550	0	0.3575991	-0.5858	0.1894606	0.229722
551	1	0.2694991	-0.997166	0.1973344	0.1968693
552	0	0.1827463	-1.497851	0.2481449	0.1493501
553	1	0.3895552	-0.449182	0.188937	0.2378019
554	0	0.7004704	0.8495387	0.2202927	0.2098116
555	1	0.4308999	-0.27818	0.1915268	0.2452252
556	0	0.5794038	0.3203262	0.2182058	0.243695
557	1	0.5852361	0.3443058	0.190304	0.2427348
558	0	0.4576133	-0.169955	0.19438	0.2482034
559	1	0.0294057	-3.496719	0.4242788	0.028541
560	1	0.3169406	-0.767868	0.1907783	0.2164892
561	0	0.5469087	0.1881884	0.210236	0.2477996
562	0	0.3968316	-0.418685	0.1896809	0.2393563
563	0	0.3451991	-0.64021	0.1899051	0.2260367
564	0	0.6278678	0.5230805	0.1990588	0.2336498
565	0	0.3011644	-0.841759	0.205679	0.2104644
566	1	0.0911004	-2.300273	0.2556449	0.0828011
567	1	0.2279792	-1.219757	0.2052245	0.1760047

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
568	1	0.1856446	-1.478563	0.2103039	0.1511807
569	0	0.4272151	-0.293222	0.2044824	0.2447024
570	1	0.33402	-0.690059	0.1967033	0.2224506
571	1	0.2338256	-1.186834	0.2027338	0.1791512
572	1	0.1698911	-1.586399	0.2138914	0.1410281
573	0	0.4190011	-0.326875	0.2270297	0.2434392
574	1	0.1126346	-2.064108	0.259653	0.099948
575	1	0.2481108	-1.108713	0.2025697	0.1865518
576	1	0.2558818	-1.067484	0.2011759	0.1904063
577	1	0.1551077	-1.695089	0.2316872	0.1310493
578	0	0.4562832	-0.175315	0.2091086	0.2480888
579	1	0.1951523	-1.416873	0.2150463	0.1570679
580	1	0.2920465	-0.885465	0.2064269	0.2067553
581	1	0.1247522	-1.948177	0.2283267	0.1091891
582	1	0.53868	0.1550299	0.2269204	0.2485039
583	1	0.3563165	-0.591388	0.1886834	0.2293551
584	1	0.4028727	-0.39351	0.2013484	0.2405663
585	1	0.1447742	-1.77619	0.2221388	0.1238146
586	1	0.1738819	-1.558362	0.2128791	0.143647
587	1	0.1398428	-1.816596	0.2210885	0.1202868
588	1	0.4342222	-0.264645	0.1918361	0.2456733
589	0	0.5339389	0.1359645	0.2257172	0.2488482
590	1	0.3386712	-0.669222	0.2106092	0.223973
591	1	0.0538941	-2.865333	0.3043248	0.0509895

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG78 Parameter=PPG ≤ 7.8 mmol/L (SMPG) Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
592	0	0.335779	-0.682162	0.2101636	0.2230314
593	1	0.3613508	-0.569506	0.2154482	0.2307764
594	0	0.5425151	0.170472	0.2279094	0.2481925
595	1	0.378492	-0.495954	0.1989456	0.2352358
596	1	0.2433606	-1.134343	0.2031492	0.1841362
597	0	0.2578007	-1.057431	0.202728	0.1913395
598	1	0.1942718	-1.422488	0.208772	0.1565303
599	1	0.35479	-0.59805	0.2132713	0.228914
600	0	0.3633958	-0.560656	0.1978576	0.2313393
601	1	0.1508218	-1.72817	0.2168182	0.1280746
602	1	0.2044612	-1.358641	0.2121491	0.1626568
603	1	0.1610375	-1.650529	0.2134893	0.1351044
604	1	0.1006767	-2.189728	0.2474568	0.0905409
605	1	0.256867	-1.062316	0.2046896	0.1908864
606	1	0.4533922	-0.186974	0.2086075	0.2478277
607	1	0.322263	-0.743391	0.2082196	0.2184096
608	1	0.1242221	-1.953041	0.2318405	0.108791
609	1	0.6341482	0.5500544	0.2558034	0.2320043
610	0	0.3380603	-0.67195	0.2117276	0.2237755
611	1	0.2154277	-1.292513	0.2037316	0.1690186
612	0	0.3594138	-0.577909	0.1976245	0.2302355
613	1	0.3490031	-0.623424	0.2133985	0.2271999
614	1	0.1962255	-1.410054	0.2058736	0.157721
615	1	0.2758255	-0.965264	0.2053387	0.1997458

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG78 Parameter=PPG <=7.8 mmol/L (SMPG) Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
616	1	0.1391538	-1.822336	0.24066	0.11979
617	1	0.2225607	-1.250805	0.2073795	0.1730275
618	1	0.3512113	-0.613719	0.2137526	0.2278619
619	0	0.4392151	-0.244348	0.2313744	0.2463052
620	1	0.2542426	-1.076111	0.2014114	0.1896033
621	0	0.323154	-0.739315	0.2083405	0.2187255
622	1	0.155528	-1.691886	0.2412941	0.131339
623	1	0.4698653	-0.120685	0.2115799	0.2490919
624	1	0.3711566	-0.527258	0.1892652	0.2333994
625	1	0.3739368	-0.515364	0.1985839	0.2341081
626	0	0.2219086	-1.254579	0.2093631	0.1726652
627	0	0.526418	0.1057704	0.2238523	0.2493021
628	1	0.3834513	-0.474925	0.1887621	0.2364164
629	1	0.1182692	-2.008924	0.2682405	0.1042816
630	1	0.0773011	-2.479595	0.310835	0.0713256
631	1	0.268139	-1.004085	0.2049897	0.1962405
632	1	0.3305086	-0.705886	0.209378	0.2212726
633	1	0.2154277	-1.292513	0.2037316	0.1690186
634	1	0.4202377	-0.321798	0.1906329	0.243638
635	0	0.2880889	-0.904684	0.1955861	0.2050937
636	0	0.1511228	-1.725822	0.2415937	0.1282847
637	1	0.1321963	-1.881677	0.2570017	0.1147205
638	1	0.2403887	-1.15055	0.2057386	0.182602
639	1	0.4459132	-0.217197	0.1930382	0.2470746

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Parameter Code=PPG78 Parameter=PPG ≤ 7.8 mmol/L (SMPG) Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
640	1	0.4415685	-0.234799	0.1797338	0.2465858
641	1	0.1868225	-1.470791	0.21792	0.1519198
642	1	0.111103	-2.079523	0.2720613	0.0987591
643	1	0.2947691	-0.872333	0.1945868	0.2078803
644	1	0.4471044	-0.212377	0.193219	0.2472021
645	0	0.514838	0.0593693	0.2030485	0.2497798
646	0	0.30409	-0.827897	0.1989818	0.2116193
647	1	0.3754978	-0.508702	0.1850682	0.2344992
648	1	0.1954863	-1.414748	0.2211245	0.1572714
649	1	0.2810637	-0.939191	0.1967416	0.2020669
650	1	0.2400009	-1.152675	0.2037492	0.1824004
651	1	0.1796134	-1.518969	0.2088005	0.1473524
652	1	0.1787692	-1.524709	0.2209702	0.1468108
653	1	0.1275693	-1.922623	0.2482506	0.1112954
654	1	0.1030461	-2.163828	0.2422416	0.0924276
655	1	0.1494458	-1.738954	0.2173122	0.1271118
656	1	0.152552	-1.714724	0.2192096	0.1292799
657	1	0.1395149	-1.819325	0.224335	0.1200505
658	0	0.3137173	-0.782798	0.1967244	0.2152987
659	1	0.1000942	-2.196178	0.2445274	0.0900754
660	0	0.2379989	-1.163682	0.2048088	0.1813554
661	0	0.3144893	-0.779214	0.2072102	0.2155858
662	1	0.1541664	-1.70229	0.2156639	0.1303992
663	0	0.1708056	-1.579929	0.2136529	0.141631

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG78 Parameter=PPG ≤ 7.8 mmol/L (SMPG) Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
664	1	0.1058164	-2.134205	0.243548	0.0946193
665	0	0.5507994	0.2039011	0.2300934	0.2474194
666	1	0.1259368	-1.937372	0.2276945	0.1100768
667	0	0.3226063	-0.74182	0.1966275	0.2185315
668	1	0.2142398	-1.299555	0.2062421	0.1683411
669	1	0.1423874	-1.795601	0.223113	0.1221133
670	1	0.0833769	-2.397325	0.2632456	0.0764252
671	1	0.1824061	-1.50013	0.2109547	0.1491341
672	1	0.1893457	-1.454267	0.2069545	0.1534939
673	0	0.3892032	-0.450663	0.1999063	0.2377241
674	0	0.2265193	-1.228071	0.2339558	0.1752083
675	1	0.3089292	-0.80513	0.2335814	0.213492
676	1	0.184391	-1.486877	0.2419061	0.1503909
677	1	0.2367296	-1.170694	0.2446307	0.1806887
678	1	0.3807987	-0.486159	0.2365427	0.2357911
679	1	0.1053579	-2.13906	0.3079413	0.0942576
680	1	0.1396212	-1.818439	0.2650806	0.1201271
681	1	0.1538517	-1.704705	0.2517731	0.1301814
682	1	0.1285425	-1.913907	0.2636651	0.1120194
683	1	0.1547707	-1.697663	0.2588859	0.1308167
684	1	0.3116507	-0.792414	0.2308296	0.2145245
685	1	0.268624	-1.001615	0.2306737	0.1964651
686	1	0.1224523	-1.96941	0.2738458	0.1074577
687	1	0.4485229	-0.206641	0.235125	0.2473501

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG78 Parameter=PPG ≤ 7.8 mmol/L (SMPG) Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
688	0	0.1984957	-1.395723	0.2469435	0.1590952
689	1	0.4944399	-0.022241	0.2405248	0.2499691
690	1	0.2716446	-0.986294	0.2379834	0.1978538
691	1	0.2207158	-1.2615	0.2347373	0.1720003
692	1	0.1847155	-1.48472	0.2418224	0.1505957
693	1	0.2057063	-1.351004	0.237194	0.1633912
694	0	0.5313324	0.125494	0.2463881	0.2490183
695	1	0.1806151	-1.512185	0.2509186	0.1479933
696	1	0.381053	-0.485081	0.236574	0.2358516
697	1	0.3814423	-0.483431	0.2464276	0.2359441
698	1	0.2979424	-0.857115	0.2304521	0.2091727
699	1	0.3116507	-0.792414	0.2308296	0.2145245
700	1	0.1034746	-2.159201	0.2863228	0.0927676
701	1	0.406149	-0.379908	0.2498123	0.241192
702	1	0.1167753	-2.023328	0.2772329	0.1031389
703	1	0.1121301	-2.069166	0.225764	0.0995569
704	1	0.1270622	-1.927188	0.2549317	0.1109174
705	1	0.2037535	-1.362998	0.2325117	0.162238
706	1	0.4121374	-0.355136	0.2529196	0.2422802
707	0	0.2564685	-1.064406	0.2334247	0.1906924
708	1	0.1438849	-1.783391	0.2481127	0.1231821
709	1	0.1488104	-1.743962	0.2173852	0.1266658
710	1	0.0528217	-2.886566	0.2662784	0.0500315
711	1	0.0697884	-2.589944	0.2610706	0.064918

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Parameter Code=PPG78 Parameter=PPG <=7.8 mmol/L (SMPG) Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
712	1	0.0397255	-3.185226	0.2885796	0.0381474
713	1	0.1422023	-1.797117	0.2132946	0.1219808
714	0	0.0820909	-2.414271	0.3058259	0.075352
715	1	0.1104683	-2.085966	0.2233518	0.0982651
716	1	0.0921167	-2.288059	0.2307086	0.0836312
717	1	0.0538024	-2.867134	0.2648536	0.0509077
718	1	0.1183407	-2.008238	0.2212569	0.1043362
719	1	0.1124516	-2.06594	0.2228838	0.0998062
720	1	0.1089594	-2.101415	0.2793397	0.0970872
721	1	0.0693299	-2.597029	0.246777	0.0645233
722	1	0.1646473	-1.624048	0.2419578	0.1375386
723	1	0.2309139	-1.203158	0.227069	0.1775927
724	1	0.2231054	-1.24766	0.2321177	0.1733294
725	1	0.0693361	-2.596932	0.3225664	0.0645286
726	1	0.0489119	-2.967587	0.2712129	0.0465195
727	0	0.1159392	-2.03146	0.2738616	0.1024973
728	1	0.1903093	-1.448002	0.220381	0.1540917
729	1	0.1329059	-1.875506	0.2191178	0.1152419
730	1	0.2561367	-1.066146	0.2325617	0.1905307
731	1	0.048251	-2.981884	0.273485	0.0459229
732	0	0.4671581	-0.131557	0.2537888	0.2489214
733	1	0.104691	-2.146156	0.2252602	0.0937308
734	1	0.1521967	-1.717475	0.2180045	0.1290328
735	1	0.1436985	-1.784905	0.2176485	0.1230492

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG78 Parameter=PPG <=7.8 mmol/L (SMPG) Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
736	1	0.0768975	-2.485267	0.2397847	0.0709843
737	1	0.0733028	-2.537028	0.2426069	0.0679295
738	1	0.2088296	-1.331995	0.2216645	0.1652198
739	0	0.20532	-1.35337	0.233613	0.1631637
740	1	0.0822237	-2.41251	0.2365244	0.0754629
741	1	0.2293345	-1.212073	0.2046163	0.1767402
742	1	0.0664399	-2.642707	0.2488131	0.0620257
743	1	0.2978585	-0.857516	0.2411069	0.2091388
744	1	0.1445672	-1.777863	0.2182112	0.1236675
745	1	0.0799737	-2.442705	0.2380733	0.0735779
746	0	0.1516409	-1.721789	0.2180102	0.128646
747	1	0.0587307	-2.774267	0.2573166	0.0552814
748	1	0.0821423	-2.413589	0.2365788	0.075395
749	1	0.110015	-2.090587	0.2235593	0.0979117
750	1	0.1174784	-2.016529	0.2229853	0.1036772
751	1	0.1054546	-2.138035	0.2249775	0.0943339
752	1	0.3794864	-0.491729	0.2295209	0.2354765
753	1	0.100152	-2.195536	0.233089	0.0901216
754	1	0.2663027	-1.013463	0.2211204	0.1953856
755	1	0.070709	-2.575849	0.2448189	0.0657092
756	1	0.0355342	-3.301078	0.2999495	0.0342715
757	1	0.3008457	-0.843274	0.2128307	0.2103376
758	1	0.1060665	-2.131565	0.2247751	0.0948164
759	1	0.5038229	0.015292	0.2381642	0.2499854

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG78 Parameter=PPG ≤ 7.8 mmol/L (SMPG) Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
760	1	0.2332029	-1.190314	0.2258597	0.1788193
761	1	0.1424465	-1.795117	0.2183201	0.1221555
762	1	0.1594086	-1.662635	0.2482979	0.1339975
763	1	0.1707931	-1.580017	0.2175853	0.1416228
764	0	0.075984	-2.498207	0.2404764	0.0702104
765	1	0.0622019	-2.713149	0.2711334	0.0583328
766	1	0.1402828	-1.812943	0.2179007	0.1206036
767	1	0.1434333	-1.787062	0.2176658	0.1228602
768	0	0.0840318	-2.388787	0.2353443	0.0769704
769	1	0.1599616	-1.658514	0.208878	0.1343739
770	1	0.0695836	-2.593103	0.2458276	0.0647418
771	1	0.1245893	-1.949671	0.2197008	0.1090668
772	0	0.1297317	-1.903333	0.2530945	0.1129014
773	1	0.494118	-0.023529	0.2362254	0.2499654
774	0	0.3897407	-0.448402	0.2212169	0.2378429
775	1	0.642388	0.5857441	0.2754715	0.2297256
776	0	0.468635	-0.125625	0.2655879	0.2490162
777	0	0.4733287	-0.106786	0.2635697	0.2492886
778	0	0.3592696	-0.578536	0.2433485	0.230195
779	1	0.3031187	-0.83249	0.2132221	0.2112378
780	1	0.1206452	-1.986335	0.2214674	0.1060899
781	0	0.2032782	-1.36593	0.2221573	0.1619562
782	1	0.1400499	-1.814876	0.2139593	0.1204359
783	1	0.2538172	-1.078356	0.2063986	0.189394

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Parameter Code=PPG78 Parameter=PPG <=7.8 mmol/L (SMPG) Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
784	1	0.1898587	-1.450928	0.2370687	0.1538124
785	1	0.0838003	-2.391798	0.2461287	0.0767778
786	1	0.114034	-2.050182	0.222335	0.1010303
787	1	0.1793574	-1.520707	0.2181513	0.1471883
788	1	0.0900273	-2.313301	0.2318122	0.0819224
789	1	0.1930003	-1.430632	0.2207168	0.1557512
790	1	0.1058622	-2.133722	0.2248423	0.0946554
791	1	0.1320662	-1.882812	0.2167018	0.1146247
792	1	0.1420094	-1.7987	0.2133529	0.1218427
793	1	0.1334059	-1.871174	0.2186104	0.1156088
794	1	0.4036761	-0.390171	0.2225556	0.2407217
795	0	0.2227321	-1.249815	0.2043678	0.1731225
796	1	0.0854141	-2.370961	0.2340912	0.0781185
797	1	0.0632366	-2.695547	0.2521289	0.0592378
798	1	0.1294668	-1.905682	0.2191486	0.1127051
799	1	0.1171203	-2.019988	0.2215464	0.1034031
800	1	0.3226631	-0.74156	0.2500003	0.2185516
801	1	0.1657421	-1.616109	0.2182682	0.1382717
802	1	0.0928225	-2.279648	0.2384435	0.0842065
803	1	0.1087176	-2.103908	0.2645008	0.0968981
804	1	0.1826159	-1.498724	0.2390363	0.1492673
805	1	0.3919981	-0.438921	0.2461019	0.2383356
806	1	0.0698387	-2.589169	0.2994184	0.0649613
807	0	0.3193386	-0.756813	0.2182375	0.2173614

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NN1218-4131

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Parameter Code=PPG78 Parameter=PPG <=7.8 mmol/L (SMPG) Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
808	0	0.1821001	-1.502183	0.2370038	0.1489397
809	0	0.348098	-0.62741	0.2186335	0.2269258
810	1	0.2929606	-0.881048	0.2329736	0.2071347
811	1	0.3271994	-0.720879	0.2388261	0.22014
812	1	0.3785983	-0.495502	0.2465656	0.2352616
813	1	0.3535008	-0.603686	0.2188409	0.228538
814	1	0.2101486	-1.32403	0.2308441	0.1659861
815	1	0.1038559	-2.155097	0.2679613	0.0930699
816	1	0.5684487	0.2755248	0.293476	0.2453148
817	1	0.1524013	-1.71589	0.2172769	0.1291751
818	1	0.2241902	-1.241412	0.2242495	0.173929
819	0	0.2917007	-0.887139	0.2414591	0.2066114
820	1	0.0581374	-2.785051	0.2580495	0.0547574
821	1	0.2550446	-1.071886	0.2065202	0.1899968
822	1	0.0302999	-3.465844	0.3419693	0.0293818
823	1	0.2400833	-1.152223	0.2333462	0.1824433
824	1	0.3292626	-0.711522	0.2182344	0.2208487
825	0	0.1827435	-1.49787	0.2368848	0.1493483
826	1	0.0806531	-2.433506	0.2371126	0.0741482
827	1	0.1854208	-1.480044	0.2377548	0.1510399
828	1	0.094777	-2.256655	0.2291839	0.0857943
829	1	0.1541549	-1.702378	0.2179953	0.1303912
830	0	0.141065	-1.806473	0.2178373	0.1211657
831	1	0.2497542	-1.099923	0.2060168	0.1873771

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG78 Parameter=PPG <=7.8 mmol/L (SMPG) Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
832	1	0.1533132	-1.708848	0.2179971	0.1298082
833	1	0.114034	-2.050182	0.222335	0.1010303
834	1	0.1800545	-1.515978	0.2399424	0.1476349
835	1	0.1098754	-2.092014	0.2270212	0.0978028
836	1	0.0926223	-2.282029	0.2304508	0.0840434
837	1	0.0910931	-2.300361	0.2312415	0.0827951
838	1	0.2133563	-1.304812	0.2042081	0.1678354
839	1	0.069981	-2.586981	0.2608354	0.0650837
840	1	0.0860454	-2.362906	0.2340948	0.0786416
841	1	0.0878025	-2.340767	0.2327164	0.0800932
842	1	0.2671088	-1.009341	0.2078601	0.1957617
843	1	0.1613172	-1.64846	0.2181009	0.1352939
844	0	0.2368519	-1.170017	0.2050258	0.1807531
845	1	0.0689356	-2.603156	0.2621232	0.0641835
846	1	0.0987997	-2.210633	0.234023	0.0890383
847	1	0.1108062	-2.082533	0.2232504	0.0985282
848	0	0.1882537	-1.461398	0.218977	0.1528142
849	1	0.1008659	-2.18764	0.2266234	0.090692
850	1	0.197485	-1.402088	0.2200594	0.1584847
851	0	0.2058536	-1.350103	0.2042572	0.1634779
852	1	0.056246	-2.82013	0.261472	0.0530824
853	0	0.2917007	-0.887139	0.2414591	0.2066114
854	1	0.0866008	-2.355864	0.2333969	0.0791011
855	1	0.088276	-2.334869	0.2327863	0.0804834

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Parameter Code=PPG78 Parameter=PPG <=7.8 mmol/L (SMPG) Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
856	1	0.174572	-1.553565	0.2188117	0.1440966
857	0	0.1400918	-1.814527	0.2184689	0.1204661
858	1	0.137446	-1.836667	0.2181597	0.1185546
859	1	0.1377019	-1.83451	0.2181344	0.1187401
860	1	0.0690395	-2.601538	0.3000674	0.0642731
861	1	0.0506433	-2.930977	0.2901532	0.0480786
862	1	0.0925797	-2.282535	0.2302234	0.0840087
863	1	0.0727189	-2.545655	0.2430915	0.0674309
864	1	0.2405753	-1.149528	0.2052758	0.1826988
865	1	0.16704	-1.606752	0.2075904	0.1391376
866	0	0.3549369	-0.597408	0.2236924	0.2289567
867	1	0.0704967	-2.579084	0.2450069	0.0655269
868	1	0.2741263	-0.973787	0.2318693	0.1989811
869	1	0.0690028	-2.60211	0.3004683	0.0642414
870	0	0.2894777	-0.897922	0.2408712	0.2056804
871	1	0.3500582	-0.618783	0.2187041	0.2275175
872	1	0.3023223	-0.836264	0.2361217	0.2109235
873	1	0.1180353	-2.011169	0.2589758	0.1041029
874	0	0.1799184	-1.5169	0.2192644	0.1475478
875	1	0.4127394	-0.352652	0.2500679	0.2423856
876	0	0.4228456	-0.311103	0.2551389	0.2440472
877	0	0.3677523	-0.541871	0.2447178	0.2325106
878	1	0.1181709	-2.009867	0.2722074	0.1042065
879	1	0.224599	-1.239064	0.2320301	0.1741543

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Parameter Code=PPG78 Parameter=PPG <=7.8 mmol/L (SMPG) Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
880	1	0.4862472	-0.055025	0.2667945	0.2498109
881	1	0.2403783	-1.150606	0.2052618	0.1825966
882	1	0.1399201	-1.815954	0.2140004	0.1203424
883	0	0.344468	-0.642507	0.2185232	0.2258757
884	1	0.1316702	-1.886271	0.2188352	0.1143332
885	1	0.3912806	-0.441932	0.2213537	0.2381801
886	0	0.3554309	-0.595251	0.2238048	0.2290998
887	1	0.0545827	-2.851909	0.2627084	0.0516034
888	1	0.3544872	-0.599373	0.2188831	0.228826
889	1	0.02687	-3.589507	0.3246876	0.026148
890	0	0.2395508	-1.155144	0.2272302	0.1821662
891	1	0.0917386	-2.292589	0.2392993	0.0833226
892	0	0.4984312	-0.006275	0.2370763	0.2499975
893	1	0.3796136	-0.491189	0.2467439	0.2355071
894	1	0.2819183	-0.934966	0.232259	0.2024404
895	1	0.1109535	-2.081038	0.2777256	0.0986428
896	1	0.5812766	0.3280162	0.2567442	0.2433941
897	1	0.2145882	-1.297487	0.2225822	0.1685401
898	1	0.223326	-1.246388	0.227808	0.1734515
899	1	0.2480409	-1.109088	0.2333176	0.1865166
900	1	0.1061358	-2.130835	0.2292265	0.094871
901	1	0.2852043	-0.918791	0.2324523	0.2038628
902	1	0.0964251	-2.237592	0.2357205	0.0871273
903	1	0.0845754	-2.381744	0.2345956	0.0774224

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG78 Parameter=PPG <=7.8 mmol/L (SMPG) Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
904	1	0.1871369	-1.468722	0.2051572	0.1521167
905	0	0.3169576	-0.767789	0.2157397	0.2164955
906	1	0.1908022	-1.444806	0.2363144	0.1543967
907	1	0.2284443	-1.217116	0.2265775	0.1762575
908	1	0.1840925	-1.488863	0.2196771	0.1502024
909	1	0.1377698	-1.833938	0.2186457	0.1187893
910	1	0.0650915	-2.664654	0.3056175	0.0608546
911	1	0.2409696	-1.147371	0.205304	0.1829032
912	1	0.2761064	-0.963858	0.2201875	0.1998717
913	0	0.0838659	-2.390943	0.2354502	0.0768324
914	1	0.1827148	-1.498062	0.218436	0.1493301
915	1	0.1403518	-1.812371	0.218451	0.1206532
916	1	0.4436276	-0.226453	0.2467985	0.2468221
917	0	0.434115	-0.265081	0.2262294	0.2456592
918	1	0.1622937	-1.64126	0.2084265	0.1359545
919	0	0.1564181	-1.685124	0.2180055	0.1319515
920	0	0.1702638	-1.583759	0.2185132	0.1412741
921	0	0.3277929	-0.718184	0.2178617	0.2203447
922	1	0.1109535	-2.081038	0.2777256	0.0986428
923	1	0.1095376	-2.095473	0.2236368	0.0975391
924	1	0.157396	-1.677732	0.2492217	0.1326225
925	1	0.3924664	-0.436956	0.2687437	0.2384365
926	1	0.0576357	-2.79425	0.2596503	0.0543138
927	1	0.4064808	-0.378533	0.2488338	0.2412542

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG78 Parameter=PPG ≤ 7.8 mmol/L (SMPG) Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
928	1	0.0645914	-2.672901	0.2506911	0.0604194
929	1	0.1893616	-1.454163	0.2371422	0.1535038
930	1	0.1178109	-2.013325	0.2590995	0.1039315
931	0	0.353334	-0.604416	0.2424316	0.2284891
932	1	0.6964673	0.8305316	0.2955496	0.2114006
933	0	0.2340938	-1.185338	0.2261306	0.1792939
934	1	0.2943026	-0.874578	0.2330729	0.2076886
935	1	0.1800262	-1.51617	0.2058273	0.1476168
936	1	0.1770169	-1.536691	0.2379992	0.1456819
937	1	0.3500582	-0.618783	0.2187041	0.2275175
938	0	0.2748151	-0.970328	0.2202991	0.1992917
939	0	0.1635869	-1.631778	0.2173052	0.1368262
940	1	0.0571229	-2.803731	0.2788645	0.0538599
941	0	0.161824	-1.644719	0.2172664	0.135637
942	1	0.0581479	-2.784859	0.3152853	0.0547667
943	1	0.1070386	-2.121353	0.224444	0.0955814
944	1	0.0484495	-2.977571	0.2731513	0.0461021
945	1	0.3830478	-0.476632	0.2304058	0.2363222
946	0	0.0699665	-2.587205	0.2461852	0.0650712
947	1	0.1788817	-1.523942	0.2181137	0.146883
948	1	0.2516428	-1.08987	0.2315257	0.1883187
949	1	0.1282563	-1.916465	0.2193346	0.1118066
950	1	0.0482773	-2.981312	0.2722574	0.0459466
951	1	0.0767445	-2.487424	0.2398994	0.0708548

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Parameter Code=PPG78 Parameter=PPG <=7.8 mmol/L (SMPG) Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
952	1	0.1447633	-1.776279	0.2175826	0.1238069
953	1	0.4127936	-0.352428	0.2235506	0.2423951
954	1	0.1334059	-1.871174	0.2186104	0.1156088
955	1	0.0871721	-2.348663	0.2431021	0.0795731
956	1	0.3340431	-0.689955	0.2182866	0.2224583
957	0	0.0323104	-3.399523	0.3725213	0.0312664
958	1	0.2215754	-1.256509	0.2237794	0.1724797
959	1	0.1099591	-2.091159	0.2235067	0.0978681
960	1	0.1712835	-1.576558	0.2069328	0.1419454
961	1	0.309765	-0.801218	0.214403	0.2138107
962	1	0.1131653	-2.058809	0.222572	0.1003589
963	1	0.294935	-0.871535	0.2403369	0.2079483
964	1	0.0973994	-2.226461	0.2280254	0.0879127
965	1	0.0580004	-2.787556	0.2774645	0.0546363
966	1	0.2058536	-1.350103	0.2042572	0.1634779
967	1	0.1010301	-2.185831	0.2324951	0.090823
968	1	0.1347242	-1.859819	0.2189247	0.1165736
969	0	0.1215634	-1.977708	0.2210441	0.1067857
970	1	0.1669384	-1.607482	0.2183259	0.13907
971	1	0.0721011	-2.554854	0.2442719	0.0669025
972	0	0.277834	-0.955231	0.2200434	0.2006423
973	0	0.1478893	-1.751252	0.2116801	0.1260181
974	1	0.2044468	-1.35873	0.2042851	0.1626483
975	1	0.1162312	-2.028615	0.2217652	0.1027215

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG78 Parameter=PPG <=7.8 mmol/L (SMPG) Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
976	0	0.1214244	-1.97901	0.2205792	0.1066805
977	1	0.1446298	-1.777357	0.2175905	0.123712

Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

Model Information

Data Set	WORK.ENDPOINT
Distribution	Binomial
Link Function	Logit
Dependent Variable	aval

Number of Observations Read	977
Number of Observations Used	977
Number of Events	69
Number of Trials	977

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Response Profile

Ordered Value	aval	Total Frequency
1	0	69
2	1	908

Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

PROC GENMOD is modeling the probability that avar='0'. One way to change this to model the probability that avar='1' is to specify the DESCENDING option in the PROC statement.

Parameter Information					
Parameter	Effect	TRTPN	REGION1	BOLAD1	
Prm1	Intercept				
Prm2	TRTPN	2			
Prm3	TRTPN	3			
Prm4	TRTPN	4			
Prm5	REGION1		ASIA (EXCLUDING JAPAN)		
Prm6	REGION1		EUROPE		
Prm7	REGION1		JAPAN		
Prm8	REGION1		NORTH AMERICA		
Prm9	BOLAD1			BOLUS INSULIN ALGORITHM (SLIDING SCALE)	
Prm10	BOLAD1			CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY	
Prm11	P9PPRABL				

Criteria For Assessing Goodness Of Fit

Criterion	DF	Value	Value/DF
Log Likelihood		-226.9173	
Full Log Likelihood		-226.9173	
AIC (smaller is better)		469.8346	
AICC (smaller is better)		469.9834	
BIC (smaller is better)		508.9105	

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Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

Algorithm converged.

Analysis Of Maximum Likelihood Parameter Estimates

Parameter		DF	Estimate	Standard Error	Wald 95% Confidence Limits		Wald Chi-Square
Intercept		1	1.2406	0.6951	-0.1219	2.6030	3.18
TRTPN	2	1	-0.0412	0.2955	-0.6204	0.5380	0.02
TRTPN	3	1	-0.5629	0.3329	-1.2154	0.0896	2.86
TRTPN	4	0	0.0000	0.0000	0.0000	0.0000	.
REGION1	ASIA (EXCLUDING JAPAN)	1	-0.4423	0.5193	-1.4601	0.5755	0.73
REGION1	EUROPE	1	0.1511	0.3194	-0.4750	0.7772	0.22
REGION1	JAPAN	1	0.1235	0.3807	-0.6225	0.8696	0.11
REGION1	NORTH AMERICA	0	0.0000	0.0000	0.0000	0.0000	.
BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	1	-0.0405	0.2818	-0.5928	0.5117	0.02

Analysis Of Maximum Likelihood Parameter Estimates

Parameter		Pr > ChiSq
Intercept		0.0743
TRTPN	2	0.8891
TRTPN	3	0.0909
TRTPN	4	.
REGION1	ASIA (EXCLUDING JAPAN)	0.3944
REGION1	EUROPE	0.6363
REGION1	JAPAN	0.7455
REGION1	NORTH AMERICA	.
BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.8856

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG7870 Parameter=PPG <=7.8 mmol/L and HbA1c <7.0% without severe hypo and with minimal weight gain

The GENMOD Procedure

Analysis Of Maximum Likelihood Parameter Estimates

Parameter		DF	Estimate	Standard Error	Wald 95% Confidence Limits	Wald Chi-Square
BOLAD1 CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0	0.0000	0.0000	0.0000 0.0000	.
P9PPRABL		1	-0.4144	0.0730	-0.5574 -0.2714	32.24
Scale		0	1.0000	0.0000	1.0000 1.0000	

Analysis Of Maximum Likelihood Parameter Estimates

Parameter	Pr > ChiSq
BOLAD1 CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY	.
P9PPRABL	<.0001
Scale	

NOTE: The scale parameter was held fixed.

Coefficients for TRTPN Least Squares Means Using WORK.ENDPOINT Margins

Parameter	Geographic Region Grouping Method 1
Intercept	
Planned Treatment (N) 2	
Planned Treatment (N) 3	
Planned Treatment (N) 4	
Geographic Region Grouping Method 1 ASIA (EXCLUDING JAPAN)	ASIA (EXCLUDING JAPAN)
Geographic Region Grouping Method 1 EUROPE	EUROPE
Geographic Region Grouping Method 1 JAPAN	JAPAN

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Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

Coefficients for TRTPN Least Squares Means Using WORK.ENDPOINT Margins

Parameter

Geographic Region
Grouping Method 1

Geographic Region Grouping Method 1 NORTH AMERICA

NORTH AMERICA

Bolus Adjustment Method at Timepoint 1 BOLUS INSULIN ALGORITHM (SLIDING SCALE)

Bolus Adjustment Method at Timepoint 1 CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

PPG all meals (SMPG) (mmol/L) at Baseline

Coefficients for TRTPN Least Squares Means Using WORK.ENDPOINT Margins

Bolus Adjustment Method at Timepoint 1	Planned Treatment (N)	Row1	Row2	Row3
	1	1	1	1
	2	1		
	3		1	
	4			1
		0.1351	0.1351	0.1351
		0.3367	0.3367	0.3367
		0.2467	0.2467	0.2467
		0.2815	0.2815	0.2815
BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.5793	0.5793	0.5793
CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0.4207	0.4207	0.4207
		9.5719	9.5719	9.5719

Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG7870 Parameter=PPG <=7.8 mmol/L and HbA1c <7.0% without severe hypo and with minimal weight gain

The GENMOD Procedure

TRTPN Least Squares Means

Planned Treatment (N)	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
2	WORK.ENDPOINT	-2.7689	0.2347	-11.80	<.0001	0.05	-3.2290	-2.3088
3	WORK.ENDPOINT	-3.2906	0.2817	-11.68	<.0001	0.05	-3.8428	-2.7384
4	WORK.ENDPOINT	-2.7277	0.2274	-12.00	<.0001	0.05	-3.1734	-2.2821

Differences of TRTPN Least Squares Means

Planned Treatment (N)	Planned Treatment (N)	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
2	4	WORK.ENDPOINT	-0.04120	0.2955	-0.14	0.8891	0.05	-0.6204	0.5380
3	4	WORK.ENDPOINT	-0.5629	0.3329	-1.69	0.0909	0.05	-1.2154	0.08965

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) / NovoRapid (meal)	WORK.ENDPOINT	-0.04120	0.2955	-0.14	0.8891	0.05	-0.6204	0.5380

Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
TRTPN	Faster aspart (post) / NovoRapid (meal)	WORK.ENDPOINT	-0.5629	0.3329	-1.69	0.0909	0.05	-1.2154	0.08965

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
1	1	0.0987884	-2.21076	0.3867538	0.0890293
2	1	0.0575476	-2.795873	0.39246	0.0542359
3	1	0.0249126	-3.667154	0.4472121	0.0242919
4	1	0.0080062	-4.819495	0.5771667	0.0079421
5	1	0.0300912	-3.472968	0.4308999	0.0291857
6	1	0.2655764	-1.017183	0.3960991	0.1950456
7	1	0.0198879	-3.897555	0.4427567	0.0194924
8	1	0.0126169	-4.360024	0.4815146	0.0124577
9	1	0.1151106	-2.03957	0.3902471	0.1018601
10	1	0.1324799	-1.879208	0.3268445	0.114929
11	1	0.0865585	-2.356399	0.3856167	0.0790661
12	1	0.010734	-4.523549	0.4976923	0.0106188
13	1	0.1057837	-2.134551	0.4256174	0.0945935
14	1	0.1989579	-1.39282	0.4048448	0.1593737
15	1	0.0992443	-2.20565	0.3868245	0.0893949

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Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
16	1	0.3489309	-0.623742	0.4780577	0.2271781
17	1	0.0305771	-3.45645	0.3934062	0.0296421
18	1	0.1071047	-2.120663	0.3232757	0.0956333
19	1	0.0732711	-2.537495	0.3682775	0.0679024
20	1	0.0042769	-5.450244	0.6698811	0.0042586
21	1	0.0110309	-4.495963	0.5251047	0.0109092
22	1	0.0189633	-3.946102	0.4462855	0.0186037
23	1	0.024602	-3.680019	0.4089059	0.0239967
24	1	0.0037343	-5.586462	0.625375	0.0037203
25	1	0.0169385	-4.06108	0.4551748	0.0166516
26	1	0.0191065	-3.938437	0.4457193	0.0187414
27	1	0.0076484	-4.865575	0.5338145	0.0075899
28	1	0.0602378	-2.747326	0.3909579	0.0566092
29	1	0.0493256	-2.958728	0.352862	0.0468926
30	1	0.0270426	-3.582926	0.4017743	0.0263113
31	1	0.0108204	-4.51544	0.5385136	0.0107033
32	1	0.0231068	-3.744251	0.4325346	0.0225729
33	0	0.1204899	-1.987799	0.3245557	0.1059721
34	1	0.11122	-2.07834	0.4287739	0.0988501
35	1	0.0279414	-3.549306	0.4222642	0.0271607
36	1	0.052391	-2.895206	0.3787617	0.0496462
37	1	0.0026343	-5.936508	0.6735406	0.0026273
38	1	0.0245935	-3.680374	0.4287055	0.0239886
39	1	0.0109256	-4.505664	0.4958671	0.0108062

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
40	0	0.1534424	-1.707853	0.4544496	0.1298978
41	1	0.0713586	-2.566005	0.3687856	0.0662666
42	1	0.1865734	-1.472431	0.4245511	0.1517637
43	1	0.016578	-4.082963	0.4687894	0.0163032
44	1	0.063673	-2.688205	0.3518065	0.0596187
45	1	0.0353477	-3.306534	0.3942215	0.0340983
46	1	0.0790233	-2.455692	0.3435176	0.0727786
47	1	0.0621407	-2.714199	0.3683947	0.0582792
48	1	0.0424056	-3.117143	0.36495	0.0406074
49	0	0.3238521	-0.736125	0.4236523	0.2189719
50	0	0.0389074	-3.206886	0.3856271	0.0373936
51	1	0.0458756	-3.034862	0.3738364	0.043771
52	0	0.0839612	-2.389704	0.3716448	0.0769117
53	1	0.0615915	-2.723661	0.3383855	0.057798
54	1	0.0100038	-4.594737	0.500374	0.0099037
55	1	0.0611319	-2.731641	0.3538591	0.0573948
56	1	0.0097292	-4.622843	0.5037375	0.0096346
57	1	0.0180046	-3.99896	0.4679662	0.0176804
58	1	0.0183752	-3.978205	0.4556047	0.0180376
59	1	0.0497108	-2.950544	0.3715825	0.0472396
60	0	0.279311	-0.947882	0.3868459	0.2012964
61	1	0.0334803	-3.362745	0.3993283	0.0323593
62	1	0.0123068	-4.38522	0.4761742	0.0121553
63	1	0.0251785	-3.656265	0.4175889	0.0245445

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
64	1	0.0212323	-3.830768	0.4211166	0.0207815
65	1	0.0229997	-3.749006	0.4143274	0.0224707
66	1	0.0481064	-2.985038	0.3724346	0.0457922
67	1	0.0243276	-3.691517	0.4097895	0.0237357
68	1	0.1282444	-1.916571	0.3428442	0.1117978
69	1	0.0669478	-2.634548	0.3494856	0.0624658
70	1	0.1805141	-1.512869	0.3591658	0.1479287
71	1	0.2136542	-1.303038	0.3563334	0.1680061
72	1	0.0220436	-3.792442	0.4178861	0.0215577
73	1	0.0685817	-2.608683	0.3329538	0.0638783
74	0	0.0214551	-3.820104	0.4469009	0.0209948
75	1	0.0409766	-3.152914	0.3679174	0.0392975
76	1	0.0134426	-4.295793	0.4663518	0.0132619
77	1	0.1933736	-1.428237	0.3476275	0.1559803
78	1	0.0174924	-4.028343	0.4715382	0.0171864
79	1	0.0501561	-2.941157	0.3658501	0.0476405
80	1	0.0695675	-2.593352	0.3323161	0.0647279
81	1	0.0647476	-2.670319	0.3510063	0.0605554
82	1	0.054083	-2.861635	0.3463566	0.051158
83	1	0.158295	-1.670969	0.334264	0.1332377
84	0	0.1634256	-1.632957	0.3528958	0.1367177
85	1	0.0409468	-3.153673	0.3779807	0.0392702
86	1	0.0531594	-2.879835	0.3619925	0.0503335
87	1	0.0224886	-3.772002	0.4161977	0.0219829

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
88	0	0.0876274	-2.342955	0.3249125	0.0799489
89	1	0.0321685	-3.40407	0.3902604	0.0311337
90	1	0.2018809	-1.37458	0.3512156	0.161125
91	1	0.0804525	-2.436215	0.3269953	0.0739799
92	1	0.0820739	-2.414497	0.3264377	0.0753378
93	1	0.0160048	-4.118734	0.473372	0.0157486
94	1	0.068725	-2.606442	0.348366	0.0640018
95	1	0.0270626	-3.582168	0.4094514	0.0263302
96	1	0.0435301	-3.089796	0.3756134	0.0416353
97	1	0.0832092	-2.399521	0.3670536	0.0762855
98	1	0.0037659	-5.577998	0.6893629	0.0037517
99	1	0.0709973	-2.57147	0.4084975	0.0659567
100	1	0.1136256	-2.054231	0.323705	0.1007148
101	1	0.0518705	-2.905741	0.3965195	0.0491799
102	1	0.0560186	-2.824422	0.4049873	0.0528805
103	0	0.0428226	-3.106923	0.3641178	0.0409888
104	1	0.0469679	-3.010185	0.38427	0.0447619
105	1	0.0851793	-2.37397	0.3670031	0.0779237
106	1	0.0399842	-3.178465	0.3700881	0.0383855
107	1	0.0132408	-4.311123	0.4680126	0.0130655
108	1	0.1245282	-1.950231	0.389602	0.1090209
109	1	0.0540487	-2.862305	0.3948063	0.0511275
110	1	0.1585884	-1.668769	0.3868456	0.1334381
111	0	0.0390975	-3.201816	0.3955889	0.0375688

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
112	1	0.0853786	-2.371415	0.3670011	0.0780891
113	1	0.0214543	-3.820145	0.4477775	0.020994
114	1	0.0085515	-4.753063	0.5685153	0.0084784
115	1	0.004531	-5.392276	0.5997206	0.0045104
116	1	0.1135899	-2.054585	0.3710045	0.1006872
117	1	0.0994729	-2.203095	0.3868606	0.0895781
118	1	0.214885	-1.295727	0.4123547	0.1687094
119	0	0.0521224	-2.900631	0.3963107	0.0494056
120	1	0.0344854	-3.332125	0.4047148	0.0332962
121	0	0.1180046	-2.011464	0.3910399	0.1040795
122	1	0.0210137	-3.841344	0.4388435	0.0205721
123	1	0.0310085	-3.441993	0.4132436	0.030047
124	1	0.0211283	-3.83579	0.4629638	0.0206818
125	1	0.0541568	-2.860194	0.4048842	0.0512238
126	1	0.0101532	-4.579761	0.5035138	0.0100501
127	1	0.0765829	-2.489707	0.4106603	0.070718
128	1	0.0249725	-3.664688	0.4077405	0.0243489
129	1	0.2556618	-1.06864	0.4495312	0.1902989
130	1	0.024168	-3.698259	0.4297514	0.0235839
131	1	0.0330438	-3.376319	0.4141982	0.0319519
132	1	0.0751384	-2.510312	0.3292253	0.0694926
133	1	0.0136185	-4.282614	0.4989244	0.013433
134	1	0.0997303	-2.200225	0.3681209	0.0897842
135	1	0.0388299	-3.208962	0.4089942	0.0373221

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Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
136	1	0.0516525	-2.910182	0.3495199	0.0489845
137	1	0.0410005	-3.152306	0.4088291	0.0393195
138	1	0.1983478	-1.396653	0.4045603	0.1590059
139	1	0.0576622	-2.793761	0.4051536	0.0543373
140	1	0.0370125	-3.258786	0.4103291	0.0356425
141	1	0.101613	-2.17943	0.3232486	0.0912878
142	1	0.0399721	-3.17878	0.3833134	0.0383744
143	1	0.0773658	-2.478688	0.3441293	0.0713803
144	1	0.0977158	-2.222866	0.3234414	0.0881675
145	1	0.054701	-2.849618	0.3696517	0.0517088
146	1	0.0437434	-3.084686	0.375438	0.0418299
147	1	0.0388237	-3.209126	0.3727479	0.0373165
148	1	0.1146271	-2.044325	0.3406198	0.1014877
149	1	0.079644	-2.447194	0.3704291	0.0733008
150	1	0.0158446	-4.128954	0.4746886	0.0155936
151	1	0.0364193	-3.275558	0.3787109	0.0350929
152	1	0.0081488	-4.801698	0.5257294	0.0080824
153	1	0.1061312	-2.130883	0.3232472	0.0948674
154	1	0.1525525	-1.71472	0.3492957	0.1292803
155	1	0.1322461	-1.881244	0.3937301	0.1147571
156	1	0.0129111	-4.336674	0.4708021	0.0127444
157	0	0.0572902	-2.800628	0.3574314	0.0540081
158	1	0.0202554	-3.878871	0.4536891	0.0198451
159	1	0.017123	-4.050061	0.4741974	0.0168298

Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
160	1	0.0686966	-2.606886	0.3684932	0.0639773
161	1	0.008486	-4.760817	0.5206166	0.008414
162	1	0.0458197	-3.036139	0.3738749	0.0437202
163	1	0.050293	-2.938288	0.3514333	0.0477636
164	1	0.0217699	-3.805218	0.4189536	0.0212959
165	1	0.0430325	-3.101813	0.3637043	0.0411807
166	1	0.0329163	-3.380316	0.3886441	0.0318328
167	1	0.0069509	-4.96191	0.5906241	0.0069026
168	1	0.0371322	-3.255432	0.3897391	0.0357534
169	1	0.0153621	-4.160374	0.4521164	0.0151261
170	1	0.069382	-2.596222	0.3479754	0.0645681
171	1	0.0685616	-2.608997	0.348465	0.0638609
172	1	0.1525932	-1.714405	0.3323962	0.1293085
173	1	0.0321921	-3.403312	0.3909073	0.0311558
174	1	0.0492059	-2.961283	0.3530428	0.0467847
175	1	0.0139957	-4.254911	0.4619708	0.0137998
176	1	0.0041483	-5.480905	0.6745396	0.0041311
177	1	0.0499528	-2.945434	0.3714645	0.0474575
178	1	0.0364193	-3.275558	0.3787109	0.0350929
179	1	0.0157207	-4.136934	0.4849898	0.0154735
180	1	0.0357968	-3.293444	0.3803619	0.0345154
181	1	0.03273	-3.386185	0.3892305	0.0316588
182	1	0.0306909	-3.452617	0.3931695	0.029749
183	1	0.0205016	-3.86654	0.4242064	0.0200812

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
184	1	0.0495658	-2.953618	0.352502	0.047109
185	1	0.1315655	-1.887188	0.3435622	0.114256
186	1	0.0232406	-3.738342	0.4376884	0.0227004
187	1	0.0053471	-5.225841	0.581388	0.0053185
188	1	0.0157207	-4.136934	0.4849898	0.0154735
189	1	0.0421843	-3.122608	0.3905968	0.0404048
190	1	0.0709023	-2.572912	0.3314981	0.0658751
191	1	0.0274608	-3.567152	0.4193467	0.0267067
192	1	0.1060101	-2.132161	0.3232443	0.0947719
193	1	0.0138205	-4.267687	0.4633323	0.0136295
194	1	0.0183688	-3.978559	0.4643243	0.0180314
195	1	0.0143996	-4.226047	0.48735	0.0141923
196	1	0.0421986	-3.122253	0.3653688	0.0404179
197	1	0.0909254	-2.302388	0.3406444	0.082658
198	1	0.0394967	-3.191241	0.3711891	0.0379367
199	1	0.3258825	-0.726868	0.4095246	0.2196831
200	1	0.0228851	-3.754116	0.4147404	0.0223614
201	1	0.0697127	-2.591112	0.3477835	0.0648528
202	1	0.0188751	-3.950857	0.4317657	0.0185188
203	1	0.0333977	-3.3653	0.3995647	0.0322823
204	1	0.0460631	-3.030585	0.3719663	0.0439413
205	1	0.1017771	-2.177633	0.3784452	0.0914185
206	1	0.0372236	-3.252877	0.3895191	0.035838
207	1	0.1470609	-1.757842	0.3306949	0.125434

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
208	1	0.0025952	-5.951483	0.6850623	0.0025885
209	1	0.034387	-3.335083	0.3864143	0.0332046
210	1	0.1117261	-2.073229	0.429071	0.0992434
211	1	0.0618435	-2.719309	0.3684142	0.0580189
212	1	0.0311144	-3.438475	0.428223	0.0301463
213	1	0.0353464	-3.306574	0.4028387	0.034097
214	1	0.0095835	-4.638084	0.5538065	0.0094916
215	1	0.0345706	-3.32957	0.4045253	0.0333755
216	1	0.027528	-3.564637	0.423606	0.0267702
217	1	0.1659292	-1.614757	0.3369236	0.1383967
218	1	0.1032283	-2.161858	0.3398782	0.0925722
219	1	0.0113803	-4.464428	0.4851349	0.0112508
220	1	0.1046145	-2.146972	0.3797223	0.0936703
221	1	0.1063439	-2.128642	0.3399602	0.0950349
222	0	0.1355569	-1.852694	0.3445024	0.1171812
223	1	0.0213922	-3.823103	0.4204638	0.0209346
224	1	0.0461894	-3.027716	0.3579091	0.0440559
225	1	0.0150104	-4.183888	0.4818186	0.0147851
226	1	0.0619919	-2.716754	0.3684041	0.0581489
227	1	0.0052528	-5.243727	0.5838285	0.0052252
228	1	0.0977158	-2.222866	0.3234414	0.0881675
229	1	0.0079449	-4.827249	0.5289495	0.0078818
230	1	0.0153302	-4.162485	0.4882099	0.0150951
231	1	0.0228281	-3.756671	0.4149474	0.022307

Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
232	1	0.0435301	-3.089796	0.3756134	0.0416353
233	1	0.0195001	-3.917641	0.4287423	0.0191199
234	1	0.0770242	-2.483484	0.3283598	0.0710914
235	1	0.0054708	-5.202846	0.5782604	0.0054409
236	1	0.01328	-4.308124	0.5069365	0.0131037
237	1	0.0412664	-3.145564	0.380644	0.0395635
238	1	0.0814747	-2.422476	0.3427167	0.0748366
239	1	0.1168822	-2.022292	0.3240616	0.1032207
240	1	0.1374007	-1.837049	0.3280293	0.1185217
241	1	0.0149427	-4.188479	0.4550047	0.0147194
242	1	0.0044963	-5.399993	0.6646413	0.0044761
243	1	0.0630161	-2.699275	0.4510281	0.0590451
244	1	0.0253198	-3.650523	0.4932529	0.0246787
245	1	0.0767601	-2.487204	0.4515191	0.070868
246	1	0.0021852	-6.123838	0.7146952	0.0021805
247	1	0.0565588	-2.814254	0.4520534	0.0533599
248	1	0.0095758	-4.638894	0.5769266	0.0094841
249	1	0.0116579	-4.440042	0.5361507	0.011522
250	1	0.0551712	-2.840563	0.4880301	0.0521273
251	1	0.120604	-1.986723	0.4721087	0.1060587
252	1	0.0142642	-4.235636	0.5218387	0.0140607
253	1	0.0399275	-3.179944	0.4672993	0.0383333
254	1	0.0111116	-4.488588	0.5398468	0.0109882
255	1	0.0429534	-3.103736	0.4851556	0.0411084

Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
256	1	0.0102482	-4.570351	0.5463178	0.0101432
257	1	0.062117	-2.714606	0.4511125	0.0582585
258	1	0.0252568	-3.653078	0.4933346	0.0246189
259	1	0.0094554	-4.651669	0.5782991	0.009366
260	1	0.0299281	-3.478574	0.4751395	0.0290324
261	1	0.0200871	-3.887386	0.5025292	0.0196836
262	1	0.0000519	-9.86627	1.3522494	0.0000519
263	1	0.012056	-4.406067	0.5490261	0.0119106
264	1	0.0114478	-4.458446	0.5543418	0.0113167
265	0	0.0090801	-4.692551	0.5827276	0.0089976
266	1	0.0052334	-5.247447	0.6104127	0.005206
267	1	0.0738911	-2.528399	0.458138	0.0684312
268	1	0.0033958	-5.68181	0.6596496	0.0033843
269	1	0.0025014	-5.988419	0.6973701	0.0024951
270	1	0.0198808	-3.897921	0.5081393	0.0194855
271	1	0.0708256	-2.574076	0.4509442	0.0658093
272	1	0.0241489	-3.699069	0.4948719	0.0235658
273	1	0.0747394	-2.516068	0.4975306	0.0691534
274	1	0.0251313	-3.658188	0.4934991	0.0244997
275	1	0.0354825	-3.302588	0.4721325	0.0342235
276	1	0.0769191	-2.484963	0.4585427	0.0710025
277	1	0.007659	-4.864185	0.5719658	0.0076003
278	1	0.0612118	-2.730251	0.4579323	0.0574649
279	1	0.1421377	-1.797647	0.4813606	0.1219346

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
280	1	0.0490175	-2.965318	0.461159	0.0466148
281	1	0.0504454	-2.935101	0.4864916	0.0479007
282	1	0.1219992	-1.973633	0.4652957	0.1071154
283	0	0.0791474	-2.453988	0.4518756	0.0728831
284	1	0.0861163	-2.362005	0.4532556	0.0787003
285	1	0.0698233	-2.589407	0.4508966	0.064948
286	1	0.0691624	-2.599627	0.4508738	0.064379
287	1	0.0780373	-2.469318	0.4517017	0.0719475
288	1	0.0534651	-2.873779	0.4874253	0.0506066
289	1	0.0813876	-2.423641	0.4593304	0.0747637
290	1	0.0875343	-2.344119	0.4535906	0.0798721
291	1	0.0186654	-3.962242	0.5060775	0.018317
292	1	0.0520979	-2.901126	0.4534267	0.0493837
293	1	0.0318393	-3.414697	0.4717096	0.0308256
294	0	0.1831255	-1.495314	0.5653106	0.1495905
295	1	0.0367725	-3.265539	0.4705732	0.0354203
296	1	0.0137066	-4.276073	0.5404092	0.0135188
297	1	0.0873305	-2.346674	0.4535415	0.0797039
298	1	0.0148693	-4.193477	0.5191483	0.0146482
299	1	0.0379978	-3.23149	0.4853522	0.0365539
300	1	0.0328793	-3.381481	0.4700225	0.0317982
301	1	0.0348755	-3.320474	0.4729157	0.0336592
302	1	0.0420358	-3.126288	0.4654841	0.0402688
303	1	0.0162294	-4.104568	0.5205553	0.015966

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
304	1	0.0463496	-3.024085	0.4625414	0.0442013
305	1	0.0401238	-3.174834	0.4671185	0.0385139
306	1	0.0962438	-2.239675	0.4631983	0.0869809
307	0	0.0302789	-3.466557	0.488429	0.0293621
308	1	0.0189149	-3.948708	0.5073918	0.0185571
309	1	0.0081044	-4.807215	0.5921887	0.0080387
310	1	0.029611	-3.489553	0.4889173	0.0287341
311	1	0.0463496	-3.024085	0.4625414	0.0442013
312	1	0.0706576	-2.576631	0.4509351	0.0656651
313	1	0.0363518	-3.277481	0.4856782	0.0350304
314	1	0.0264256	-3.606642	0.4880465	0.0257273
315	1	0.0203759	-3.872814	0.5018179	0.0199608
316	1	0.0156239	-4.143209	0.5283397	0.0153798
317	0	0.0767601	-2.487204	0.4515191	0.070868
318	1	0.054509	-2.853338	0.4877893	0.0515378
319	1	0.0093129	-4.667	0.5799533	0.0092262
320	1	0.0194436	-3.920602	0.5051403	0.0190655
321	1	0.0181199	-3.992459	0.5155901	0.0177916
322	1	0.0099588	-4.59929	0.5727072	0.0098596
323	0	0.0363784	-3.276723	0.4651437	0.035055
324	1	0.0553442	-2.837249	0.452367	0.0522812
325	1	0.0147684	-4.200384	0.5291919	0.0145503
326	1	0.1064339	-2.127696	0.5170389	0.0951057
327	1	0.0087223	-4.733117	0.5838128	0.0086462

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
328	1	0.0794977	-2.449192	0.4589715	0.0731778
329	1	0.0293187	-3.499773	0.4891448	0.0284591
330	1	0.0180745	-3.995014	0.5157974	0.0177478
331	1	0.0253939	-3.647524	0.4905927	0.0247491
332	1	0.165415	-1.618477	0.4845649	0.1380529
333	1	0.0254017	-3.647209	0.4853323	0.0247565
334	1	0.1114366	-2.07615	0.4684942	0.0990185
335	1	0.0602098	-2.747822	0.4513505	0.0565846
336	1	0.0747394	-2.516068	0.4975306	0.0691534
337	1	0.1255675	-1.940731	0.4741606	0.1098003
338	1	0.0732161	-2.538305	0.4511182	0.0678555
339	1	0.0497371	-2.949987	0.4608359	0.0472633
340	1	0.0725256	-2.548525	0.4510595	0.0672656
341	1	0.1891924	-1.455266	0.5033139	0.1533986
342	1	0.0241489	-3.699069	0.4948719	0.0235658
343	1	0.0402345	-3.171965	0.4609521	0.0386157
344	1	0.0749471	-2.513069	0.4582663	0.06933
345	1	0.0620587	-2.715607	0.3282745	0.0582074
346	1	0.0643218	-2.677373	0.311473	0.0601845
347	1	0.1860833	-1.475664	0.2912866	0.1514563
348	0	0.0820412	-2.414931	0.2944714	0.0753104
349	0	0.0994693	-2.203135	0.2855074	0.0895751
350	1	0.1938384	-1.425259	0.2976692	0.1562651
351	1	0.070634	-2.576992	0.3162468	0.0656448

Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
352	1	0.0898107	-2.315949	0.342881	0.0817447
353	1	0.120969	-1.983286	0.3064628	0.1063355
354	1	0.0206945	-3.856973	0.4323918	0.0202663
355	1	0.0901878	-2.311344	0.3430089	0.0820539
356	1	0.0183197	-3.981288	0.4481311	0.0179841
357	1	0.0346321	-3.327727	0.3740094	0.0334328
358	1	0.0528762	-2.885476	0.3341759	0.0500803
359	1	0.1327171	-1.877145	0.3089354	0.1151033
360	1	0.056199	-2.821017	0.3297711	0.0530407
361	1	0.1386559	-1.826499	0.3103048	0.1194305
362	1	0.1101526	-2.089183	0.3057324	0.098019
363	1	0.0749843	-2.512532	0.3135616	0.0693617
364	1	0.1014452	-2.181268	0.306021	0.0911541
365	1	0.1224716	-1.96923	0.3070943	0.1074723
366	1	0.0818673	-2.417242	0.340543	0.0751651
367	1	0.0090874	-4.691742	0.4976702	0.0090048
368	1	0.1449279	-1.774949	0.3699696	0.1239238
369	1	0.0940377	-2.265302	0.3443907	0.0851946
370	1	0.0250212	-3.662692	0.3851508	0.0243951
371	1	0.0551571	-2.840833	0.3408563	0.0521148
372	1	0.0224373	-3.774339	0.4242158	0.0219338
373	1	0.0451041	-3.052629	0.347078	0.0430697
374	1	0.0875779	-2.343574	0.3421527	0.079908
375	1	0.1689508	-1.593081	0.3839871	0.1404064

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Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
376	0	0.1596294	-1.660988	0.3155319	0.1341479
377	1	0.1296723	-1.903859	0.2809121	0.1128574
378	1	0.1596294	-1.660988	0.3155319	0.1341479
379	1	0.0571084	-2.803999	0.3401803	0.0538471
380	1	0.0211663	-3.833952	0.4295362	0.0207183
381	1	0.0187126	-3.959666	0.4126327	0.0183625
382	1	0.0505501	-2.932918	0.3430773	0.0479948
383	1	0.0542051	-2.85925	0.34124	0.0512669
384	1	0.0549777	-2.844281	0.3323344	0.0519552
385	1	0.0630033	-2.699492	0.3278249	0.0590339
386	1	0.0809028	-2.430143	0.3239185	0.0743576
387	1	0.1143973	-2.046591	0.2818865	0.1013106
388	1	0.1230656	-1.963714	0.2810476	0.1079205
389	1	0.0906414	-2.305828	0.324447	0.0824255
390	1	0.1066168	-2.125775	0.305918	0.0952496
391	1	0.0980351	-2.21925	0.2860284	0.0884242
392	1	0.1270963	-1.92688	0.2809174	0.1109428
393	1	0.0986475	-2.212344	0.2858018	0.0889161
394	1	0.2203087	-1.263868	0.3032949	0.1717728
395	1	0.0589194	-2.770858	0.3299967	0.0554479
396	1	0.1237866	-1.95705	0.286105	0.1084635
397	1	0.0216382	-3.811418	0.4069534	0.02117
398	1	0.1245641	-1.949902	0.2809812	0.1090479
399	1	0.0503732	-2.936611	0.336801	0.0478357

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
400	1	0.1449291	-1.77494	0.2819616	0.1239246
401	1	0.0506611	-2.930607	0.3331753	0.0480946
402	1	0.0414828	-3.14011	0.3507748	0.0397619
403	1	0.0443768	-3.069646	0.348496	0.0424075
404	1	0.0113611	-4.466134	0.4693358	0.011232
405	1	0.0490907	-2.963749	0.3399577	0.0466808
406	0	0.0630855	-2.698102	0.3389216	0.0591057
407	1	0.1736905	-1.559695	0.3204121	0.1435221
408	1	0.0238685	-3.711037	0.3892782	0.0232988
409	0	0.1378043	-1.833647	0.3094143	0.1188143
410	1	0.0682385	-2.614068	0.318628	0.063582
411	1	0.1815917	-1.505601	0.391485	0.1486162
412	1	0.0542051	-2.85925	0.34124	0.0512669
413	0	0.2777548	-0.955626	0.3303848	0.2006071
414	1	0.045542	-3.042509	0.3423824	0.0434679
415	0	0.2026185	-1.370008	0.3005233	0.1615642
416	1	0.1075613	-2.115897	0.2885166	0.0959919
417	1	0.2203087	-1.263868	0.3032949	0.1717728
418	1	0.2195189	-1.268472	0.3029901	0.1713303
419	1	0.0054509	-5.206507	0.5890894	0.0054212
420	0	0.1143973	-2.046591	0.2818865	0.1013106
421	1	0.0493489	-2.958233	0.3358164	0.0469135
422	1	0.0061963	-5.077588	0.5702627	0.0061579
423	1	0.1437618	-1.784391	0.2865744	0.1230943

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Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
424	1	0.0233588	-3.733146	0.3987595	0.0228132
425	0	0.1015284	-2.180357	0.2902595	0.0912204
426	1	0.2079155	-1.337536	0.2986449	0.1646867
427	1	0.0555059	-2.83416	0.3302207	0.052425
428	0	0.1603708	-1.655472	0.2890179	0.134652
429	1	0.2258524	-1.231881	0.3088864	0.1748431
430	0	0.1092768	-2.098149	0.3059454	0.0973354
431	1	0.1280943	-1.917914	0.2859282	0.1116862
432	1	0.0571838	-2.8026	0.3285738	0.0539139
433	1	0.0497281	-2.950178	0.3400799	0.0472552
434	1	0.0806648	-2.433348	0.2954606	0.074158
435	1	0.0614454	-2.726193	0.3239061	0.0576698
436	1	0.137029	-1.840189	0.2860696	0.118252
437	1	0.0218827	-3.799934	0.4406592	0.0214038
438	1	0.0228741	-3.754612	0.4198461	0.0223508
439	1	0.0487903	-2.970203	0.3404549	0.0464098
440	1	0.0118427	-4.424131	0.4800217	0.0117024
441	0	0.1849999	-1.482833	0.3247207	0.150775
442	1	0.0289861	-3.511525	0.3976526	0.0281459
443	1	0.2154934	-1.292125	0.3050286	0.169056
444	1	0.022356	-3.778051	0.3952316	0.0218562
445	1	0.1246135	-1.949449	0.3074186	0.1090849
446	1	0.0274239	-3.568535	0.3775341	0.0266718
447	1	0.0316999	-3.419227	0.3920622	0.0306951

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
448	1	0.0653119	-2.661038	0.3203189	0.0610463
449	1	0.0477139	-2.993642	0.3449515	0.0454373
450	1	0.0777238	-2.473684	0.33964	0.0716828
451	1	0.0239846	-3.706065	0.4140376	0.0234094
452	1	0.1250665	-1.945302	0.3070006	0.1094249
453	1	0.0750759	-2.511211	0.2999945	0.0694395
454	1	0.1058001	-2.134378	0.3057666	0.0946065
455	1	0.1577763	-1.674867	0.3489756	0.132883
456	1	0.0136052	-4.283602	0.4620589	0.0134201
457	1	0.0887522	-2.328967	0.3242367	0.0808752
458	1	0.0861372	-2.361739	0.291798	0.0787176
459	1	0.0468095	-3.013728	0.3407736	0.0446184
460	1	0.1409233	-1.807642	0.3108785	0.121064
461	1	0.0430099	-3.102364	0.3459423	0.04116
462	1	0.0496739	-2.951326	0.3351515	0.0472064
463	1	0.0276086	-3.561632	0.4096309	0.0268463
464	1	0.0405229	-3.164521	0.3499369	0.0388808
465	1	0.2109649	-1.319119	0.2997616	0.1664587
466	1	0.0561731	-2.821505	0.3318182	0.0530177
467	1	0.0400337	-3.177177	0.3642231	0.038431
468	1	0.0792074	-2.453164	0.3239829	0.0729336
469	1	0.0471702	-3.005675	0.3403355	0.0449451
470	0	0.0956974	-2.245973	0.3252271	0.0865394
471	0	0.1460437	-1.765974	0.2868148	0.1247149

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
472	1	0.0806648	-2.433348	0.2954606	0.074158
473	1	0.0792074	-2.453164	0.3239829	0.0729336
474	1	0.0399546	-3.179237	0.3586245	0.0383582
475	1	0.1220753	-1.972923	0.2811035	0.1071729
476	1	0.0445517	-3.06553	0.3437177	0.0425669
477	1	0.1541167	-1.702672	0.3471829	0.1303647
478	1	0.0677129	-2.622365	0.3132255	0.0631278
479	1	0.1825855	-1.498927	0.2943215	0.1492481
480	1	0.1291536	-1.908463	0.2809084	0.1124729
481	1	0.0563697	-2.817803	0.3229279	0.0531921
482	1	0.0486936	-2.972288	0.3430402	0.0463226
483	1	0.0809028	-2.430143	0.3239185	0.0743576
484	1	0.0437743	-3.083947	0.3448165	0.0418581
485	1	0.0308726	-3.446526	0.3953673	0.0299195
486	0	0.15188	-1.719932	0.2875748	0.1288125
487	1	0.1512878	-1.724536	0.2874886	0.1283998
488	1	0.0164268	-4.092278	0.4386667	0.016157
489	1	0.0685162	-2.609709	0.3257614	0.0638217
490	1	0.1071201	-2.120501	0.2886266	0.0956454
491	1	0.2179039	-1.277923	0.3059092	0.1704218
492	1	0.1052623	-2.140075	0.3274351	0.0941821
493	1	0.0561731	-2.821505	0.3318182	0.0530177
494	1	0.0368444	-3.263513	0.3569	0.0354868
495	1	0.1397007	-1.817778	0.340411	0.1201844

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
496	1	0.0875592	-2.343808	0.2965868	0.0798926
497	1	0.0478476	-2.990705	0.3448431	0.0455582
498	1	0.1279652	-1.919071	0.3353533	0.1115901
499	1	0.1032432	-2.161697	0.2842934	0.0925841
500	1	0.1809098	-1.510196	0.2897371	0.1481814
501	1	0.1087822	-2.103241	0.3284479	0.0969486
502	1	0.1436194	-1.785548	0.3421996	0.1229929
503	0	0.0756723	-2.502654	0.3052213	0.069946
504	1	0.0404335	-3.166823	0.3500905	0.0387986
505	1	0.1449291	-1.77494	0.2819616	0.1239246
506	1	0.0994476	-2.203378	0.2909868	0.0895577
507	1	0.189558	-1.452885	0.2963517	0.1536257
508	1	0.0589194	-2.770858	0.3299967	0.0554479
509	0	0.2234886	-1.245451	0.3045327	0.1735414
510	1	0.0592532	-2.764854	0.3184317	0.0557423
511	1	0.0326781	-3.387827	0.3666324	0.0316102
512	1	0.0753678	-2.507016	0.299736	0.0696875
513	1	0.131765	-1.885442	0.2809499	0.114403
514	1	0.0346708	-3.326573	0.3753049	0.0334687
515	1	0.0725141	-2.548697	0.3081538	0.0672558
516	1	0.0625969	-2.706398	0.3280146	0.0586785
517	1	0.1039685	-2.153888	0.3270877	0.093159
518	1	0.0444155	-3.068735	0.3468622	0.0424428
519	1	0.0766441	-2.488841	0.3043781	0.0707698

Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
520	1	0.0953995	-2.24942	0.2926044	0.0862984
521	1	0.0147504	-4.201623	0.4966138	0.0145329
522	1	0.0592532	-2.764854	0.3184317	0.0557423
523	1	0.0175213	-4.026661	0.4717541	0.0172143
524	1	0.0922881	-2.286012	0.2884744	0.083771
525	1	0.1839639	-1.489719	0.2947108	0.1501212
526	1	0.0232335	-3.738653	0.4268994	0.0226937
527	1	0.02824	-3.538368	0.4010125	0.0274425
528	1	0.0830875	-2.401118	0.2937508	0.0761839
529	1	0.0249873	-3.664082	0.3917901	0.0243629
530	1	0.0383102	-3.222977	0.3634631	0.0368425
531	1	0.1015284	-2.180357	0.2902595	0.0912204
532	1	0.2833306	-0.928	0.3328495	0.2030544
533	1	0.0517798	-2.907586	0.331013	0.0490987
534	1	0.1032432	-2.161697	0.2842934	0.0925841
535	1	0.1981918	-1.397634	0.2990601	0.1589118
536	1	0.0389083	-3.206862	0.3616689	0.0373944
537	1	0.2056499	-1.351349	0.2978279	0.163358
538	1	0.0685901	-2.608552	0.3122398	0.0638855
539	1	0.1023938	-2.170906	0.2845474	0.0919093
540	1	0.2833798	-0.927758	0.3301965	0.2030757
541	1	0.2226486	-1.250298	0.3076733	0.1730762
542	1	0.0508155	-2.927402	0.3363601	0.0482333
543	1	0.0942141	-2.263233	0.2931317	0.0853378

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Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
544	1	0.0873028	-2.347021	0.3086941	0.079681
545	1	0.0390283	-3.203657	0.3526032	0.0375051
546	0	0.180533	-1.51274	0.2937533	0.1479409
547	1	0.0660046	-2.649748	0.3094024	0.061648
548	0	0.0854858	-2.370043	0.3092815	0.078178
549	1	0.0533147	-2.876756	0.3340657	0.0504722
550	1	0.0994476	-2.203378	0.2909868	0.0895577
551	1	0.0380053	-3.231283	0.3545538	0.0365609
552	1	0.0210899	-3.837645	0.4401759	0.0206451
553	1	0.0703004	-2.582083	0.3252786	0.0653583
554	1	0.257945	-1.056677	0.3188491	0.1914094
555	1	0.0847496	-2.379496	0.3239554	0.0775671
556	1	0.1583653	-1.670442	0.3492664	0.1332857
557	1	0.1604034	-1.65523	0.2845591	0.1346742
558	1	0.15307	-1.710723	0.287754	0.1296395
559	1	0.0034983	-5.651962	0.720614	0.0034861
560	1	0.0492832	-2.959632	0.3379346	0.0468544
561	1	0.1385977	-1.826986	0.3399156	0.1193884
562	1	0.1186376	-2.005395	0.2865522	0.1045627
563	1	0.0938219	-2.267837	0.2933118	0.0850194
564	1	0.1910141	-1.443434	0.2928394	0.1545277
565	0	0.0767224	-2.487737	0.3394601	0.070836
566	1	0.0247205	-3.67509	0.412291	0.0241094
567	1	0.0835551	-2.394996	0.3099768	0.0765736

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
568	1	0.0628787	-2.701605	0.3233097	0.058925
569	0	0.1357463	-1.851078	0.3096089	0.1173193
570	1	0.0893813	-2.321213	0.3079269	0.0813923
571	1	0.0523244	-2.896549	0.34211	0.0495866
572	1	0.0557581	-2.829359	0.3313129	0.0526492
573	1	0.207972	-1.337193	0.3342385	0.1647197
574	1	0.0189084	-3.949058	0.4440005	0.0185509
575	1	0.0571084	-2.803999	0.3401803	0.0538471
576	1	0.0590586	-2.768352	0.3264212	0.0555706
577	1	0.0289761	-3.511879	0.3918094	0.0281365
578	0	0.1529832	-1.711392	0.3143375	0.1295794
579	1	0.0398383	-3.182274	0.3584195	0.0382512
580	1	0.1193123	-1.998958	0.3062832	0.1050769
581	1	0.021913	-3.798518	0.3971019	0.0214328
582	1	0.2108131	-1.320031	0.3369268	0.166371
583	1	0.0600553	-2.750555	0.3293315	0.0564487
584	1	0.1224007	-1.96989	0.3070841	0.1074188
585	1	0.0450362	-3.054206	0.3484935	0.043008
586	1	0.057533	-2.796143	0.3291028	0.0542229
587	1	0.0255153	-3.642632	0.3834807	0.0248642
588	1	0.0860018	-2.363461	0.3240182	0.0786055
589	1	0.2070799	-1.342618	0.3352794	0.1641978
590	1	0.092513	-2.283331	0.3438275	0.0839543
591	1	0.0128115	-4.34452	0.4991022	0.0126473

Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
592	1	0.0912339	-2.298661	0.343371	0.0829103
593	1	0.164566	-1.62464	0.3171763	0.137484
594	0	0.2138729	-1.301737	0.3382895	0.1681313
595	1	0.1099496	-2.091256	0.3059643	0.0978607
596	1	0.0548076	-2.847559	0.3315448	0.0518038
597	0	0.0604693	-2.743245	0.3393334	0.0568128
598	1	0.0669088	-2.635173	0.319695	0.062432
599	1	0.0998392	-2.199013	0.3467036	0.0898713
600	1	0.1026696	-2.167908	0.306025	0.0921285
601	1	0.0282536	-3.537874	0.3751786	0.0274553
602	1	0.0425625	-3.113287	0.3522417	0.0407509
603	1	0.0308916	-3.445891	0.3684968	0.0299373
604	1	0.0280824	-3.544127	0.3971855	0.0272938
605	1	0.098992	-2.208475	0.3062706	0.0891926
606	1	0.1512019	-1.725205	0.3137872	0.1283399
607	1	0.0853954	-2.3712	0.3414922	0.078103
608	1	0.0368369	-3.263722	0.3676319	0.03548
609	1	0.2990045	-0.852043	0.3789247	0.2096008
610	0	0.1485517	-1.746006	0.3121646	0.1264841
611	1	0.046453	-3.021748	0.3459275	0.0442951
612	1	0.1008017	-2.188349	0.3061418	0.0906407
613	1	0.155971	-1.688516	0.3143675	0.1316441
614	1	0.04066	-3.161	0.3517517	0.0390068
615	1	0.1097305	-2.093496	0.3057267	0.0976898

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Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
616	1	0.0250227	-3.662629	0.4089221	0.0243966
617	1	0.0480837	-2.985533	0.3416484	0.0457717
618	1	0.1574907	-1.677019	0.3148453	0.1326873
619	0	0.1443056	-1.77998	0.3696137	0.1234815
620	1	0.0584932	-2.778572	0.3270534	0.0550717
621	0	0.0857733	-2.366371	0.3416028	0.0784163
622	1	0.0289231	-3.513765	0.403637	0.0280866
623	1	0.1615592	-1.646672	0.3171519	0.1354578
624	1	0.1058337	-2.134023	0.2889627	0.0946329
625	1	0.1077193	-2.114252	0.30592	0.0961159
626	1	0.0282985	-3.536242	0.3795806	0.0274976
627	1	0.2012679	-1.378389	0.332751	0.1607591
628	1	0.0683331	-2.612581	0.3258158	0.0636637
629	1	0.0200482	-3.889362	0.4527585	0.0196463
630	1	0.0067763	-4.987526	0.5572821	0.0067304
631	1	0.1053176	-2.139488	0.3057835	0.0942258
632	1	0.0889303	-2.326767	0.3425878	0.0810217
633	1	0.046453	-3.021748	0.3459275	0.0442951
634	1	0.0808265	-2.43117	0.3239203	0.0742936
635	1	0.0703607	-2.581162	0.3103323	0.0654101
636	1	0.0163905	-4.094526	0.4389338	0.0161219
637	1	0.0232344	-3.738612	0.4324983	0.0226946
638	1	0.0535329	-2.87244	0.3336452	0.0506671
639	1	0.0905244	-2.307249	0.3244326	0.0823297

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
640	1	0.0877599	-2.341299	0.2908444	0.0800581
641	1	0.0374654	-3.246151	0.3644074	0.0360618
642	1	0.0108406	-4.513559	0.4917594	0.0107231
643	1	0.0729093	-2.542835	0.3077702	0.0675935
644	1	0.1466675	-1.760981	0.2868862	0.1251561
645	0	0.1916938	-1.439042	0.2970027	0.1549473
646	1	0.0454796	-3.043945	0.3443194	0.0434112
647	1	0.0650222	-2.665794	0.3105975	0.0607943
648	1	0.0397174	-3.185438	0.3651262	0.03814
649	1	0.0677332	-2.622043	0.3132024	0.0631454
650	1	0.0536934	-2.869277	0.333038	0.0508104
651	1	0.0359148	-3.290031	0.3585638	0.0346249
652	1	0.0352288	-3.310028	0.3706401	0.0339877
653	1	0.022282	-3.78144	0.4230959	0.0217856
654	1	0.0170568	-4.054	0.4223445	0.0167659
655	1	0.027905	-3.550649	0.3761525	0.0271263
656	1	0.0482739	-2.981386	0.3425227	0.0459435
657	1	0.0428889	-3.105307	0.3529015	0.0410494
658	1	0.0808331	-2.431081	0.3107289	0.0742991
659	1	0.016426	-4.092326	0.4264119	0.0161562
660	1	0.0887848	-2.328564	0.3082608	0.0809021
661	1	0.0821385	-2.41364	0.3406104	0.0753918
662	1	0.0291077	-3.507213	0.3728865	0.0282604
663	1	0.0561631	-2.821694	0.330795	0.0530088

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
664	1	0.0299346	-3.478349	0.3898925	0.0290385
665	1	0.02206069	-1.262133	0.341325	0.1719395
666	1	0.0221891	-3.785717	0.3959293	0.0216967
667	1	0.0845142	-2.382535	0.3093447	0.0773716
668	1	0.0765952	-2.489534	0.313157	0.0707284
669	1	0.0440575	-3.077202	0.3504554	0.0421165
670	1	0.0220948	-3.790068	0.4261408	0.0216067
671	1	0.0613898	-2.727156	0.3248014	0.0576211
672	1	0.0386653	-3.213379	0.3543571	0.0371703
673	0	0.1153114	-2.037599	0.306276	0.1020147
674	1	0.0356686	-3.297163	0.4660423	0.0343964
675	1	0.0338998	-3.349857	0.4742449	0.0327506
676	1	0.0264995	-3.603773	0.4825527	0.0257973
677	1	0.0222493	-3.782943	0.4996757	0.0217543
678	1	0.0817941	-2.418216	0.4523439	0.0751038
679	1	0.0071734	-4.930173	0.609516	0.007122
680	1	0.0105907	-4.537135	0.5436523	0.0104785
681	1	0.0205962	-3.861836	0.500558	0.020172
682	1	0.016148	-4.109678	0.5210057	0.0158873
683	1	0.0121999	-4.39405	0.532752	0.0120511
684	1	0.0583575	-2.781038	0.4516643	0.0549519
685	1	0.0461381	-3.02888	0.4563712	0.0440094
686	1	0.0088716	-4.71599	0.5585785	0.0087929
687	1	0.0665569	-2.640823	0.4576829	0.0621271

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
688	1	0.0173555	-4.036339	0.5099485	0.0170543
689	1	0.0814832	-2.422364	0.4593495	0.0748437
690	1	0.0275321	-3.564484	0.4855186	0.0267741
691	1	0.0343312	-3.336767	0.4678573	0.0331525
692	1	0.0265655	-3.601218	0.4823925	0.0258598
693	1	0.0309842	-3.442803	0.4731889	0.0300242
694	1	0.0955791	-2.247341	0.4629926	0.0864437
695	1	0.0151526	-4.174314	0.517956	0.014923
696	1	0.0818901	-2.416939	0.4523622	0.0751841
697	1	0.0494753	-2.955541	0.4862333	0.0470275
698	1	0.0542852	-2.85769	0.4526759	0.0513383
699	1	0.0583575	-2.781038	0.4516643	0.0549519
700	1	0.0070979	-4.940837	0.5792303	0.0070475
701	1	0.0555721	-2.832898	0.4881795	0.0524839
702	1	0.0083272	-4.779867	0.5642398	0.0082578
703	1	0.0317165	-3.418689	0.3695017	0.0307105
704	1	0.0219515	-3.796726	0.4335115	0.0214696
705	1	0.0414266	-3.141523	0.3839436	0.0397105
706	1	0.1262747	-1.934306	0.3947087	0.1103294
707	1	0.0587133	-2.774582	0.3790227	0.055266
708	1	0.0259228	-3.626368	0.4195868	0.0252508
709	1	0.0772961	-2.479665	0.3166202	0.0713214
710	1	0.0211795	-3.833315	0.4170201	0.0207309
711	1	0.0173671	-4.035659	0.4373491	0.0170655

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
712	1	0.0087692	-4.727696	0.487745	0.0086923
713	1	0.0432563	-3.096392	0.3425242	0.0413852
714	1	0.0122855	-4.386972	0.5262025	0.0121346
715	1	0.0529081	-2.884839	0.3322309	0.0501089
716	1	0.0421176	-3.12426	0.3480644	0.0403437
717	1	0.0216621	-3.810293	0.4143707	0.0211928
718	1	0.057717	-2.792754	0.3273854	0.0543858
719	1	0.0322433	-3.401672	0.3654223	0.0312036
720	1	0.0177	-4.01633	0.4778093	0.0173867
721	1	0.0295896	-3.490298	0.3801182	0.028714
722	1	0.031141	-3.437594	0.4061922	0.0301712
723	1	0.0847472	-2.379528	0.3571043	0.0775651
724	1	0.0793561	-2.451127	0.3492213	0.0730587
725	1	0.0099186	-4.603372	0.5560545	0.0098203
726	1	0.0113193	-4.469858	0.4572321	0.0111912
727	1	0.0192001	-3.933454	0.4675501	0.0188314
728	1	0.0647914	-2.669596	0.3502048	0.0605935
729	1	0.0400765	-3.176064	0.3558564	0.0384704
730	1	0.0982157	-2.217209	0.3640489	0.0885694
731	1	0.0189608	-3.946239	0.430333	0.0186013
732	1	0.2454197	-1.123192	0.3744234	0.1851889
733	1	0.0494468	-2.956146	0.3364724	0.0470019
734	1	0.0479325	-2.988843	0.3511483	0.0456349
735	1	0.0739068	-2.52817	0.317686	0.0684446

Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
736	1	0.0198705	-3.898451	0.3998194	0.0194756
737	1	0.0187107	-3.959773	0.4051742	0.0183606
738	1	0.1200873	-1.991604	0.3186962	0.1056663
739	1	0.0706753	-2.576362	0.3541142	0.0656803
740	1	0.036555	-3.271698	0.3599319	0.0352187
741	1	0.0829225	-2.403286	0.3127946	0.0760463
742	1	0.0165453	-4.084971	0.4167626	0.0162715
743	1	0.1931787	-1.429487	0.3484162	0.1558607
744	1	0.0447712	-3.060385	0.352591	0.0427668
745	1	0.0353158	-3.307469	0.3630326	0.0340686
746	1	0.0476998	-2.993953	0.3512365	0.0454245
747	1	0.0141913	-4.240831	0.4323276	0.0139899
748	1	0.03651	-3.272976	0.3600412	0.035177
749	1	0.0313445	-3.430871	0.3669567	0.030362
750	1	0.0336885	-3.35633	0.3637475	0.0325536
751	1	0.029682	-3.487083	0.3700937	0.028801
752	1	0.1751022	-1.54989	0.3387955	0.1444414
753	1	0.0274274	-3.568402	0.384247	0.0266752
754	1	0.0613743	-2.727426	0.3545077	0.0576075
755	1	0.0178847	-4.005764	0.4093313	0.0175648
756	1	0.0130686	-4.32439	0.4782484	0.0128978
757	1	0.1227796	-1.966368	0.317602	0.1077048
758	1	0.0299036	-3.479418	0.3696519	0.0290093
759	1	0.1811384	-1.508654	0.351308	0.1483273

Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
760	1	0.0503573	-2.936943	0.3678919	0.0478214
761	1	0.0439051	-3.080826	0.3530847	0.0419775
762	1	0.0294118	-3.496505	0.417748	0.0285468
763	1	0.0923362	-2.285438	0.3146479	0.0838102
764	1	0.0195741	-3.913781	0.4011376	0.0191909
765	1	0.015044	-4.18162	0.4557177	0.0148176
766	1	0.0716653	-2.561386	0.318546	0.0665293
767	1	0.0737321	-2.530725	0.3177484	0.0682957
768	1	0.0375578	-3.243592	0.3575546	0.0361472
769	1	0.0505852	-2.932187	0.3316834	0.0480263
770	1	0.0175292	-4.026205	0.4112166	0.0172219
771	1	0.0363644	-3.277123	0.3567923	0.035042
772	0	0.0381289	-3.227907	0.3987437	0.0366751
773	1	0.1744164	-1.554645	0.3490412	0.1439953
774	0	0.113247	-2.057996	0.3362	0.1004221
775	1	0.3030458	-0.832836	0.4023352	0.2112091
776	0	0.1594398	-1.662402	0.4112186	0.1340187
777	0	0.2498286	-1.099527	0.3830389	0.1874143
778	0	0.0998431	-2.198969	0.3837287	0.0898745
779	1	0.1241622	-1.953592	0.3180218	0.1087459
780	1	0.0348726	-3.320559	0.3605563	0.0336565
781	1	0.0709383	-2.572365	0.3517069	0.065906
782	1	0.042394	-3.11743	0.3440642	0.0405967
783	1	0.0957928	-2.244871	0.3123636	0.0866165

Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
784	1	0.0379609	-3.232498	0.3943096	0.0365199
785	1	0.0218617	-3.800914	0.4094668	0.0213838
786	1	0.0550732	-2.842445	0.3299099	0.0520401
787	1	0.0983962	-2.215173	0.314848	0.0887144
788	1	0.0409275	-3.154164	0.3503484	0.0392524
789	1	0.0660496	-2.649017	0.3504535	0.061687
790	1	0.0298295	-3.481973	0.3697987	0.0289397
791	1	0.0392442	-3.197915	0.3502548	0.0377041
792	1	0.0431788	-3.098267	0.3426601	0.0413144
793	1	0.067209	-2.630373	0.3206658	0.062692
794	1	0.1203618	-1.989009	0.3366113	0.1058748
795	0	0.0795849	-2.448	0.3133659	0.0732512
796	1	0.0226866	-3.763032	0.3887965	0.0221719
797	1	0.0155569	-4.147571	0.4228689	0.0153149
798	1	0.064691	-2.671255	0.3221317	0.0605061
799	1	0.0569646	-2.806674	0.328071	0.0537196
800	1	0.1379205	-1.83267	0.3884812	0.1188985
801	1	0.0537199	-2.868754	0.3497349	0.0508341
802	1	0.0248908	-3.66805	0.3947328	0.0242713
803	1	0.0303091	-3.465529	0.421667	0.0293905
804	1	0.0354917	-3.302319	0.3983969	0.0342321
805	1	0.1834705	-1.493009	0.3575161	0.1498091
806	1	0.017286	-4.040422	0.4876362	0.0169872
807	1	0.0814078	-2.423372	0.3413018	0.0747805

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Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
808	0	0.0599365	-2.752662	0.3631668	0.0563441
809	0	0.0936325	-2.270067	0.3376809	0.0848655
810	1	0.1174503	-2.0168	0.3428669	0.1036557
811	1	0.0856766	-2.367604	0.3795625	0.0783362
812	1	0.1090387	-2.100598	0.3871915	0.0971492
813	1	0.0960451	-2.241961	0.3372473	0.0868205
814	1	0.0432992	-3.095357	0.3800823	0.0414243
815	1	0.0168447	-4.066731	0.4587455	0.016561
816	1	0.2337676	-1.187158	0.4509644	0.1791203
817	1	0.0797016	-2.446408	0.3160208	0.0733493
818	1	0.1318968	-1.884291	0.3222402	0.1145001
819	1	0.1186646	-2.005138	0.3762142	0.1045833
820	1	0.0140137	-4.253607	0.4336557	0.0138173
821	1	0.0964588	-2.237206	0.3124059	0.0871545
822	1	0.0062225	-5.073343	0.5801682	0.0061838
823	1	0.0532206	-2.87862	0.3810543	0.0503882
824	1	0.0855114	-2.369715	0.3397949	0.0781992
825	1	0.060225	-2.747552	0.3628702	0.056598
826	1	0.0211006	-3.837129	0.3946876	0.0206553
827	1	0.0367211	-3.266992	0.3961027	0.0353727
828	1	0.0258914	-3.627612	0.3789555	0.025221
829	1	0.0487553	-2.970957	0.3508573	0.0463782
830	0	0.0721769	-2.553721	0.3183382	0.0669674
831	1	0.0936024	-2.270422	0.3122646	0.084841

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Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
832	1	0.048401	-2.978622	0.3509786	0.0460584
833	1	0.0550732	-2.842445	0.3299099	0.0520401
834	1	0.0347986	-3.322759	0.4003404	0.0335877
835	1	0.0308956	-3.445758	0.3720726	0.0299411
836	1	0.0424067	-3.117116	0.3475284	0.0406084
837	1	0.0415335	-3.138834	0.3491695	0.0398085
838	1	0.0749411	-2.513154	0.3145496	0.069325
839	1	0.0174271	-4.032148	0.4369164	0.0171234
840	1	0.038682	-3.212931	0.3550217	0.0371857
841	1	0.0234934	-3.72726	0.3860782	0.0229415
842	1	0.1031126	-2.163109	0.313115	0.0924804
843	1	0.0518047	-2.90708	0.3500478	0.0491209
844	0	0.086791	-2.353462	0.3123907	0.0792583
845	1	0.017102	-4.051311	0.4392836	0.0168095
846	1	0.0269543	-3.586287	0.3860913	0.0262278
847	1	0.0531123	-2.880771	0.3320016	0.0502914
848	1	0.104808	-2.144909	0.3155336	0.0938232
849	1	0.0280354	-3.54585	0.3736258	0.0272495
850	1	0.1115858	-2.074644	0.3167015	0.0991344
851	0	0.0713052	-2.566811	0.3158343	0.0662208
852	1	0.0228742	-3.754608	0.4080576	0.0223509
853	1	0.1186646	-2.005138	0.3762142	0.1045833
854	1	0.0230866	-3.745146	0.3874269	0.0225536
855	1	0.0399362	-3.179715	0.3523505	0.0383413

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
856	1	0.0576136	-2.794657	0.3494989	0.0542943
857	1	0.0429499	-3.103821	0.3536831	0.0411052
858	1	0.0698178	-2.589492	0.3193555	0.0649432
859	1	0.0699839	-2.586937	0.3192789	0.0650861
860	1	0.0099949	-4.595632	0.5173543	0.009895
861	1	0.0116621	-4.439683	0.4898117	0.0115261
862	1	0.0251292	-3.658273	0.3810752	0.0244977
863	1	0.018524	-3.969993	0.4060877	0.0181808
864	1	0.0887342	-2.329189	0.312283	0.0808605
865	1	0.0536127	-2.870865	0.3281969	0.0507384
866	1	0.1577469	-1.675089	0.3308618	0.1328628
867	1	0.0178175	-4.009597	0.409683	0.0175
868	1	0.1065317	-2.126668	0.342877	0.0951827
869	1	0.0170275	-4.055752	0.4895603	0.0167375
870	1	0.117335	-2.017913	0.3753873	0.1035675
871	1	0.0945035	-2.259847	0.3375149	0.0855726
872	1	0.0755572	-2.504301	0.3778682	0.0698483
873	1	0.0337103	-3.355661	0.4106973	0.0325739
874	0	0.0600178	-2.751221	0.349587	0.0564156
875	1	0.1992792	-1.390806	0.3630481	0.159567
876	1	0.1321434	-1.882139	0.3974825	0.1146815
877	1	0.1038154	-2.155533	0.3851655	0.0930377
878	1	0.0196878	-3.907872	0.4644303	0.0193002
879	1	0.0801034	-2.440943	0.3488817	0.0736869

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Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
880	1	0.2614965	-1.038205	0.3879811	0.1931161
881	1	0.088631	-2.330466	0.3122872	0.0807755
882	1	0.0423421	-3.118708	0.3441588	0.0405493
883	0	0.0921256	-2.287953	0.3379942	0.0836385
884	1	0.0660964	-2.648259	0.3212881	0.0617277
885	1	0.114019	-2.05033	0.336224	0.1010187
886	0	0.1580867	-1.672534	0.3310109	0.1330953
887	1	0.0129604	-4.332814	0.4420563	0.0127924
888	1	0.0964897	-2.236851	0.3371763	0.0871794
889	1	0.0054501	-5.206651	0.5499098	0.0054204
890	1	0.1440456	-1.782087	0.3265978	0.1232964
891	1	0.0245214	-3.68338	0.3963903	0.0239201
892	1	0.1773793	-1.534205	0.3500274	0.1459159
893	1	0.1095361	-2.095488	0.3873917	0.097538
894	1	0.1109892	-2.080677	0.3427399	0.0986706
895	1	0.0181247	-3.99219	0.4747976	0.0177962
896	1	0.242657	-1.138167	0.3754877	0.1837746
897	1	0.1244746	-1.950723	0.3199193	0.1089807
898	1	0.0472737	-3.003375	0.3727984	0.0450389
899	1	0.0558551	-2.827518	0.3799474	0.0527353
900	1	0.0295479	-3.491749	0.376539	0.0286748
901	1	0.1128941	-2.061514	0.3427392	0.1001491
902	1	0.0261292	-3.618226	0.3894264	0.0254465
903	1	0.0224051	-3.775807	0.3897874	0.0219031

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
904	1	0.0625416	-2.70734	0.3204973	0.0586302
905	1	0.1327408	-1.87694	0.32086	0.1151207
906	1	0.0377444	-3.238442	0.3924744	0.0363198
907	1	0.0834733	-2.396065	0.3565179	0.0765055
908	1	0.0619193	-2.718005	0.3497673	0.0580853
909	1	0.0420145	-3.126817	0.3543268	0.0402493
910	1	0.0158307	-4.12985	0.4989615	0.01558
911	1	0.0889411	-2.326634	0.3122751	0.0810306
912	1	0.0648482	-2.668659	0.3513583	0.0606429
913	1	0.0374656	-3.246147	0.3577685	0.0360619
914	1	0.100802	-2.188345	0.3150526	0.090641
915	1	0.0430551	-3.101266	0.3536144	0.0412013
916	1	0.2252001	-1.235615	0.3638711	0.174485
917	1	0.1369551	-1.840814	0.3389685	0.1181984
918	1	0.0515759	-2.911747	0.3304861	0.0489159
919	0	0.0497121	-2.950517	0.3505592	0.0472408
920	0	0.0557019	-2.830428	0.349552	0.0525992
921	1	0.1396532	-1.818173	0.3234008	0.1201502
922	1	0.0181247	-3.99219	0.4747976	0.0177962
923	1	0.0523466	-2.896102	0.3328729	0.0496064
924	1	0.0289055	-3.51439	0.4196256	0.02807
925	1	0.2826719	-0.931246	0.3941469	0.2027685
926	1	0.0235696	-3.723947	0.4046409	0.023014
927	1	0.1944318	-1.421467	0.3613032	0.1566281

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
928	1	0.0159732	-4.120742	0.4202273	0.015718
929	1	0.0378212	-3.236331	0.3945047	0.0363908
930	1	0.0336271	-3.358216	0.4109454	0.0324964
931	0	0.0971211	-2.22963	0.3828032	0.0876886
932	1	0.3675285	-0.542834	0.4325066	0.2324513
933	1	0.139691	-1.817859	0.3249659	0.1201774
934	1	0.1182472	-2.009135	0.3429069	0.1042648
935	1	0.0593258	-2.763552	0.3228751	0.0558063
936	1	0.0576741	-2.793544	0.3656107	0.0543478
937	1	0.0945035	-2.259847	0.3375149	0.0855726
938	0	0.0643849	-2.676325	0.3517534	0.0602395
939	1	0.0873237	-2.34676	0.3148708	0.0796982
940	1	0.0135339	-4.288934	0.469662	0.0133507
941	1	0.0861096	-2.36209	0.3149844	0.0786947
942	1	0.0080595	-4.812814	0.5442168	0.0079945
943	1	0.0508463	-2.926763	0.334674	0.048261
944	1	0.0190561	-3.941129	0.4297195	0.018693
945	1	0.1777006	-1.532004	0.3400305	0.1461231
946	1	0.0299256	-3.478659	0.3789721	0.02903
947	1	0.0980567	-2.219006	0.3148245	0.0884416
948	1	0.0957543	-2.245315	0.3626947	0.0865855
949	1	0.0639223	-2.68403	0.3226214	0.0598362
950	1	0.0111388	-4.486119	0.4590836	0.0110147
951	1	0.0198208	-3.901006	0.4000382	0.0194279

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
952	1	0.0746094	-2.51795	0.3174426	0.0690428
953	1	0.1251768	-1.944295	0.3371115	0.1095076
954	1	0.067209	-2.630373	0.3206658	0.062692
955	1	0.0229816	-3.749812	0.403703	0.0224534
956	1	0.0875307	-2.344164	0.3391676	0.0798691
957	1	0.0039072	-5.541011	0.6427562	0.003892
958	1	0.1298624	-1.902176	0.3215751	0.1129981
959	1	0.0526007	-2.890991	0.3325803	0.0498339
960	1	0.055457	-2.835094	0.3263111	0.0523815
961	1	0.1282475	-1.916544	0.3193255	0.1118001
962	1	0.0545437	-2.852665	0.3304555	0.0515687
963	1	0.1906033	-1.446095	0.3471701	0.1542737
964	1	0.026809	-3.591841	0.3765653	0.0260903
965	1	0.0137921	-4.269771	0.4671464	0.0136019
966	1	0.0713052	-2.566811	0.3158343	0.0662208
967	1	0.0277358	-3.556904	0.3830704	0.0269665
968	1	0.0407976	-3.157478	0.3552551	0.0391332
969	1	0.0352182	-3.310339	0.3596595	0.0339779
970	1	0.0542419	-2.858534	0.3496734	0.0512997
971	1	0.0310585	-3.440333	0.375252	0.0300938
972	1	0.0654708	-2.658439	0.3508389	0.0611844
973	1	0.0455617	-3.042056	0.3387021	0.0434858
974	1	0.0706314	-2.577031	0.3161104	0.0656426
975	1	0.056418	-2.816894	0.3285851	0.053235

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
976	0	0.0596293	-2.758127	0.3257536	0.0560736
977	1	0.0745212	-2.519228	0.3174725	0.0689678

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Parameter Code=PPG78W Parameter=PPG <=7.8 mmol/L (SMPG) without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Model Information

Data Set	WORK.ENDPOINT
Distribution	Binomial
Link Function	Logit
Dependent Variable	aval

Number of Observations Read	977
Number of Observations Used	977
Number of Events	208
Number of Trials	977

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Response Profile

Ordered Value	aval	Total Frequency
1	0	208
2	1	769

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The GENMOD Procedure

PROC GENMOD is modeling the probability that aval='0'. One way to change this to model the probability that aval='1' is to specify the DESCENDING option in the PROC statement.

Parameter Information

Parameter	Effect	TRTPN	REGION1	BOLAD1
Prm1	Intercept			
Prm2	TRTPN	2		
Prm3	TRTPN	3		
Prm4	TRTPN	4		
Prm5	REGION1		ASIA (EXCLUDING JAPAN)	
Prm6	REGION1		EUROPE	
Prm7	REGION1		JAPAN	
Prm8	REGION1		NORTH AMERICA	
Prm9	BOLAD1			BOLUS INSULIN ALGORITHM (SLIDING SCALE)
Prm10	BOLAD1			CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY
Prm11	P9PPRABL			

Criteria For Assessing Goodness Of Fit

Criterion	DF	Value	Value/DF
Log Likelihood		-448.0957	
Full Log Likelihood		-448.0957	
AIC (smaller is better)		912.1914	
AICC (smaller is better)		912.3402	
BIC (smaller is better)		951.2673	

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Parameter Code=PPG78W Parameter=PPG ≤ 7.8 mmol/L (SMPG) without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Algorithm converged.

Analysis Of Maximum Likelihood Parameter Estimates

Parameter		DF	Estimate	Standard Error	Wald 95% Confidence Limits		Wald Chi-Square
Intercept		1	1.4849	0.4598	0.5836	2.3861	10.43
TRTPN	2	1	0.3034	0.2010	-0.0906	0.6974	2.28
TRTPN	3	1	-0.0354	0.2095	-0.4461	0.3753	0.03
TRTPN	4	0	0.0000	0.0000	0.0000	0.0000	.
REGION1	ASIA (EXCLUDING JAPAN)	1	0.0195	0.2964	-0.5614	0.6004	0.00
REGION1	EUROPE	1	0.5052	0.2086	0.0964	0.9140	5.87
REGION1	JAPAN	1	-0.5257	0.2761	-1.0668	0.0154	3.63
REGION1	NORTH AMERICA	0	0.0000	0.0000	0.0000	0.0000	.
BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	1	0.3707	0.1881	0.0020	0.7394	3.88

Analysis Of Maximum Likelihood Parameter Estimates

Parameter		Pr > ChiSq
Intercept		0.0012
TRTPN	2	0.1312
TRTPN	3	0.8658
TRTPN	4	.
REGION1	ASIA (EXCLUDING JAPAN)	0.9475
REGION1	EUROPE	0.0154
REGION1	JAPAN	0.0569
REGION1	NORTH AMERICA	.
BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.0488

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Parameter Code=PPG78W Parameter=PPG <=7.8 mmol/L (SMPG) without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Analysis Of Maximum Likelihood Parameter Estimates

Parameter	DF	Estimate	Standard Error	Wald 95% Confidence Limits	Wald Chi-Square
BOLAD1 CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY	0	0.0000	0.0000	0.0000 0.0000	.
P9PPRABL	1	-0.3532	0.0459	-0.4433 -0.2632	59.13
Scale	0	1.0000	0.0000	1.0000 1.0000	

Analysis Of Maximum Likelihood Parameter Estimates

Parameter	Pr > ChiSq
BOLAD1 CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY	.
P9PPRABL	<.0001
Scale	

NOTE: The scale parameter was held fixed.

Coefficients for TRTPN Least Squares Means Using WORK.ENDPOINT Margins

Parameter	Geographic Region Grouping Method 1
Intercept	
Planned Treatment (N) 2	
Planned Treatment (N) 3	
Planned Treatment (N) 4	
Geographic Region Grouping Method 1 ASIA (EXCLUDING JAPAN)	ASIA (EXCLUDING JAPAN)
Geographic Region Grouping Method 1 EUROPE	EUROPE
Geographic Region Grouping Method 1 JAPAN	JAPAN

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG78W Parameter=PPG <=7.8 mmol/L (SMPG) without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Coefficients for TRTPN Least Squares Means Using WORK.ENDPOINT Margins

Parameter	Geographic Region Grouping Method 1
Geographic Region Grouping Method 1 NORTH AMERICA	NORTH AMERICA
Bolus Adjustment Method at Timepoint 1 BOLUS INSULIN ALGORITHM (SLIDING SCALE)	
Bolus Adjustment Method at Timepoint 1 CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY	
PPG all meals (SMPG) (mmol/L) at Baseline	

Coefficients for TRTPN Least Squares Means Using WORK.ENDPOINT Margins

Bolus Adjustment Method at Timepoint 1	Planned Treatment (N)	Row1	Row2	Row3
	1	1	1	1
	2	1		
	3		1	
	4			1
		0.1351	0.1351	0.1351
		0.3367	0.3367	0.3367
		0.2467	0.2467	0.2467
		0.2815	0.2815	0.2815
BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.5793	0.5793	0.5793
CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0.4207	0.4207	0.4207
		9.5719	9.5719	9.5719

Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG78W Parameter=PPG <=7.8 mmol/L (SMPG) without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

TRTPN Least Squares Means

Planned Treatment (N)	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
2	WORK.ENDPOINT	-1.3349	0.1444	-9.25	<.0001	0.05	-1.6178	-1.0519
3	WORK.ENDPOINT	-1.6737	0.1573	-10.64	<.0001	0.05	-1.9820	-1.3653
4	WORK.ENDPOINT	-1.6383	0.1531	-10.70	<.0001	0.05	-1.9384	-1.3381

Differences of TRTPN Least Squares Means

Planned Treatment (N)	Planned Treatment (N)	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
2	4	WORK.ENDPOINT	0.3034	0.2010	1.51	0.1312	0.05	-0.09057	0.6974
3	4	WORK.ENDPOINT	-0.03542	0.2095	-0.17	0.8658	0.05	-0.4461	0.3753

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) / NovoRapid (meal)	WORK.ENDPOINT	0.3034	0.2010	1.51	0.1312	0.05	-0.09057	0.6974

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Parameter Code=PPG78W Parameter=PPG <=7.8 mmol/L (SMPG) without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
TRTPN	Faster aspart (post) / NovoRapid (meal)	WORK.ENDPOINT	-0.03542	0.2095	-0.17	0.8658	0.05	-0.4461	0.3753

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
1	1	0.1481042	-1.749548	0.2833516	0.1261694
2	1	0.0954962	-2.2483	0.2817404	0.0863767
3	1	0.0478349	-2.990984	0.3059647	0.0455467
4	1	0.018465	-3.973243	0.3756297	0.018124
5	1	0.0559638	-2.825459	0.2980365	0.0528319
6	1	0.4190051	-0.326859	0.2906434	0.2434398
7	1	0.0438763	-3.081513	0.2978649	0.0419512
8	1	0.0300109	-3.475723	0.3180746	0.0291103
9	1	0.1674756	-1.603625	0.2866103	0.1394275
10	1	0.1977899	-1.400165	0.2497837	0.1586691
11	1	0.1331152	-1.873691	0.2815582	0.1153955
12	1	0.0262085	-3.615113	0.3268498	0.0255216
13	1	0.1709766	-1.578722	0.2991351	0.1417436
14	1	0.1992726	-1.390847	0.3031706	0.159563
15	1	0.1486547	-1.745192	0.283431	0.1265565

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG78W Parameter=PPG ≤ 7.8 mmol/L (SMPG) without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
16	1	0.3240368	-0.735281	0.3458542	0.219037
17	1	0.0911037	-2.300232	0.257633	0.0828038
18	1	0.1671472	-1.605982	0.2458044	0.139209
19	1	0.0857575	-2.366572	0.2785653	0.0784032
20	1	0.0162127	-4.105616	0.4154358	0.0159498
21	1	0.0173617	-4.035977	0.357473	0.0170602
22	1	0.0421727	-3.122894	0.2996386	0.0403942
23	1	0.0765054	-2.490804	0.2647471	0.0706523
24	1	0.0107596	-4.521143	0.3995433	0.0106438
25	1	0.0383867	-3.220902	0.3041781	0.0369131
26	1	0.0424374	-3.11636	0.2993528	0.0406365
27	1	0.0292731	-3.501376	0.3321537	0.0284162
28	1	0.0991309	-2.206919	0.2813061	0.0893039
29	0	0.0894514	-2.320352	0.2543457	0.0814498
30	1	0.0825616	-2.408041	0.2613928	0.0757451
31	1	0.023798	-3.714066	0.3541179	0.0232317
32	1	0.049697	-2.950835	0.2928431	0.0472272
33	0	0.1835126	-1.492728	0.2476443	0.1498357
34	1	0.1778757	-1.530807	0.3012682	0.1462359
35	1	0.0380873	-3.229043	0.3029156	0.0366366
36	1	0.064677	-2.671486	0.2823638	0.0604939
37	1	0.008006	-4.819523	0.4279045	0.0079419
38	1	0.0523325	-2.896386	0.2910182	0.0495938
39	1	0.0266004	-3.599867	0.3258524	0.0258929

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG78W Parameter=PPG ≤ 7.8 mmol/L (SMPG) without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
40	0	0.228817	-1.215003	0.3180352	0.1764598
41	1	0.1763589	-1.541214	0.2525124	0.1452564
42	1	0.3522764	-0.609048	0.2953218	0.2281777
43	1	0.0363108	-3.278654	0.3122987	0.0349923
44	1	0.1478905	-1.751243	0.2469286	0.1260189
45	1	0.0929354	-2.278309	0.2639553	0.0842984
46	1	0.1746463	-1.553049	0.2452216	0.144145
47	1	0.158753	-1.667536	0.2506903	0.1335505
48	1	0.0790456	-2.455386	0.2596901	0.0727974
49	0	0.478193	-0.087283	0.308493	0.2495245
50	0	0.1003476	-2.193369	0.2600681	0.0902779
51	1	0.1255524	-1.940869	0.2504178	0.109789
52	0	0.1992585	-1.390935	0.2560395	0.1595546
53	1	0.10717	-2.11998	0.248499	0.0956846
54	1	0.0365967	-3.270513	0.3131936	0.0352574
55	1	0.1432851	-1.788269	0.2475438	0.1227545
56	1	0.0357614	-3.29447	0.3150812	0.0344825
57	1	0.0537311	-2.868536	0.3009418	0.050844
58	1	0.0395682	-3.189358	0.3052183	0.0380025
59	1	0.1336579	-1.868997	0.2500002	0.1157934
60	0	0.3529038	-0.606299	0.2888252	0.2283627
61	1	0.0889743	-2.326224	0.2663252	0.0810578
62	1	0.0434418	-3.09192	0.299769	0.0415546
63	1	0.0514202	-2.914935	0.2853232	0.0487762

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG78W Parameter=PPG ≤ 7.8 mmol/L (SMPG) without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
64	1	0.0679064	-2.619303	0.2707217	0.0632951
65	1	0.0724528	-2.549609	0.2673683	0.0672034
66	1	0.1302898	-1.898399	0.2501289	0.1133143
67	1	0.0758158	-2.500605	0.2651705	0.0700678
68	0	0.2509598	-1.0935	0.2515901	0.187979
69	1	0.1537475	-1.705506	0.2462964	0.1301092
70	0	0.3209558	-0.749383	0.2652241	0.2179432
71	1	0.2871972	-0.909036	0.2699751	0.204715
72	1	0.0700036	-2.586634	0.269117	0.0651031
73	1	0.1169152	-2.021972	0.2465934	0.1032461
74	0	0.0620312	-2.716079	0.2898972	0.0581834
75	1	0.0768542	-2.485877	0.2610453	0.0709476
76	1	0.046722	-3.015692	0.2944107	0.044539
77	1	0.265855	-1.015756	0.2644094	0.1951761
78	1	0.0524717	-2.893582	0.3028419	0.0497184
79	1	0.1227264	-1.966861	0.2517868	0.1076647
80	1	0.1182712	-2.008904	0.246388	0.1042831
81	1	0.149822	-1.735998	0.2467021	0.1273754
82	1	0.0964253	-2.23759	0.2516203	0.0871275
83	1	0.2274684	-1.222662	0.2554279	0.1757265
84	0	0.2990666	-0.851747	0.2604405	0.2096258
85	1	0.1148486	-2.042144	0.2515951	0.1016584
86	1	0.1284661	-1.91459	0.2503294	0.1119625
87	1	0.0711465	-2.56921	0.2682847	0.0660847

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG78W Parameter=PPG ≤ 7.8 mmol/L (SMPG) without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
88	0	0.1424041	-1.795464	0.2446853	0.1221252
89	1	0.0948689	-2.255584	0.2562844	0.0858688
90	1	0.2748768	-0.970018	0.2667205	0.1993196
91	1	0.1329689	-1.87496	0.2449536	0.1152881
92	1	0.1351177	-1.856447	0.2448522	0.1168609
93	1	0.0352588	-3.309145	0.3147781	0.0340156
94	1	0.1568905	-1.681549	0.246022	0.1322759
95	1	0.0545897	-2.851774	0.2811865	0.0516097
96	1	0.1205009	-1.987695	0.2508769	0.1059804
97	1	0.095439	-2.248962	0.2785986	0.0863304
98	1	0.0145643	-4.214514	0.4269495	0.0143521
99	1	0.1244277	-1.951153	0.2866607	0.1089455
100	1	0.1751794	-1.549355	0.2466161	0.1444916
101	1	0.0877076	-2.341952	0.2830989	0.080015
102	1	0.1027744	-2.166771	0.2829983	0.0922119
103	0	0.0796821	-2.446674	0.2593128	0.0733329
104	1	0.0589951	-2.769494	0.284749	0.0555147
105	1	0.0973359	-2.227183	0.2786969	0.0878616
106	1	0.0753232	-2.507657	0.2620458	0.0696496
107	1	0.0461434	-3.028759	0.2953126	0.0440142
108	1	0.2657436	-1.016326	0.2708374	0.195124
109	1	0.0907157	-2.304927	0.2824999	0.0824864
110	1	0.16437	-1.626066	0.2924313	0.1373525
111	0	0.0505538	-2.932841	0.2899284	0.0479981

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG78W Parameter=PPG ≤ 7.8 mmol/L (SMPG) without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
112	0	0.0975274	-2.225005	0.2787083	0.0880158
113	1	0.0304748	-3.459907	0.3159377	0.0295461
114	1	0.0195197	-3.916616	0.3707747	0.0191387
115	1	0.0126719	-4.355618	0.3845973	0.0125113
116	1	0.1240159	-1.954938	0.2823303	0.108636
117	1	0.1489305	-1.743014	0.2834711	0.1267502
118	1	0.2128076	-1.308084	0.3075842	0.1675205
119	0	0.0880567	-2.337596	0.2830242	0.0803027
120	1	0.0454808	-3.043917	0.2942754	0.0434123
121	0	0.1708426	-1.579667	0.2872616	0.1416554
122	1	0.0459309	-3.033598	0.2959202	0.0438213
123	1	0.0415839	-3.137569	0.2984349	0.0398547
124	1	0.0416972	-3.134729	0.3138866	0.0399586
125	1	0.0999966	-2.197262	0.2827011	0.0899973
126	1	0.025013	-3.663028	0.3300423	0.0243874
127	1	0.1322215	-1.881458	0.2884181	0.114739
128	1	0.0774338	-2.477736	0.2641912	0.0714378
129	1	0.3151825	-0.776001	0.3260455	0.2158425
130	1	0.0515815	-2.911632	0.291513	0.0489209
131	1	0.0667817	-2.637209	0.284595	0.0623219
132	0	0.1258545	-1.938121	0.2454771	0.1100151
133	1	0.0207525	-3.854117	0.3431393	0.0203218
134	1	0.1111467	-2.079082	0.2801248	0.0987931
135	1	0.0762409	-2.494553	0.2827167	0.0704282

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
136	1	0.0928796	-2.278971	0.2529294	0.084253
137	1	0.0722838	-2.552125	0.2880049	0.0670589
138	0	0.1987518	-1.394114	0.3030029	0.1592495
139	1	0.1052096	-2.140635	0.283297	0.0941405
140	1	0.0733031	-2.537023	0.2831501	0.0679298
141	1	0.1602896	-1.656075	0.2452684	0.1345968
142	1	0.1025312	-2.169411	0.2590464	0.0920186
143	1	0.1718388	-1.572651	0.2452703	0.1423103
144	1	0.1553685	-1.6931	0.2449829	0.1312292
145	1	0.1439371	-1.782967	0.2499594	0.1232192
146	1	0.1209633	-1.98334	0.250828	0.1063312
147	1	0.0735229	-2.533792	0.2632815	0.0681173
148	1	0.2310489	-1.202398	0.2488012	0.1776653
149	1	0.1915548	-1.439939	0.2547301	0.1548616
150	1	0.0349636	-3.317857	0.315492	0.0337412
151	1	0.0697576	-2.590419	0.2660882	0.0648915
152	1	0.0308606	-3.446927	0.3275329	0.0299082
153	1	0.1659379	-1.614694	0.2456989	0.1384025
154	1	0.2846643	-0.921441	0.2575268	0.2036305
155	0	0.2773747	-0.957521	0.2738756	0.200438
156	1	0.0451942	-3.050539	0.2968312	0.0431517
157	0	0.1362169	-1.847073	0.2487095	0.1176618
158	1	0.0591798	-2.766172	0.2934243	0.0556776
159	0	0.0515589	-2.912095	0.3042611	0.0489006

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG78W Parameter=PPG ≤ 7.8 mmol/L (SMPG) without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
160	1	0.171354	-1.576061	0.2519041	0.1419918
161	1	0.0319201	-3.41208	0.3246222	0.0309012
162	1	0.1254329	-1.941958	0.2504268	0.1096995
163	1	0.0908807	-2.302929	0.2537364	0.0826214
164	1	0.069298	-2.597524	0.2696455	0.0644958
165	1	0.0800021	-2.442318	0.2591257	0.0736018
166	1	0.064181	-2.679715	0.2708621	0.0600618
167	1	0.0175005	-4.027871	0.3805779	0.0171942
168	1	0.096673	-2.23475	0.2619109	0.0873274
169	1	0.0521407	-2.90026	0.2867589	0.0494221
170	1	0.1580463	-1.672837	0.245932	0.1330677
171	1	0.1566026	-1.683727	0.2460454	0.1320783
172	1	0.2210278	-1.259687	0.2540879	0.1721745
173	1	0.0630137	-2.699317	0.2719651	0.0590429
174	1	0.0892741	-2.32253	0.2544232	0.0813043
175	1	0.0482988	-2.980844	0.2920406	0.045966
176	0	0.0158011	-4.131751	0.4181843	0.0155514
177	1	0.134163	-1.864641	0.2499861	0.1161633
178	1	0.0697576	-2.590419	0.2660882	0.0648915
179	1	0.0480557	-2.986145	0.3100599	0.0457464
180	0	0.0687747	-2.605665	0.2668735	0.0640448
181	1	0.0961861	-2.240339	0.2558525	0.0869343
182	1	0.0913746	-2.296965	0.2575301	0.0830253
183	1	0.0660017	-2.649795	0.2722708	0.0616454

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG78W Parameter=PPG ≤ 7.8 mmol/L (SMPG) without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
184	1	0.0898068	-2.315996	0.2541916	0.0817415
185	0	0.2556973	-1.068453	0.2523396	0.1903162
186	1	0.0662122	-2.646384	0.2851651	0.0618282
187	1	0.0217008	-3.808468	0.3597164	0.0212298
188	1	0.0480557	-2.986145	0.3100599	0.0457464
189	1	0.0538946	-2.865324	0.2876087	0.0509899
190	1	0.1201003	-1.991481	0.2461321	0.1056762
191	1	0.0758259	-2.500461	0.2759594	0.0700763
192	1	0.1657873	-1.615783	0.245686	0.1383019
193	1	0.0478007	-2.991734	0.2927758	0.0455158
194	1	0.0267283	-3.59494	0.3246011	0.0260139
195	1	0.0322761	-3.400619	0.3223944	0.0312344
196	1	0.0787291	-2.459742	0.2598805	0.0725308
197	1	0.1942901	-1.422372	0.2455739	0.1565414
198	1	0.0745682	-2.518547	0.262556	0.0690078
199	1	0.3970179	-0.417906	0.3025553	0.2393947
200	1	0.0721606	-2.553965	0.2675701	0.0669534
201	1	0.1586268	-1.668481	0.2458889	0.1334644
202	1	0.0617069	-2.721667	0.2761131	0.0578991
203	1	0.0887979	-2.328402	0.2664359	0.0809128
204	1	0.1147525	-2.04309	0.2542231	0.1015844
205	1	0.229672	-1.210164	0.2621565	0.1769227
206	1	0.0968634	-2.232572	0.2618115	0.0874809
207	0	0.2147189	-1.296712	0.2528325	0.1686147

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NN1218-4131

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG78W Parameter=PPG ≤ 7.8 mmol/L (SMPG) without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
208	1	0.0118091	-4.427008	0.4212939	0.0116696
209	1	0.1000401	-2.196779	0.2546993	0.0900321
210	1	0.1785136	-1.526451	0.3014678	0.1466465
211	1	0.1581721	-1.671892	0.2506464	0.1331537
212	1	0.0575376	-2.796057	0.2967694	0.0542271
213	1	0.0464357	-3.022137	0.293372	0.0442795
214	1	0.0214865	-3.818608	0.3625716	0.0210249
215	1	0.0455755	-3.041739	0.2941839	0.0434983
216	1	0.0376114	-3.242111	0.3035883	0.0361968
217	1	0.2359981	-1.174746	0.2572855	0.180303
218	1	0.2137305	-1.302584	0.246926	0.1680498
219	1	0.040721	-3.159437	0.3047056	0.0390628
220	1	0.2343286	-1.184029	0.2632028	0.1794187
221	1	0.2185271	-1.27427	0.2473878	0.170773
222	0	0.2613331	-1.039051	0.2532701	0.1930381
223	1	0.0683211	-2.612769	0.2703962	0.0636533
224	1	0.0847759	-2.379157	0.2565391	0.077589
225	1	0.0334176	-3.364683	0.3193711	0.0323009
226	1	0.1584624	-1.669714	0.2506682	0.133352
227	1	0.0213794	-3.823714	0.361145	0.0209224
228	1	0.1553685	-1.6931	0.2449829	0.1312292
229	1	0.0302159	-3.468707	0.3293707	0.0293029
230	1	0.0470691	-3.007925	0.3118015	0.0448536
231	1	0.0720149	-2.556142	0.2676714	0.0668288

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG78W Parameter=PPG ≤ 7.8 mmol/L (SMPG) without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
232	1	0.1205009	-1.987695	0.2508769	0.1059804
233	1	0.0633667	-2.693354	0.2745679	0.0593513
234	1	0.1283919	-1.915252	0.2452559	0.1119075
235	1	0.0221208	-3.788867	0.3578873	0.0216315
236	1	0.0418037	-3.132069	0.3220246	0.0400561
237	1	0.105166	-2.141098	0.2578822	0.0941061
238	1	0.1787652	-1.524736	0.2451981	0.1468082
239	1	0.179148	-1.522131	0.2470836	0.147054
240	1	0.2035539	-1.364229	0.2507652	0.1621197
241	1	0.0509693	-2.924217	0.2882995	0.0483714
242	1	0.0331255	-3.373764	0.3748232	0.0320282
243	1	0.255087	-1.071663	0.2470408	0.1900176
244	1	0.191835	-1.43813	0.2570111	0.1550344
245	0	0.2909257	-0.890892	0.2497596	0.2062879
246	1	0.0280206	-3.546394	0.3946178	0.0272355
247	1	0.2369145	-1.169671	0.2464933	0.180786
248	1	0.0842089	-2.386487	0.3104522	0.0771178
249	1	0.1080208	-2.111119	0.2798979	0.0963523
250	0	0.3213188	-0.747718	0.2633772	0.218073
251	1	0.4685996	-0.125767	0.2690916	0.249014
252	0	0.1259907	-1.936883	0.2714624	0.1101171
253	1	0.2417932	-1.142873	0.2486026	0.1833292
254	1	0.1040978	-2.152501	0.2821318	0.0932614
255	0	0.2744726	-0.972047	0.2579204	0.1991374

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
256	0	0.097775	-2.222195	0.2860836	0.088215
257	1	0.2526119	-1.084731	0.2469299	0.1887991
258	1	0.1914976	-1.440308	0.2570404	0.1548263
259	1	0.0833729	-2.397377	0.3113107	0.0764219
260	1	0.1498294	-1.735594	0.2560452	0.1273805
261	1	0.110621	-2.084413	0.2718527	0.098384
262	1	0.0007605	-7.180835	0.81562	0.0007599
263	1	0.0740185	-2.526539	0.3006704	0.0685398
264	1	0.071016	-2.571187	0.3040335	0.0659727
265	0	0.0807482	-2.432224	0.3140852	0.0742279
266	1	0.0573591	-2.799354	0.3267307	0.054069
267	0	0.35721	-0.587494	0.2515122	0.229611
268	1	0.0403256	-3.169607	0.3586985	0.0386995
269	1	0.0313417	-3.430962	0.3833059	0.0303594
270	0	0.1474328	-1.75488	0.2688535	0.1256964
271	1	0.2758896	-0.964943	0.2483806	0.1997745
272	1	0.1855012	-1.479512	0.2576204	0.1510905
273	0	0.3843519	-0.471117	0.2742594	0.2366255
274	1	0.1908241	-1.444664	0.2570999	0.1544103
275	1	0.2231479	-1.247415	0.2503918	0.1733529
276	0	0.3657557	-0.550469	0.2524407	0.2319785
277	1	0.0777971	-2.47266	0.3021087	0.0717448
278	1	0.3187434	-0.759553	0.2483791	0.217146
279	0	0.5088496	0.0354019	0.2780335	0.2499217

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG78W Parameter=PPG ≤ 7.8 mmol/L (SMPG) without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
280	1	0.2768932	-0.959925	0.2472454	0.2002234
281	0	0.3040042	-0.828302	0.2610551	0.2115856
282	1	0.3886186	-0.453123	0.2650096	0.2375942
283	0	0.2968008	-0.862579	0.2503828	0.2087101
284	1	0.3134213	-0.784172	0.2523809	0.2151884
285	1	0.2732867	-0.978011	0.2481752	0.1986011
286	1	0.2715599	-0.986722	0.2480447	0.1978151
287	1	0.2940807	-0.875647	0.2500886	0.2075973
288	1	0.3151759	-0.776031	0.262516	0.21584
289	1	0.3779643	-0.498198	0.2539014	0.2351073
290	1	0.3167113	-0.768927	0.2528153	0.2164053
291	1	0.1539642	-1.703841	0.2628235	0.1302593
292	1	0.2237889	-1.243721	0.2465162	0.1737074
293	1	0.1568981	-1.681491	0.254217	0.1322811
294	0	0.5984419	0.3989771	0.3324092	0.2403092
295	1	0.2286703	-1.215835	0.2497747	0.1763802
296	1	0.111331	-2.077217	0.2879145	0.0989364
297	1	0.3162402	-0.771105	0.2527524	0.2162323
298	1	0.1300014	-1.900946	0.2699264	0.113101
299	1	0.2533272	-1.080945	0.2564288	0.1891525
300	1	0.16068	-1.653178	0.2533393	0.1348619
301	1	0.2205161	-1.262661	0.2507133	0.1718888
302	0	0.2502769	-1.097136	0.2480501	0.1876384
303	1	0.0936773	-2.26954	0.2828562	0.0849019

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG78W Parameter=PPG ≤ 7.8 mmol/L (SMPG) without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
304	1	0.2669763	-1.010018	0.2473904	0.1957
305	1	0.2425927	-1.138517	0.2485439	0.1837415
306	1	0.4154731	-0.341385	0.259305	0.2428552
307	0	0.217326	-1.281317	0.2557187	0.1700954
308	1	0.1055821	-2.136684	0.2747906	0.0944345
309	1	0.053734	-2.868478	0.3281721	0.0508466
310	1	0.2140104	-1.300919	0.2557917	0.1682099
311	1	0.2669763	-1.010018	0.2473904	0.1957
312	0	0.2754548	-0.967121	0.2483456	0.1995794
313	1	0.2459837	-1.120149	0.2560815	0.1854757
314	1	0.1814444	-1.506592	0.2578832	0.1485223
315	1	0.1641577	-1.627613	0.2607012	0.1372099
316	1	0.1230387	-1.963964	0.2806521	0.1079002
317	0	0.2909257	-0.890892	0.2497596	0.2062879
318	0	0.3189487	-0.758608	0.2630402	0.2172204
319	0	0.0823797	-2.410445	0.3123463	0.0755933
320	1	0.107866	-2.112727	0.273427	0.0962309
321	1	0.1375886	-1.835464	0.2731408	0.118658
322	1	0.0868491	-2.352729	0.3078168	0.0793063
323	0	0.1730904	-1.563881	0.2509054	0.1431301
324	0	0.2333891	-1.189273	0.2464628	0.1789186
325	1	0.0869694	-2.351213	0.2882169	0.0794057
326	0	0.4650403	-0.140067	0.2926134	0.2487778
327	1	0.0570375	-2.805317	0.3228074	0.0537842

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG78W Parameter=PPG ≤ 7.8 mmol/L (SMPG) without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
328	0	0.3728575	-0.519977	0.2532716	0.2338348
329	1	0.2125486	-1.309631	0.2558323	0.1673717
330	1	0.1373304	-1.837642	0.2732613	0.1184708
331	0	0.1763261	-1.54144	0.2592083	0.1452352
332	1	0.4624741	-0.150387	0.2818689	0.2485918
333	1	0.132425	-1.879685	0.261732	0.1148886
334	1	0.4496721	-0.201996	0.2653345	0.2474671
335	1	0.2473038	-1.113044	0.2467295	0.1861446
336	1	0.3843519	-0.471117	0.2742594	0.2366255
337	1	0.4783726	-0.086564	0.2711447	0.2495323
338	1	0.2820225	-0.934451	0.2489042	0.2024858
339	1	0.2795173	-0.946857	0.2472358	0.2013874
340	1	0.2802618	-0.943163	0.2487483	0.2017151
341	1	0.5810897	0.3272483	0.2973173	0.2434245
342	1	0.1855012	-1.479512	0.2576204	0.1510905
343	0	0.1862467	-1.474585	0.2489899	0.1515589
344	1	0.3602161	-0.574426	0.2518298	0.2304605
345	0	0.3404498	-0.661291	0.1917152	0.2245437
346	1	0.3241936	-0.734566	0.1900333	0.2190921
347	0	0.5719412	0.2897758	0.1996399	0.2448245
348	0	0.3749922	-0.510859	0.1841227	0.234373
349	0	0.4181619	-0.330324	0.1826217	0.2433025
350	1	0.4985567	-0.005773	0.2065632	0.2499979
351	1	0.258404	-1.05428	0.2025008	0.1916314

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG78W Parameter=PPG ≤ 7.8 mmol/L (SMPG) without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
352	1	0.3260949	-0.725901	0.2126712	0.219757
353	1	0.2917878	-0.886717	0.2094036	0.2066477
354	1	0.1047674	-2.145341	0.2616046	0.0937912
355	1	0.326958	-0.721976	0.2128037	0.2200564
356	1	0.0952367	-2.251308	0.2706404	0.0861667
357	1	0.1158097	-2.032724	0.2391054	0.1023978
358	0	0.2112789	-1.317234	0.2096065	0.1666401
359	1	0.3875247	-0.457729	0.2074474	0.2373493
360	1	0.2205802	-1.262288	0.207677	0.1719246
361	0	0.3978198	-0.414557	0.2089216	0.2395592
362	1	0.2734905	-0.976985	0.2080565	0.1986935
363	0	0.2690722	-0.999335	0.2017178	0.1966724
364	1	0.2581745	-1.055478	0.2074187	0.1915204
365	0	0.3690668	-0.536223	0.2051339	0.2328565
366	1	0.3074125	-0.812244	0.2100489	0.2129101
367	1	0.0600282	-2.751036	0.2926258	0.0564248
368	1	0.4341962	-0.264751	0.2354131	0.2456699
369	1	0.3356524	-0.682729	0.2141912	0.2229899
370	1	0.1330946	-1.87387	0.226056	0.1153804
371	0	0.2362564	-1.173314	0.2054677	0.1804393
372	1	0.0821552	-2.413418	0.2672561	0.0754058
373	1	0.2052417	-1.35385	0.2071685	0.1631175
374	1	0.3209414	-0.749449	0.2119002	0.217938
375	0	0.472596	-0.109726	0.245887	0.249249

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG78W Parameter=PPG ≤ 7.8 mmol/L (SMPG) without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
376	0	0.3516055	-0.611989	0.2173873	0.2279791
377	1	0.481204	-0.07522	0.1856133	0.2496467
378	0	0.3516055	-0.611989	0.2173873	0.2279791
379	0	0.2419686	-1.141917	0.2054445	0.1834198
380	1	0.1066222	-2.125718	0.259977	0.0952539
381	1	0.106499	-2.127012	0.2416494	0.095157
382	1	0.2223873	-1.251808	0.2058802	0.1729312
383	1	0.2334355	-1.189013	0.2055097	0.1789434
384	1	0.1651177	-1.620632	0.2174082	0.1378539
385	0	0.3435409	-0.647554	0.1916766	0.2255206
386	1	0.3970049	-0.41796	0.1934877	0.239392
387	0	0.4509372	-0.196885	0.1834458	0.2475928
388	1	0.4684818	-0.12624	0.1845424	0.2490066
389	1	0.4226281	-0.311994	0.195859	0.2440136
390	0	0.3385726	-0.669662	0.2023252	0.2239412
391	1	0.4148236	-0.34406	0.1826303	0.242745
392	1	0.476307	-0.094843	0.185174	0.2494386
393	0	0.4162533	-0.338173	0.1826245	0.2429865
394	1	0.6154574	0.4703111	0.210225	0.2366696
395	1	0.3299554	-0.708387	0.1919737	0.2210848
396	1	0.3872056	-0.459074	0.1928375	0.2372774
397	1	0.1686305	-1.595364	0.2296366	0.1401942
398	0	0.4714146	-0.114466	0.1847689	0.2491829
399	0	0.299501	-0.849675	0.1939111	0.2098001

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
400	0	0.508667	0.0346715	0.1886933	0.2499249
401	1	0.2787997	-0.950423	0.1996276	0.2010704
402	1	0.1933452	-1.428419	0.2086394	0.1559628
403	1	0.1863019	-1.474221	0.2163286	0.1515935
404	1	0.0718424	-2.558727	0.275377	0.0666811
405	1	0.2003748	-1.383953	0.2122496	0.1602247
406	0	0.2589085	-1.051649	0.2058295	0.1918749
407	1	0.3715329	-0.525646	0.2210325	0.2334962
408	1	0.1284113	-1.915079	0.2283438	0.1119219
409	0	0.3188276	-0.759165	0.2124015	0.2171766
410	1	0.193973	-1.424398	0.2111125	0.1563475
411	0	0.4912116	-0.035157	0.2513459	0.2499228
412	1	0.2334355	-1.189013	0.2055097	0.1789434
413	0	0.5973762	0.3945443	0.2308435	0.2405179
414	1	0.2809119	-0.939943	0.1960425	0.2020004
415	0	0.5103293	0.0413231	0.2088935	0.2498933
416	0	0.3556087	-0.594475	0.1920855	0.2291512
417	1	0.6154574	0.4703111	0.210225	0.2366696
418	0	0.6145281	0.4663864	0.2099726	0.2368833
419	1	0.0581652	-2.784543	0.3402583	0.054782
420	0	0.4509372	-0.196885	0.1834458	0.2475928
421	1	0.2740896	-0.973971	0.2008839	0.1989645
422	0	0.0644858	-2.674652	0.3285486	0.0603274
423	1	0.4226515	-0.311898	0.1954591	0.2440172

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Parameter Code=PPG78W Parameter=PPG ≤ 7.8 mmol/L (SMPG) without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
424	1	0.178192	-1.528645	0.2249733	0.1464396
425	0	0.3431201	-0.649421	0.1922401	0.2253887
426	0	0.6004922	0.4075162	0.2063019	0.2399013
427	1	0.230281	-1.206725	0.2081569	0.1772517
428	0	0.4496693	-0.202007	0.1986002	0.2474668
429	1	0.5396822	0.1590635	0.2153718	0.2484253
430	0	0.3438659	-0.646114	0.2027157	0.2256221
431	0	0.3951503	-0.425714	0.1932688	0.2390065
432	1	0.223291	-1.24659	0.2071676	0.1734322
433	1	0.153047	-1.7109	0.2212346	0.1296236
434	1	0.3713201	-0.526558	0.184394	0.2334415
435	0	0.2347898	-1.18146	0.205258	0.1796635
436	0	0.4110902	-0.35946	0.1944097	0.242095
437	0	0.1160936	-2.029954	0.2682598	0.1026159
438	1	0.1132377	-2.058088	0.254484	0.1004149
439	1	0.1994948	-1.389455	0.2124819	0.1596966
440	1	0.1073938	-2.117643	0.2730026	0.0958604
441	0	0.3869552	-0.460129	0.2241345	0.2372209
442	1	0.1906798	-1.445599	0.2331988	0.154321
443	1	0.5269019	0.1077116	0.2124349	0.2492763
444	1	0.1221525	-1.972203	0.2316827	0.1072313
445	1	0.3730017	-0.519361	0.2055903	0.2338714
446	1	0.1426307	-1.79361	0.2219043	0.1222872
447	1	0.1537563	-1.705438	0.2407049	0.1301153

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG78W Parameter=PPG ≤ 7.8 mmol/L (SMPG) without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
448	1	0.2449145	-1.125922	0.2038936	0.1849314
449	1	0.2135649	-1.303569	0.2064281	0.1679549
450	1	0.2972652	-0.860355	0.2088355	0.2088986
451	1	0.1174599	-2.016707	0.2512156	0.1036631
452	1	0.2985234	-0.854339	0.2100446	0.2094072
453	1	0.3559631	-0.592929	0.1857846	0.2292534
454	1	0.2659033	-1.015508	0.207681	0.1951987
455	1	0.5562211	0.2258396	0.2211396	0.2468392
456	0	0.1194283	-1.997855	0.2621368	0.1051652
457	1	0.4178228	-0.331718	0.1953462	0.2432469
458	1	0.3856776	-0.465518	0.1834646	0.2369304
459	1	0.285894	-0.91541	0.1953958	0.2041586
460	1	0.4016766	-0.398484	0.2095063	0.2403325
461	1	0.2707218	-0.990964	0.1975459	0.1974315
462	0	0.2752625	-0.968084	0.2005662	0.1994931
463	1	0.138617	-1.826825	0.250535	0.1194023
464	1	0.2603892	-1.043947	0.1993289	0.1925866
465	0	0.6042523	0.4232149	0.2072595	0.2391315
466	1	0.3204819	-0.751558	0.1923816	0.2177732
467	1	0.1825577	-1.499114	0.2255536	0.1492304
468	1	0.3923168	-0.437584	0.1931532	0.2384043
469	1	0.2872976	-0.908545	0.1952238	0.2047577
470	0	0.4351245	-0.260973	0.1973341	0.2457912
471	0	0.4264868	-0.296199	0.195847	0.2445958

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
472	1	0.3713201	-0.526558	0.184394	0.2334415
473	1	0.3923168	-0.437584	0.1931532	0.2384043
474	1	0.2382395	-1.162356	0.2122615	0.1814814
475	1	0.4665277	-0.13409	0.1843982	0.2488796
476	1	0.276965	-0.959566	0.1965956	0.2002554
477	0	0.5503634	0.2021391	0.2196181	0.2474635
478	1	0.2638234	-1.02619	0.2002859	0.1942206
479	1	0.4828647	-0.068568	0.2037013	0.2497064
480	1	0.4802243	-0.079144	0.1855227	0.2496089
481	0	0.2985382	-0.854269	0.1949132	0.2094131
482	1	0.2100763	-1.324466	0.2145224	0.1659442
483	1	0.3970049	-0.41796	0.1934877	0.239392
484	1	0.2738323	-0.975265	0.1970607	0.1988482
485	1	0.1507529	-1.728708	0.2425406	0.1280265
486	0	0.436113	-0.256953	0.1969063	0.2459184
487	1	0.4351481	-0.260877	0.1967947	0.2457942
488	1	0.137671	-1.83477	0.2481519	0.1187177
489	0	0.3610008	-0.571023	0.1917664	0.2306792
490	0	0.3547099	-0.5984	0.1920877	0.2288908
491	0	0.5299184	0.1198167	0.213112	0.2491049
492	1	0.4574269	-0.170706	0.200456	0.2481875
493	1	0.3204819	-0.751558	0.1923816	0.2177732
494	0	0.2444699	-1.128328	0.2026204	0.1847044
495	0	0.5259821	0.1040221	0.2136772	0.2493249

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
496	1	0.3124378	-0.788747	0.193816	0.2148204
497	1	0.207483	-1.340164	0.2154391	0.1644338
498	0	0.5044197	0.0176791	0.2089547	0.2499805
499	0	0.4267798	-0.295002	0.1826799	0.2446388
500	0	0.56472	0.2603407	0.1981244	0.2458113
501	0	0.4652292	-0.139308	0.2016908	0.248791
502	0	0.5328264	0.1314948	0.215281	0.2489224
503	0	0.2841134	-0.924148	0.1969391	0.203393
504	1	0.2600114	-1.045909	0.1993992	0.1924055
505	0	0.508667	0.0346715	0.1886933	0.2499249
506	1	0.3387109	-0.669044	0.1923596	0.2239858
507	0	0.4926702	-0.029321	0.2054567	0.2499463
508	0	0.3299554	-0.708387	0.1919737	0.2210848
509	0	0.619166	0.4860098	0.2112437	0.2357995
510	1	0.3080749	-0.809135	0.1929403	0.2131648
511	1	0.2254308	-1.234294	0.2075032	0.1746117
512	1	0.3567834	-0.589353	0.1856997	0.229489
513	1	0.4851242	-0.059521	0.1859892	0.2497787
514	1	0.2162007	-1.287946	0.2210329	0.169458
515	1	0.276199	-0.963395	0.1981279	0.1999131
516	0	0.3422145	-0.653441	0.1916911	0.2251037
517	1	0.4545063	-0.18248	0.2000125	0.2479303
518	0	0.2557525	-1.068164	0.2062877	0.1903431
519	0	0.2865142	-0.912374	0.1966069	0.2044238

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
520	1	0.3299766	-0.708291	0.1926998	0.221092
521	1	0.0853052	-2.372355	0.3010359	0.0780282
522	1	0.3080749	-0.809135	0.1929403	0.2131648
523	1	0.0976848	-2.223217	0.2863701	0.0881425
524	0	0.4010798	-0.400968	0.1828519	0.2402148
525	1	0.484825	-0.060719	0.2040434	0.2497697
526	1	0.1625733	-1.639205	0.2496358	0.1361432
527	1	0.1871736	-1.468481	0.2350608	0.1521396
528	1	0.3777557	-0.499085	0.1839339	0.2350563
529	1	0.1869769	-1.469775	0.2210599	0.1520165
530	1	0.2315392	-1.19964	0.2147733	0.1779288
531	0	0.3431201	-0.649421	0.1922401	0.2253887
532	1	0.6030267	0.4180924	0.2325559	0.2393855
533	1	0.2827625	-0.9308	0.1986106	0.2028079
534	1	0.4267798	-0.295002	0.1826799	0.2446388
535	1	0.5044436	0.017775	0.207709	0.2499803
536	1	0.2339923	-1.185904	0.2138386	0.1792399
537	1	0.5976642	0.3957421	0.2055941	0.2404617
538	1	0.2661165	-1.014416	0.1998577	0.1952985
539	1	0.4248607	-0.302851	0.182657	0.2443541
540	1	0.6806613	0.7568127	0.2309596	0.2173615
541	1	0.5357799	0.1433648	0.2144562	0.2487198
542	0	0.3011504	-0.841826	0.1937583	0.2104588
543	1	0.3273787	-0.720065	0.1928281	0.2202019

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
544	1	0.2320509	-1.196767	0.2075347	0.1782033
545	1	0.254016	-1.077307	0.2005649	0.1894919
546	0	0.4799253	-0.080342	0.2031968	0.249597
547	1	0.329374	-0.711018	0.1892093	0.2208868
548	0	0.2285724	-1.21639	0.2076795	0.176327
549	1	0.3103134	-0.798654	0.1930121	0.214019
550	1	0.3387109	-0.669044	0.1923596	0.2239858
551	1	0.2495798	-1.100855	0.201489	0.1872897
552	1	0.1514099	-1.723585	0.2572425	0.128485
553	1	0.3664505	-0.547475	0.1918978	0.2321645
554	0	0.6563164	0.6469217	0.222498	0.2255652
555	1	0.4073844	-0.374789	0.1943393	0.2414223
556	0	0.5571521	0.2296118	0.2213848	0.2467336
557	1	0.5341252	0.1367132	0.1924614	0.2488355
558	0	0.4380442	-0.249103	0.1971333	0.2461615
559	1	0.0263745	-3.60863	0.4370353	0.0256789
560	1	0.2954003	-0.869299	0.1943162	0.2081389
561	0	0.5240247	0.0961727	0.2132278	0.2494228
562	0	0.3774742	-0.500283	0.1924384	0.2349874
563	0	0.3265151	-0.72399	0.1928736	0.219903
564	0	0.5786535	0.3172485	0.2011099	0.2438136
565	0	0.2947689	-0.872334	0.2085614	0.2078802
566	1	0.0887643	-2.328817	0.2604505	0.0808852
567	1	0.2248436	-1.23766	0.2078716	0.1742889

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
568	1	0.1825725	-1.499015	0.2131686	0.1492398
569	0	0.3928115	-0.435509	0.2081885	0.2385106
570	1	0.3023244	-0.836254	0.2008781	0.2109244
571	1	0.2277945	-1.220807	0.2056568	0.1759041
572	1	0.1668786	-1.607913	0.2169147	0.1390301
573	0	0.416785	-0.335985	0.2307619	0.2430753
574	1	0.0976304	-2.223835	0.268259	0.0880987
575	1	0.2419686	-1.141917	0.2054445	0.1834198
576	1	0.228395	-1.217396	0.2062709	0.1762307
577	1	0.1357342	-1.851182	0.2389082	0.1173104
578	0	0.4215435	-0.31644	0.2127856	0.2438446
579	1	0.1721842	-1.570226	0.2212686	0.1425368
580	1	0.2890348	-0.900077	0.2091632	0.2054937
581	1	0.1202941	-1.989648	0.2327401	0.1058234
582	1	0.5042892	0.0171574	0.2307673	0.2499816
583	1	0.3337927	-0.691081	0.191856	0.2223751
584	1	0.3689359	-0.536784	0.205119	0.2328222
585	1	0.141903	-1.799573	0.2255256	0.1217666
586	1	0.1708522	-1.579599	0.2158576	0.1416617
587	1	0.1350799	-1.856771	0.2251373	0.1168333
588	1	0.4106885	-0.36112	0.194642	0.2420234
589	0	0.4994761	-0.002096	0.229545	0.2499997
590	1	0.3322343	-0.698097	0.2136344	0.2218547
591	1	0.0521812	-2.899442	0.3110437	0.0494583

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
592	0	0.3293415	-0.711165	0.2131746	0.2208757
593	1	0.3587012	-0.581006	0.218636	0.2300347
594	0	0.5081872	0.0327516	0.2317725	0.249933
595	1	0.3451929	-0.640237	0.2028203	0.2260348
596	1	0.2167151	-1.284913	0.208444	0.1697497
597	0	0.2515939	-1.09013	0.2055835	0.1882944
598	1	0.1911758	-1.442388	0.2115693	0.1546276
599	1	0.3483671	-0.626224	0.2163846	0.2270075
600	0	0.3305771	-0.705576	0.2018175	0.2212959
601	1	0.1458567	-1.767474	0.2206421	0.1245825
602	1	0.1807283	-1.511421	0.2181712	0.1480656
603	1	0.1558984	-1.689068	0.2171308	0.1315941
604	1	0.098218	-2.217184	0.2519246	0.0885712
605	1	0.253758	-1.078669	0.207326	0.1893649
606	1	0.4186751	-0.328214	0.2122852	0.2433863
607	1	0.3158311	-0.772997	0.2111709	0.2160818
608	1	0.1215145	-1.978166	0.2356483	0.1067487
609	1	0.602543	0.4160722	0.2602552	0.2394849
610	0	0.3352669	-0.684459	0.2147336	0.222863
611	1	0.2095687	-1.327527	0.2067554	0.1656497
612	0	0.3267327	-0.723	0.2016098	0.2199785
613	1	0.3462748	-0.635455	0.2164867	0.2263685
614	1	0.1905831	-1.446226	0.2090556	0.1542612
615	1	0.2727607	-0.980661	0.2080155	0.1983623

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG78W Parameter=PPG ≤ 7.8 mmol/L (SMPG) without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
616	1	0.1213528	-1.979682	0.2483536	0.1066263
617	1	0.1974161	-1.402523	0.2130423	0.158443
618	1	0.3484967	-0.625654	0.2168581	0.2270467
619	0	0.4331429	-0.269039	0.2351413	0.2455301
620	1	0.2268633	-1.226108	0.2065316	0.1753964
621	0	0.3167213	-0.768881	0.2112953	0.2164089
622	1	0.143561	-1.786023	0.2471619	0.1229513
623	1	0.4350509	-0.261273	0.2152601	0.2457816
624	1	0.3520762	-0.609926	0.1921021	0.2281185
625	1	0.3407758	-0.659839	0.2024825	0.2246476
626	0	0.2041099	-1.360803	0.2143495	0.162449
627	0	0.4918539	-0.032587	0.227652	0.2499336
628	1	0.3604363	-0.573471	0.1917555	0.230522
629	1	0.1084973	-2.106183	0.2752713	0.0967257
630	1	0.0692748	-2.597883	0.3204926	0.0644758
631	1	0.2650539	-1.019864	0.2076461	0.1948003
632	1	0.3240717	-0.735122	0.2123644	0.2190492
633	1	0.2095687	-1.327527	0.2067554	0.1656497
634	1	0.3967953	-0.418836	0.193472	0.2393488
635	0	0.2707011	-0.991068	0.1990405	0.197422
636	0	0.1374436	-1.836687	0.2483103	0.1185529
637	1	0.121566	-1.977683	0.2635597	0.1067877
638	1	0.2245482	-1.239355	0.2098285	0.1741263
639	1	0.4223326	-0.313205	0.1958266	0.2439678

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG78W Parameter=PPG ≤ 7.8 mmol/L (SMPG) without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
640	1	0.3898139	-0.448095	0.1832616	0.237859
641	1	0.1645612	-1.624674	0.2243309	0.1374808
642	1	0.1003022	-2.193872	0.2801489	0.0902416
643	1	0.2771989	-0.958399	0.1979696	0.2003597
644	1	0.4275281	-0.291944	0.1959558	0.2447478
645	0	0.4956199	-0.017521	0.2060062	0.2499808
646	0	0.2597952	-1.047033	0.2050241	0.1923017
647	1	0.3263599	-0.724695	0.1896823	0.2198491
648	1	0.1815093	-1.506155	0.226035	0.1485637
649	1	0.2638767	-1.025916	0.2002758	0.1942458
650	1	0.213589	-1.303426	0.2091003	0.1679688
651	1	0.1741908	-1.556213	0.2121694	0.1438484
652	1	0.1572116	-1.679123	0.2275723	0.1324961
653	1	0.1109616	-2.080957	0.2563208	0.0986491
654	1	0.099086	-2.207422	0.247315	0.0892679
655	1	0.1445052	-1.778364	0.2211625	0.1236235
656	1	0.1496306	-1.737501	0.2224678	0.1272413
657	1	0.1366813	-1.843132	0.2278178	0.1179995
658	1	0.2829438	-0.929906	0.2010875	0.2028866
659	1	0.0962076	-2.240091	0.2497052	0.0869517
660	0	0.2348665	-1.181033	0.2074413	0.1797042
661	0	0.3080668	-0.809173	0.2101324	0.2131616
662	1	0.1491429	-1.741339	0.2194253	0.1268993
663	0	0.167789	-1.601379	0.2166657	0.1396358

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG78W Parameter=PPG ≤ 7.8 mmol/L (SMPG) without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
664	1	0.1032972	-2.161114	0.2478526	0.0926269
665	0	0.5166214	0.0665099	0.2339939	0.2497237
666	1	0.1214536	-1.978736	0.2320767	0.1067026
667	0	0.2914144	-0.888525	0.200904	0.206492
668	1	0.2111105	-1.318244	0.2089304	0.1665429
669	1	0.1395329	-1.819175	0.2265425	0.1200635
670	1	0.0811499	-2.426825	0.2683602	0.0745646
671	1	0.1793446	-1.520795	0.2138481	0.1471801
672	1	0.1837906	-1.490874	0.2102079	0.1500116
673	0	0.3556029	-0.5945	0.2037302	0.2291495
674	0	0.1706107	-1.581305	0.2513401	0.1415027
675	1	0.2162411	-1.287708	0.2512745	0.1694809
676	1	0.136737	-1.84266	0.2601507	0.11804
677	1	0.1601824	-1.656871	0.2641063	0.134524
678	1	0.3032039	-0.832087	0.2511125	0.2112713
679	1	0.0669336	-2.634775	0.3309808	0.0624535
680	1	0.1003012	-2.193882	0.28445	0.0902409
681	1	0.112782	-2.062634	0.2706696	0.1000622
682	1	0.0933081	-2.273896	0.2831346	0.0846017
683	1	0.1118565	-2.071916	0.2778612	0.0993446
684	1	0.2420712	-1.141357	0.2465839	0.1834727
685	1	0.2054425	-1.352619	0.2472323	0.1632359
686	1	0.0873572	-2.346339	0.2936845	0.0797259
687	1	0.3355198	-0.683324	0.2495246	0.2229463

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG78W Parameter=PPG ≤ 7.8 mmol/L (SMPG) without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
688	0	0.1459155	-1.767002	0.2648503	0.1246242
689	1	0.3782203	-0.497109	0.2539336	0.2351697
690	1	0.1868429	-1.470656	0.2565933	0.1519326
691	1	0.1658868	-1.615063	0.252238	0.1383684
692	1	0.1369943	-1.840482	0.2600602	0.1182269
693	1	0.153755	-1.705449	0.2549988	0.1301144
694	0	0.4138872	-0.347919	0.2590501	0.2425846
695	1	0.13186	-1.884612	0.2692522	0.114473
696	1	0.303434	-0.830998	0.2511397	0.2113618
697	1	0.3003302	-0.845726	0.2606058	0.210132
698	1	0.2302861	-1.206696	0.2464577	0.1772544
699	1	0.2420712	-1.141357	0.2465839	0.1834727
700	1	0.0732369	-2.537999	0.3067206	0.0678732
701	1	0.3227453	-0.741184	0.2635828	0.2185808
702	1	0.0831126	-2.400788	0.2972335	0.0762049
703	1	0.1045002	-2.148193	0.2307584	0.0935799
704	1	0.1235442	-1.959287	0.2592711	0.1082811
705	1	0.1814351	-1.506655	0.2382049	0.1485164
706	1	0.4081173	-0.371754	0.2561865	0.2415576
707	0	0.2519936	-1.088008	0.2362097	0.1884928
708	1	0.1401465	-1.814074	0.2520595	0.1205055
709	1	0.1562658	-1.686279	0.2178662	0.1318468
710	1	0.0551935	-2.840135	0.2687054	0.0521472
711	1	0.064519	-2.6741	0.2679034	0.0603563

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG78W Parameter=PPG ≤ 7.8 mmol/L (SMPG) without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
712	1	0.0407721	-3.15813	0.2928974	0.0391098
713	1	0.1331412	-1.873466	0.21747	0.1154146
714	0	0.0712079	-2.568281	0.315602	0.0661373
715	1	0.1159196	-2.031651	0.2239369	0.1024823
716	1	0.0965871	-2.235734	0.2315792	0.0872581
717	1	0.0562258	-2.820511	0.267218	0.0530644
718	1	0.1242095	-1.953157	0.2217744	0.1087815
719	1	0.1163126	-2.027822	0.2240447	0.102784
720	1	0.0951474	-2.252344	0.2878619	0.0860944
721	1	0.072578	-2.547746	0.2483434	0.0673105
722	1	0.1606821	-1.653162	0.2455218	0.1348633
723	1	0.239296	-1.156543	0.2285887	0.1820334
724	1	0.2215471	-1.256673	0.2346183	0.172464
725	1	0.059932	-2.752741	0.3330756	0.0563402
726	1	0.0502901	-2.938348	0.2747431	0.047761
727	0	0.1014059	-2.1817	0.2821049	0.0911228
728	1	0.1972142	-1.403798	0.2214944	0.1583207
729	1	0.1375829	-1.835513	0.220095	0.1186538
730	1	0.2653817	-1.018182	0.2343969	0.1949543
731	1	0.0503836	-2.936392	0.2762267	0.0478451
732	0	0.4522701	-0.191503	0.2578466	0.2477219
733	1	0.1098345	-2.092433	0.2259142	0.0977708
734	1	0.1576358	-1.675925	0.2189425	0.1327868
735	1	0.1508916	-1.727625	0.2181151	0.1281233

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG78W Parameter=PPG ≤ 7.8 mmol/L (SMPG) without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
736	1	0.0793451	-2.451278	0.2418025	0.0730495
737	1	0.0756098	-2.503549	0.2447655	0.0698929
738	1	0.2192138	-1.270254	0.2226925	0.1711591
739	0	0.2036844	-1.363424	0.2362038	0.1621971
740	1	0.086163	-2.361411	0.2376417	0.078739
741	1	0.2170978	-1.28266	0.2076828	0.1699664
742	1	0.0684804	-2.610269	0.2512778	0.0637909
743	1	0.3119318	-0.791103	0.2435049	0.2146304
744	1	0.1497061	-1.736908	0.2191517	0.1272942
745	1	0.0837923	-2.391902	0.2392578	0.0767711
746	0	0.1570583	-1.680281	0.2189479	0.132391
747	1	0.0604761	-2.743124	0.2601928	0.0568188
748	1	0.0860773	-2.3625	0.2376985	0.078668
749	1	0.1137787	-2.052712	0.2247543	0.1008331
750	1	0.10958	-2.095038	0.227811	0.0975722
751	1	0.1090359	-2.100627	0.2262445	0.0971471
752	1	0.3646538	-0.555222	0.232865	0.2316814
753	1	0.0931464	-2.275809	0.2385048	0.0844701
754	1	0.239818	-1.153678	0.2256868	0.1823053
755	1	0.0729149	-2.542752	0.2470871	0.0675983
756	1	0.0370145	-3.25873	0.3038226	0.0356444
757	1	0.286953	-0.910229	0.2158147	0.204611
758	1	0.1096723	-2.094093	0.2260318	0.0976443
759	1	0.4713335	-0.114792	0.2414483	0.2491782

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
760	1	0.2087841	-1.33227	0.2309675	0.1651933
761	1	0.1475017	-1.754331	0.2192641	0.125745
762	1	0.1407296	-1.809243	0.2550967	0.1209248
763	1	0.1793556	-1.520719	0.2181985	0.1471872
764	0	0.0783958	-2.464346	0.2425288	0.0722499
765	1	0.0574043	-2.798519	0.278429	0.054109
766	1	0.1472997	-1.755939	0.2183617	0.1256025
767	1	0.1506128	-1.729803	0.2181319	0.1279286
768	0	0.0880682	-2.337453	0.2364109	0.0803122
769	1	0.1501408	-1.733497	0.2126975	0.1275986
770	1	0.0717458	-2.560176	0.2481456	0.0665984
771	1	0.1163435	-2.027521	0.2243186	0.1028077
772	0	0.1279951	-1.918803	0.2566999	0.1116124
773	1	0.4615772	-0.153995	0.2394925	0.2485237
774	0	0.3582305	-0.583053	0.2246326	0.2299014
775	1	0.6133173	0.4612781	0.2794876	0.2371592
776	0	0.4650615	-0.139982	0.2693148	0.2487793
777	0	0.4738828	-0.104564	0.2674268	0.2493179
778	0	0.3549495	-0.597353	0.2462952	0.2289603
779	1	0.2891863	-0.899339	0.2162112	0.2055576
780	1	0.1125908	-2.064547	0.2261982	0.0999141
781	0	0.2106656	-1.320918	0.2233824	0.1662856
782	1	0.131085	-1.891399	0.2181837	0.1139018
783	1	0.2409229	-1.147626	0.2093769	0.1828791

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG78W Parameter=PPG ≤ 7.8 mmol/L (SMPG) without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
784	1	0.1856787	-1.478337	0.2402899	0.1512021
785	1	0.0777009	-2.474003	0.2522343	0.0716635
786	1	0.1196747	-1.995514	0.2228859	0.1053527
787	1	0.1883411	-1.460825	0.2188409	0.1528687
788	1	0.0943856	-2.261225	0.2327289	0.085477
789	1	0.2000061	-1.386257	0.2218516	0.1600036
790	1	0.1094598	-2.096271	0.2261023	0.0974784
791	1	0.1234665	-1.960005	0.2211199	0.1082226
792	1	0.1329568	-1.875064	0.2175327	0.1152793
793	1	0.1400658	-1.814744	0.2190709	0.1204474
794	1	0.3718595	-0.524248	0.2259134	0.23358
795	0	0.2106895	-1.320774	0.2074713	0.1662995
796	1	0.0881974	-2.335846	0.2358223	0.0804186
797	1	0.065154	-2.663629	0.2547551	0.0609089
798	1	0.1359209	-1.849591	0.2196158	0.1174464
799	1	0.1229245	-1.965023	0.2220726	0.1078141
800	1	0.3339443	-0.690399	0.2527775	0.2224255
801	1	0.1717093	-1.573561	0.2192367	0.1422252
802	1	0.0862152	-2.360749	0.2441504	0.0787821
803	1	0.1070387	-2.121353	0.2686551	0.0955814
804	1	0.1619598	-1.643718	0.245219	0.1357288
805	1	0.3917482	-0.43997	0.2491773	0.2382816
806	1	0.0684087	-2.611394	0.3051404	0.063729
807	0	0.2901819	-0.894501	0.2221572	0.2059764

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG78W Parameter=PPG ≤ 7.8 mmol/L (SMPG) without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
808	0	0.1803907	-1.513703	0.2397839	0.1478499
809	0	0.3178168	-0.763823	0.2223024	0.2168093
810	1	0.2918428	-0.886451	0.2354639	0.2066706
811	1	0.322764	-0.741098	0.2416451	0.2185874
812	1	0.374373	-0.513502	0.249615	0.2342179
813	1	0.3230335	-0.739866	0.2224699	0.2186829
814	1	0.1873528	-1.467304	0.2364011	0.1522517
815	1	0.1007028	-2.18944	0.2729962	0.0905617
816	1	0.565894	0.2651182	0.2982479	0.245658
817	1	0.16004	-1.657931	0.2177722	0.1344272
818	1	0.2352717	-1.17878	0.2254873	0.1799189
819	0	0.3020803	-0.837411	0.2437844	0.2108278
820	1	0.0598603	-2.754014	0.2609607	0.0562771
821	1	0.2421198	-1.141092	0.2094958	0.1834978
822	1	0.0276894	-3.558626	0.3521707	0.0269227
823	1	0.2356479	-1.17669	0.2361871	0.1801179
824	1	0.2996923	-0.848764	0.2220601	0.2098768
825	0	0.1810356	-1.509347	0.2396585	0.1482617
826	1	0.0832485	-2.399007	0.2389962	0.0763181
827	1	0.181274	-1.50774	0.2410278	0.1484137
828	1	0.0979322	-2.220414	0.2306653	0.0883415
829	1	0.1596708	-1.660679	0.218935	0.1341761
830	0	0.1481223	-1.749405	0.2182993	0.1261821
831	1	0.2369624	-1.169406	0.2090048	0.1808112

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NN1218-4131

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG78W Parameter=PPG ≤ 7.8 mmol/L (SMPG) without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
832	1	0.1587961	-1.667213	0.218936	0.1335799
833	1	0.1196747	-1.995514	0.2228859	0.1053527
834	1	0.1596088	-1.661142	0.2461888	0.1341338
835	1	0.1023606	-2.171267	0.2320903	0.0918829
836	1	0.0971198	-2.229645	0.2313108	0.0876875
837	1	0.0955085	-2.248157	0.2321343	0.0863867
838	1	0.201602	-1.376312	0.2073749	0.1609586
839	1	0.0646999	-2.671108	0.2676572	0.0605138
840	1	0.0901899	-2.311318	0.2351079	0.0820557
841	1	0.0906805	-2.305355	0.2343777	0.0824575
842	1	0.2538976	-1.077932	0.2108189	0.1894336
843	1	0.1671126	-1.60623	0.2190549	0.139186
844	0	0.224403	-1.24019	0.2080574	0.1740463
845	1	0.0637184	-2.687443	0.2690053	0.0596584
846	1	0.0918666	-2.291054	0.2394904	0.0834271
847	1	0.1162755	-2.028183	0.223832	0.1027555
848	0	0.1976683	-1.400932	0.2197577	0.1585956
849	1	0.104264	-2.15072	0.2279742	0.093393
850	1	0.2073395	-1.341038	0.2209455	0.1643498
851	0	0.1943406	-1.422049	0.2074843	0.1565723
852	1	0.0587983	-2.773045	0.2636877	0.055341
853	0	0.3020803	-0.837411	0.2437844	0.2108278
854	1	0.0894311	-2.3206	0.2350927	0.0814332
855	1	0.0925403	-2.283005	0.2337439	0.0839766

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG78W Parameter=PPG ≤ 7.8 mmol/L (SMPG) without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
856	1	0.1808795	-1.5104	0.2198205	0.1481621
857	0	0.1450539	-1.773933	0.2194185	0.1240133
858	1	0.1443159	-1.779896	0.2186186	0.1234889
859	1	0.1445851	-1.777718	0.2185935	0.1236803
860	1	0.0665908	-2.640278	0.3066421	0.0621564
861	1	0.0465974	-3.018492	0.2982797	0.0444261
862	1	0.0956475	-2.24655	0.2317578	0.086499
863	1	0.0750031	-2.512261	0.2452741	0.0693776
864	1	0.2280246	-1.219499	0.2082927	0.1760294
865	1	0.1569332	-1.681226	0.21129	0.1323052
866	1	0.3403036	-0.661942	0.2268882	0.224497
867	1	0.0726944	-2.546019	0.2472844	0.0674099
868	1	0.2728713	-0.980103	0.2343174	0.1984126
869	1	0.0675806	-2.624461	0.3062354	0.0630135
870	0	0.2997894	-0.848301	0.2431649	0.2099157
871	1	0.3197086	-0.755111	0.2223583	0.217495
872	1	0.297837	-0.857619	0.2388848	0.2091301
873	1	0.116325	-2.027701	0.2628671	0.1027935
874	0	0.1864302	-1.473375	0.2203045	0.151674
875	1	0.4126912	-0.352851	0.2533225	0.2423772
876	0	0.418901	-0.327286	0.2584846	0.243423
877	0	0.3634716	-0.560328	0.2477074	0.23136
878	1	0.1034103	-2.159894	0.2803648	0.0927166
879	1	0.2230479	-1.247992	0.234525	0.1732976

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG78W Parameter=PPG ≤ 7.8 mmol/L (SMPG) without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
880	1	0.4869297	-0.052293	0.2707934	0.2498292
881	1	0.227833	-1.220588	0.2082795	0.1759251
882	1	0.1309611	-1.892488	0.2182277	0.1138103
883	0	0.3145206	-0.779069	0.2222185	0.2155974
884	1	0.1382396	-1.829989	0.2192979	0.1191294
885	1	0.359734	-0.576519	0.2247624	0.2303254
886	0	0.3407927	-0.659764	0.2270033	0.224653
887	1	0.0561717	-2.821531	0.265841	0.0530165
888	1	0.3239868	-0.73551	0.222505	0.2190194
889	1	0.0274811	-3.566392	0.3305568	0.0267259
890	0	0.2513055	-1.091662	0.2286933	0.1881511
891	1	0.0851912	-2.373817	0.2450516	0.0779337
892	0	0.4659101	-0.136571	0.2403503	0.2488379
893	1	0.3753938	-0.509146	0.2497993	0.2344733
894	1	0.2807186	-0.9409	0.2347212	0.2019157
895	1	0.0969339	-2.231767	0.2861665	0.0875377
896	1	0.5500845	0.2010122	0.2603277	0.2474915
897	1	0.2252365	-1.235407	0.2236867	0.174505
898	1	0.1995839	-1.388897	0.2331005	0.1597502
899	1	0.2435838	-1.133131	0.2361279	0.1842507
900	1	0.0988142	-2.21047	0.2344239	0.08905
901	1	0.2840286	-0.924565	0.2349218	0.2033564
902	1	0.0896204	-2.318279	0.2412809	0.0815886
903	1	0.0873256	-2.346736	0.2363522	0.0796998

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG78W Parameter=PPG ≤ 7.8 mmol/L (SMPG) without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
904	1	0.1762684	-1.541837	0.208576	0.1451979
905	0	0.3027999	-0.834	0.2187676	0.2111121
906	1	0.1694867	-1.589269	0.2423	0.140761
907	1	0.2367396	-1.170639	0.2280684	0.1806939
908	1	0.1907628	-1.445061	0.2207447	0.1543723
909	1	0.1426399	-1.793535	0.2196024	0.1222938
910	1	0.0637077	-2.687622	0.3116043	0.059649
911	1	0.2284082	-1.217321	0.2083195	0.1762379
912	1	0.2490688	-1.103585	0.224615	0.1870336
913	0	0.0878935	-2.339631	0.2365214	0.0801682
914	1	0.1918619	-1.437957	0.2191588	0.1550509
915	1	0.1453242	-1.771755	0.2193999	0.1242051
916	1	0.4286569	-0.287333	0.2506409	0.2449102
917	0	0.4018107	-0.397926	0.2295036	0.2403589
918	1	0.1523776	-1.716073	0.2122052	0.1291587
919	0	0.1620226	-1.643256	0.2189485	0.1357713
920	0	0.1764057	-1.540892	0.2195005	0.1452867
921	0	0.3134784	-0.783907	0.2209289	0.2152097
922	1	0.0969339	-2.231767	0.2861665	0.0875377
923	1	0.1149394	-2.041251	0.2242318	0.1017283
924	1	0.1388961	-1.824489	0.2560783	0.119604
925	1	0.4094108	-0.366402	0.272739	0.2417936
926	1	0.0602614	-2.74691	0.2617858	0.05663
927	1	0.4063713	-0.378987	0.2520327	0.2412337

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG78W Parameter=PPG ≤ 7.8 mmol/L (SMPG) without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
928	1	0.0665608	-2.64076	0.2532474	0.0621304
929	1	0.1851852	-1.481604	0.240369	0.1508917
930	1	0.1161014	-2.029879	0.2629967	0.1026218
931	0	0.3489884	-0.623489	0.2453504	0.2271955
932	1	0.6700644	0.7084764	0.3000972	0.2210781
933	0	0.2456122	-1.122153	0.2275122	0.1852868
934	1	0.293195	-0.879917	0.2355672	0.2072317
935	1	0.1694188	-1.589752	0.209336	0.1407161
936	1	0.1752958	-1.54855	0.2408331	0.1445672
937	1	0.3197086	-0.755111	0.2223583	0.217495
938	0	0.2478488	-1.110119	0.2247444	0.1864198
939	0	0.1717905	-1.57299	0.2178639	0.1422785
940	1	0.0526505	-2.889993	0.2865039	0.0498784
941	0	0.1699392	-1.586058	0.2178133	0.1410599
942	1	0.0559667	-2.825404	0.3225349	0.0528344
943	1	0.1123073	-2.067387	0.2250679	0.0996944
944	1	0.0505924	-2.932036	0.2758785	0.0480328
945	1	0.3681931	-0.539976	0.2337736	0.232627
946	0	0.0732486	-2.537826	0.2477256	0.0678833
947	1	0.1878422	-1.464092	0.2187988	0.1525575
948	1	0.2607375	-1.042139	0.2333022	0.1927534
949	1	0.134647	-1.860481	0.2198049	0.1165172
950	1	0.0496322	-2.952208	0.2758358	0.0471689
951	1	0.0791862	-2.453456	0.2419229	0.0729157

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG78W Parameter=PPG ≤ 7.8 mmol/L (SMPG) without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
952	1	0.1520112	-1.718913	0.2180517	0.1289038
953	1	0.3808048	-0.486134	0.2268773	0.2357925
954	1	0.1400658	-1.814744	0.2190709	0.1204474
955	1	0.0808805	-2.430444	0.2490531	0.0743388
956	1	0.3042832	-0.826984	0.2220699	0.2116949
957	0	0.0308847	-3.446122	0.3821193	0.0299308
958	1	0.2325397	-1.194026	0.2249803	0.178465
959	1	0.1153833	-2.036895	0.2240972	0.10207
960	1	0.1610097	-1.650735	0.210566	0.1350856
961	1	0.2957209	-0.867759	0.2174091	0.20827
962	1	0.1187599	-2.004226	0.2231307	0.104656
963	1	0.3089015	-0.80526	0.2426863	0.2134814
964	1	0.1006591	-2.189923	0.2294478	0.0905268
965	1	0.0534712	-2.873658	0.2850423	0.050612
966	1	0.1943406	-1.422049	0.2074843	0.1565723
967	1	0.0939776	-2.266008	0.2378778	0.0851458
968	1	0.1394735	-1.81967	0.2198933	0.1200206
969	0	0.1134641	-2.055835	0.2257481	0.10059
970	1	0.1729519	-1.564849	0.219299	0.1430396
971	1	0.0754975	-2.505156	0.2457278	0.0697976
972	0	0.2507018	-1.094873	0.2244474	0.1878504
973	0	0.1385782	-1.827149	0.2157325	0.1193743
974	1	0.1929802	-1.430761	0.2075245	0.1557388
975	1	0.1219883	-1.973734	0.222298	0.1071072

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=PPG78W Parameter=PPG ≤ 7.8 mmol/L (SMPG) without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
976	0	0.127456	-1.923641	0.2210778	0.111211
977	1	0.1518709	-1.720002	0.2180593	0.1288061

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Parameter Code=PPG78 Parameter=PPG <=7.8 mmol/L (SMPG) Study Identifier=NN1218-4131

The GENMOD Procedure

Model Information

Data Set	WORK.ENDPOINT
Distribution	Binomial
Link Function	Logit
Dependent Variable	aval

Number of Observations Read	977
Number of Observations Used	977
Number of Events	226
Number of Trials	977

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Response Profile

Ordered Value	aval	Total Frequency
1	0	226
2	1	751

Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

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The GENMOD Procedure

PROC GENMOD is modeling the probability that aval='0'. One way to change this to model the probability that aval='1' is to specify the DESCENDING option in the PROC statement.

Parameter Information

Parameter	Effect	TRTPN	REGION1	BOLAD1
Prm1	Intercept			
Prm2	TRTPN	2		
Prm3	TRTPN	3		
Prm4	TRTPN	4		
Prm5	REGION1		ASIA (EXCLUDING JAPAN)	
Prm6	REGION1		EUROPE	
Prm7	REGION1		JAPAN	
Prm8	REGION1		NORTH AMERICA	
Prm9	BOLAD1			BOLUS INSULIN ALGORITHM (SLIDING SCALE)
Prm10	BOLAD1			CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY
Prm11	P9PPRABL			

Criteria For Assessing Goodness Of Fit

Criterion	DF	Value	Value/DF
Log Likelihood		-463.4898	
Full Log Likelihood		-463.4898	
AIC (smaller is better)		942.9796	
AICC (smaller is better)		943.1283	
BIC (smaller is better)		982.0555	

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Parameter Code=PPG78 Parameter=PPG <=7.8 mmol/L (SMPG) Study Identifier=NN1218-4131

The GENMOD Procedure

Algorithm converged.

Analysis Of Maximum Likelihood Parameter Estimates

Parameter		DF	Estimate	Standard Error	Wald 95% Confidence Limits		Wald Chi-Square
Intercept		1	1.3632	0.4484	0.4844	2.2420	9.24
TRTPN	2	1	0.4306	0.1963	0.0459	0.8153	4.81
TRTPN	3	1	-0.0413	0.2063	-0.4457	0.3631	0.04
TRTPN	4	0	0.0000	0.0000	0.0000	0.0000	.
REGION1	ASIA (EXCLUDING JAPAN)	1	0.3627	0.2830	-0.1920	0.9174	1.64
REGION1	EUROPE	1	0.5825	0.2066	0.1775	0.9875	7.95
REGION1	JAPAN	1	-0.5226	0.2730	-1.0577	0.0125	3.66
REGION1	NORTH AMERICA	0	0.0000	0.0000	0.0000	0.0000	.
BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	1	0.4316	0.1859	0.0673	0.7960	5.39

Analysis Of Maximum Likelihood Parameter Estimates

Parameter		Pr > ChiSq
Intercept		0.0024
TRTPN	2	0.0282
TRTPN	3	0.8413
TRTPN	4	.
REGION1	ASIA (EXCLUDING JAPAN)	0.2000
REGION1	EUROPE	0.0048
REGION1	JAPAN	0.0556
REGION1	NORTH AMERICA	.
BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.0202

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The GENMOD Procedure

Analysis Of Maximum Likelihood Parameter Estimates

Parameter	DF	Estimate	Standard Error	Wald 95% Confidence Limits	Wald Chi-Square
BOLAD1 CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY	0	0.0000	0.0000	0.0000 0.0000	.
P9PPRABL	1	-0.3448	0.0446	-0.4322 -0.2575	59.90
Scale	0	1.0000	0.0000	1.0000 1.0000	

Analysis Of Maximum Likelihood Parameter Estimates

Parameter	Pr > ChiSq
BOLAD1 CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY	.
P9PPRABL	<.0001
Scale	

NOTE: The scale parameter was held fixed.

Coefficients for TRTPN Least Squares Means Using WORK.ENDPOINT Margins

Parameter	Geographic Region Grouping Method 1
Intercept	
Planned Treatment (N) 2	
Planned Treatment (N) 3	
Planned Treatment (N) 4	
Geographic Region Grouping Method 1 ASIA (EXCLUDING JAPAN)	ASIA (EXCLUDING JAPAN)
Geographic Region Grouping Method 1 EUROPE	EUROPE
Geographic Region Grouping Method 1 JAPAN	JAPAN

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Parameter Code=PPG78 Parameter=PPG <=7.8 mmol/L (SMPG) Study Identifier=NN1218-4131

The GENMOD Procedure

Coefficients for TRTPN Least Squares Means Using WORK.ENDPOINT Margins

Parameter	Geographic Region Grouping Method 1
Geographic Region Grouping Method 1 NORTH AMERICA	NORTH AMERICA
Bolus Adjustment Method at Timepoint 1 BOLUS INSULIN ALGORITHM (SLIDING SCALE)	
Bolus Adjustment Method at Timepoint 1 CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY	
PPG all meals (SMPG) (mmol/L) at Baseline	

Coefficients for TRTPN Least Squares Means Using WORK.ENDPOINT Margins

	Planned Treatment (N)	Row1	Row2	Row3
Bolus Adjustment Method at Timepoint 1				
	1	1	1	1
	2	1		
	3		1	
	4			1
		0.1351	0.1351	0.1351
		0.3367	0.3367	0.3367
		0.2467	0.2467	0.2467
		0.2815	0.2815	0.2815
BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.5793	0.5793	0.5793
CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0.4207	0.4207	0.4207
		9.5719	9.5719	9.5719

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG78 Parameter=PPG <=7.8 mmol/L (SMPG) Study Identifier=NN1218-4131

The GENMOD Procedure

TRTPN Least Squares Means

Planned Treatment (N)	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
2	WORK.ENDPOINT	-1.1407	0.1386	-8.23	<.0001	0.05	-1.4124	-0.8690
3	WORK.ENDPOINT	-1.6126	0.1547	-10.42	<.0001	0.05	-1.9159	-1.3093
4	WORK.ENDPOINT	-1.5713	0.1505	-10.44	<.0001	0.05	-1.8662	-1.2764

Differences of TRTPN Least Squares Means

Planned Treatment (N)	Planned Treatment (N)	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
2	4	WORK.ENDPOINT	0.4306	0.1963	2.19	0.0282	0.05	0.04592	0.8153
3	4	WORK.ENDPOINT	-0.04131	0.2063	-0.20	0.8413	0.05	-0.4457	0.3631

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) / NovoRapid (meal)	WORK.ENDPOINT	0.4306	0.1963	2.19	0.0282	0.05	0.04592	0.8153

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Parameter Code=PPG78 Parameter=PPG <=7.8 mmol/L (SMPG) Study Identifier=NN1218-4131

The GENMOD Procedure

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
TRTPN	Faster aspart (post) / NovoRapid (meal)	WORK.ENDPOINT	-0.04131	0.2063	-0.20	0.8413	0.05	-0.4457	0.3631

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
1	1	0.1584938	-1.669478	0.2782898	0.1333735
2	1	0.1037345	-2.156402	0.2760284	0.0929736
3	1	0.053077	-2.881473	0.2983237	0.0502599
4	1	0.0210323	-3.840438	0.3645484	0.02059
5	1	0.0618108	-2.719874	0.2909	0.0579902
6	1	0.4474847	-0.210839	0.2856251	0.2472421
7	1	0.0426555	-3.111007	0.2944525	0.040836
8	1	0.02943	-3.495869	0.3136111	0.0285639
9	1	0.1784308	-1.527015	0.2816184	0.1465933
10	1	0.1989109	-1.393115	0.2464557	0.1593453
11	1	0.1429897	-1.790677	0.2763931	0.1225437
12	1	0.0257821	-3.631953	0.3219546	0.0251174
13	1	0.1619412	-1.643855	0.2960698	0.1357163
14	1	0.1894317	-1.453707	0.2995445	0.1535473
15	1	0.1590618	-1.665225	0.2783721	0.1337612

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
16	1	0.3071051	-0.813688	0.3403231	0.2127916
17	1	0.0929137	-2.278566	0.2534915	0.0842808
18	1	0.1688146	-1.594052	0.2425294	0.1403163
19	1	0.0826941	-2.406293	0.2760796	0.0758558
20	1	0.0198406	-3.899983	0.40057	0.019447
21	1	0.0173594	-4.036108	0.3512546	0.0170581
22	1	0.0410359	-3.151407	0.2961298	0.0393519
23	0	0.0783761	-2.464618	0.2601389	0.0722333
24	1	0.0108091	-4.516497	0.3914023	0.0106923
25	1	0.0374316	-3.247091	0.3004268	0.0360304
26	1	0.0412876	-3.145028	0.2958594	0.039583
27	1	0.0307324	-3.451225	0.3241819	0.0297879
28	1	0.1075512	-2.116002	0.275671	0.0959839
29	0	0.091831	-2.291481	0.2502348	0.0833981
30	1	0.084415	-2.383818	0.2569971	0.0772891
31	1	0.026925	-3.587407	0.3439917	0.0262
32	1	0.0481802	-2.983429	0.2897102	0.0458588
33	0	0.1849018	-1.483484	0.2443566	0.1507131
34	1	0.1683907	-1.597076	0.298111	0.1400353
35	1	0.0373876	-3.248311	0.2991812	0.0359898
36	1	0.0627392	-2.703976	0.2796656	0.058803
37	1	0.0080997	-4.807801	0.4186045	0.0080341
38	1	0.0506773	-2.930271	0.2879898	0.0481091
39	1	0.0261587	-3.617068	0.3210057	0.0254744

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
40	0	0.2160626	-1.288761	0.3141524	0.1693795
41	1	0.1768921	-1.537548	0.2492566	0.1456013
42	0	0.3480804	-0.627488	0.2908621	0.2269204
43	1	0.0381602	-3.227056	0.3053172	0.036704
44	1	0.1677799	-1.601444	0.240723	0.1396298
45	1	0.1075504	-2.116011	0.2560658	0.0959833
46	1	0.1965576	-1.40795	0.2395179	0.1579227
47	1	0.1596448	-1.660873	0.2474093	0.1341583
48	1	0.0814123	-2.423312	0.2552653	0.0747843
49	0	0.5057635	0.0230551	0.303151	0.2499668
50	0	0.1157728	-2.033085	0.2524752	0.1023694
51	1	0.1270026	-1.927725	0.2469098	0.1108729
52	0	0.1992749	-1.390832	0.2527486	0.1595644
53	1	0.1094998	-2.09586	0.2447724	0.0975096
54	1	0.038205	-3.225836	0.3060727	0.0367453
55	1	0.1627931	-1.637591	0.2412349	0.1362915
56	1	0.0373547	-3.249225	0.3078734	0.0359594
57	1	0.0634328	-2.69224	0.2908595	0.0594091
58	1	0.041492	-3.139877	0.2985503	0.0397704
59	1	0.1349881	-1.857557	0.2465745	0.1167663
60	0	0.3502191	-0.618076	0.2842087	0.2275657
61	1	0.1031421	-2.162789	0.2582654	0.0925038
62	1	0.0451537	-3.051479	0.293283	0.0431148
63	1	0.0535571	-2.871963	0.2795759	0.0506887

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
64	1	0.0697802	-2.59007	0.2657572	0.064911
65	1	0.0743283	-2.522028	0.2626008	0.0688036
66	1	0.1316712	-1.886262	0.2466714	0.1143339
67	1	0.0776878	-2.474186	0.2605362	0.0716524
68	0	0.2770185	-0.959299	0.2466514	0.2002793
69	1	0.1741075	-1.556792	0.2402146	0.1437941
70	0	0.3490216	-0.623342	0.260451	0.2272055
71	1	0.286257	-0.913633	0.2660238	0.2043139
72	1	0.0718792	-2.558175	0.2642459	0.0667126
73	1	0.1191844	-2.000176	0.2430151	0.1049795
74	0	0.0728712	-2.543398	0.2803958	0.067561
75	1	0.0792136	-2.45308	0.2565442	0.0729388
76	1	0.0484731	-2.977058	0.2881877	0.0461235
77	1	0.2654518	-1.017822	0.2606468	0.1949872
78	1	0.0619955	-2.716693	0.2926636	0.0581521
79	1	0.1404028	-1.811949	0.244943	0.1206898
80	1	0.1205302	-1.987418	0.2428274	0.1060027
81	1	0.1698684	-1.58656	0.2405383	0.1410132
82	1	0.0987954	-2.210681	0.2476807	0.0890349
83	1	0.2279679	-1.219821	0.2519502	0.1759985
84	0	0.3266713	-0.723279	0.2556546	0.2199572
85	1	0.1164384	-2.026598	0.2479449	0.1028805
86	1	0.1466755	-1.760917	0.243648	0.1251618
87	1	0.0730223	-2.541165	0.2634627	0.06769

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
88	0	0.1444217	-1.77904	0.2413399	0.1235641
89	1	0.0966533	-2.234977	0.2522403	0.0873114
90	1	0.2742492	-0.97317	0.2628802	0.1990366
91	1	0.1350939	-1.856651	0.2415445	0.1168436
92	1	0.1372197	-1.838577	0.2414597	0.1183904
93	1	0.0370824	-3.256824	0.3076882	0.0357073
94	1	0.1774964	-1.533402	0.2400032	0.1459915
95	1	0.0567701	-2.8103	0.2756397	0.0535473
96	1	0.1220198	-1.973441	0.2473069	0.107131
97	1	0.0918317	-2.291472	0.2761195	0.0833986
98	1	0.0178753	-4.006298	0.4116629	0.0175558
99	1	0.1184226	-2.007453	0.2841153	0.1043987
100	1	0.1767145	-1.538768	0.2433399	0.1454865
101	1	0.0955365	-2.247833	0.2771988	0.0864093
102	1	0.0981494	-2.217958	0.2805774	0.0885161
103	0	0.0820506	-2.414806	0.2549094	0.0753183
104	1	0.0573426	-2.79966	0.2819253	0.0540544
105	1	0.0936205	-2.270209	0.2762144	0.0848557
106	1	0.0776765	-2.474343	0.2574889	0.0716429
107	1	0.0478881	-2.989816	0.2890449	0.0455948
108	1	0.2640337	-1.025107	0.2671714	0.1943199
109	1	0.098706	-2.211686	0.2766764	0.0889631
110	1	0.1566526	-1.683348	0.2893078	0.1321126
111	0	0.0493066	-2.959133	0.2868383	0.0468755

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
112	0	0.0938011	-2.268083	0.2762254	0.0850024
113	1	0.0300699	-3.473699	0.311582	0.0291657
114	1	0.0222013	-3.785154	0.3599037	0.0217084
115	1	0.0126809	-4.354897	0.3770868	0.0125201
116	1	0.1187396	-2.004421	0.279684	0.1046405
117	1	0.1593465	-1.663099	0.2784136	0.1339552
118	1	0.2021506	-1.372907	0.3037543	0.1612857
119	0	0.0959046	-2.243581	0.2771333	0.0867069
120	1	0.0444648	-3.067575	0.2909664	0.0424876
121	0	0.1818854	-1.503626	0.2822759	0.1488031
122	1	0.0446072	-3.064228	0.2926148	0.0426174
123	1	0.0407379	-3.159006	0.2949197	0.0390783
124	1	0.0464503	-3.021809	0.3057828	0.0442926
125	1	0.0955458	-2.247726	0.2802866	0.0864168
126	1	0.0246329	-3.678731	0.3249929	0.0240261
127	1	0.1257125	-1.939411	0.2858035	0.1099089
128	1	0.0793026	-2.45186	0.2596174	0.0730137
129	1	0.3276093	-0.719018	0.3204704	0.2202814
130	1	0.049966	-2.945155	0.2884561	0.0474694
131	1	0.0643298	-2.67724	0.2819589	0.0601915
132	0	0.1280498	-1.918313	0.2420034	0.111653
133	1	0.0206624	-3.858561	0.3375462	0.0202355
134	1	0.1066315	-2.12562	0.2775807	0.0952612
135	1	0.073239	-2.537967	0.2802161	0.0678751

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
136	1	0.0952563	-2.251081	0.2489063	0.0861825
137	1	0.0792178	-2.453022	0.2816175	0.0729424
138	0	0.1889425	-1.456896	0.2993846	0.1532432
139	1	0.1004312	-2.192442	0.2808684	0.0903448
140	1	0.0704741	-2.57943	0.2806154	0.0655075
141	1	0.1620632	-1.642957	0.2419861	0.1357987
142	1	0.1181887	-2.009695	0.2515357	0.1042202
143	1	0.193553	-1.427087	0.2395211	0.1560902
144	1	0.1572142	-1.679104	0.2416899	0.1324979
145	1	0.1450992	-1.773568	0.2466111	0.1240454
146	1	0.1224761	-1.969188	0.2472641	0.1074757
147	1	0.0758681	-2.499859	0.2586566	0.0701121
148	1	0.256238	-1.065615	0.2437364	0.1905801
149	1	0.1917507	-1.438674	0.2514583	0.1549824
150	1	0.0367799	-3.26533	0.3083711	0.0354272
151	1	0.0720818	-2.555143	0.2613114	0.066886
152	1	0.0323559	-3.398067	0.3197643	0.031309
153	1	0.1676246	-1.602557	0.2424232	0.1395266
154	1	0.3118851	-0.791321	0.2527147	0.2146128
155	1	0.2753398	-0.967697	0.2701171	0.1995278
156	1	0.0469279	-3.011079	0.2904886	0.0447256
157	0	0.1551192	-1.695002	0.2422309	0.1310572
158	1	0.0696354	-2.592304	0.2837326	0.0647863
159	0	0.0609528	-2.734766	0.2940118	0.0572375

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
160	1	0.1719929	-1.571569	0.2486464	0.1424113
161	1	0.0334382	-3.364046	0.3169828	0.0323201
162	1	0.1268848	-1.928788	0.2469174	0.110785
163	1	0.0932595	-2.27447	0.249663	0.0845622
164	1	0.0711731	-2.568807	0.2647435	0.0661075
165	1	0.0823715	-2.410554	0.2547331	0.0755864
166	1	0.0664639	-2.642321	0.2658341	0.0620464
167	1	0.018734	-3.958506	0.3708112	0.018383
168	1	0.1117008	-2.073484	0.2541744	0.0992238
169	1	0.0539436	-2.864364	0.280923	0.0510337
170	1	0.1787415	-1.524897	0.2399358	0.146793
171	1	0.1771862	-1.535529	0.2400209	0.1457913
172	1	0.2216687	-1.255969	0.250649	0.1725317
173	1	0.0652863	-2.661458	0.2668803	0.061024
174	1	0.0916538	-2.293607	0.2503076	0.0832534
175	1	0.0500666	-2.943037	0.2859359	0.04756
176	0	0.0193505	-3.925499	0.4032174	0.018976
177	1	0.1354854	-1.853304	0.2465648	0.1171291
178	1	0.0720818	-2.555143	0.2613114	0.066886
179	1	0.0569438	-2.807061	0.299526	0.0537012
180	0	0.0710925	-2.570027	0.2620548	0.0660384
181	1	0.0979606	-2.220092	0.2518405	0.0883643
182	1	0.0931829	-2.275376	0.2533959	0.0844999
183	1	0.0678725	-2.619838	0.2672174	0.0632658

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Parameter Code=PPG78 Parameter=PPG ≤ 7.8 mmol/L (SMPG) Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
184	1	0.0921863	-2.287228	0.2500902	0.083688
185	0	0.2819425	-0.934847	0.2474248	0.2024509
186	1	0.0776039	-2.475357	0.2759268	0.0715816
187	1	0.0229542	-3.751034	0.3505778	0.0224273
188	1	0.0569438	-2.807061	0.299526	0.0537012
189	1	0.0524899	-2.893217	0.284637	0.0497347
190	1	0.1223451	-1.970408	0.2425943	0.1073768
191	1	0.0884351	-2.332894	0.2672656	0.0806143
192	1	0.1674763	-1.60362	0.2424103	0.139428
193	1	0.0495634	-2.953669	0.2866343	0.0471069
194	1	0.0264542	-3.60553	0.3198432	0.0257544
195	1	0.0340221	-3.346129	0.3149761	0.0328646
196	1	0.0810948	-2.427564	0.2554449	0.0745184
197	1	0.217487	-1.280372	0.2401481	0.1701864
198	1	0.0769183	-2.484975	0.257971	0.0710018
199	1	0.3931356	-0.434151	0.2974453	0.23858
200	1	0.0740362	-2.526281	0.2627905	0.0685549
201	1	0.1793666	-1.520644	0.2399039	0.1471943
202	1	0.0635656	-2.690006	0.2708444	0.059525
203	1	0.1029456	-2.164916	0.2583683	0.0923478
204	1	0.131659	-1.886369	0.2471349	0.1143249
205	1	0.2289325	-1.214349	0.2587331	0.1765224
206	1	0.111912	-2.071358	0.2540825	0.0993877
207	0	0.2154949	-1.292116	0.2494285	0.1690568

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Parameter Code=PPG78 Parameter=PPG <=7.8 mmol/L (SMPG) Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
208	1	0.0126808	-4.354906	0.4097439	0.01252
209	1	0.1017832	-2.177566	0.2507759	0.0914234
210	1	0.168987	-1.592823	0.298302	0.1404304
211	1	0.1590751	-1.665126	0.2473637	0.1337702
212	1	0.0634965	-2.691169	0.2897188	0.0594647
213	1	0.045377	-3.046311	0.2901082	0.0433179
214	1	0.0243762	-3.68947	0.3520627	0.023782
215	1	0.0445552	-3.065448	0.2908795	0.04257
216	1	0.0369312	-3.261069	0.2998213	0.0355673
217	1	0.2363055	-1.173043	0.2537519	0.1804652
218	1	0.2380456	-1.163425	0.241714	0.1813799
219	1	0.0423954	-3.117394	0.2979825	0.0405981
220	1	0.2334677	-1.188833	0.2597526	0.1789605
221	1	0.2430955	-1.135783	0.2422204	0.1840001
222	0	0.2877901	-0.906141	0.2483811	0.2049669
223	1	0.0701954	-2.583691	0.2654505	0.065268
224	1	0.087154	-2.348891	0.2522965	0.0795582
225	1	0.0351942	-3.311045	0.3120824	0.0339556
226	1	0.1593597	-1.663	0.2473864	0.1339642
227	1	0.0226227	-3.765918	0.3519477	0.0221109
228	1	0.1572142	-1.679104	0.2416899	0.1324979
229	1	0.0316968	-3.41933	0.321521	0.0306921
230	1	0.0558127	-2.828324	0.3011838	0.0526976
231	1	0.0738906	-2.528407	0.2628858	0.0684308

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Parameter Code=PPG78 Parameter=PPG ≤ 7.8 mmol/L (SMPG) Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
232	1	0.1220198	-1.973441	0.2473069	0.107131
233	1	0.065231	-2.662364	0.269385	0.0609759
234	1	0.1305633	-1.895987	0.241807	0.1135165
235	1	0.0233873	-3.731897	0.3488241	0.0228403
236	1	0.049759	-2.949523	0.310928	0.0472831
237	1	0.1211001	-1.982053	0.2504679	0.1064349
238	1	0.2009595	-1.380308	0.2395583	0.1605748
239	1	0.1806147	-1.512189	0.2438031	0.147993
240	1	0.2045604	-1.358031	0.2474144	0.1627155
241	1	0.0527623	-2.887753	0.2823844	0.0499784
242	1	0.0489433	-2.966911	0.352098	0.0465479
243	1	0.3275244	-0.719403	0.2313698	0.2202522
244	1	0.2527671	-1.083908	0.240578	0.1888759
245	0	0.3675087	-0.54292	0.2348255	0.232446
246	1	0.0414007	-3.142174	0.3715239	0.0396867
247	1	0.3068075	-0.815087	0.2304199	0.2126767
248	1	0.1337011	-1.868623	0.2877876	0.1158251
249	1	0.1491939	-1.740937	0.2609456	0.1269351
250	0	0.3989436	-0.409869	0.2497554	0.2397876
251	1	0.5838223	0.3384845	0.257351	0.2429738
252	0	0.1720977	-1.570833	0.2531109	0.1424801
253	1	0.3419759	-0.654501	0.2314432	0.2250284
254	1	0.1441381	-1.781337	0.2630421	0.1233623
255	0	0.3477649	-0.628878	0.2434169	0.2268245

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
256	0	0.1359458	-1.849379	0.2667667	0.1174646
257	1	0.3247207	-0.732161	0.2312052	0.2192772
258	1	0.2523657	-1.086035	0.2405984	0.1886773
259	0	0.1324745	-1.879255	0.2886092	0.114925
260	1	0.202955	-1.367927	0.2377915	0.1617642
261	1	0.1534056	-1.708136	0.2524705	0.1298723
262	1	0.0012496	-6.683697	0.7813926	0.001248
263	1	0.1052904	-2.139777	0.2800613	0.0942043
264	1	0.1012542	-2.183366	0.2833089	0.0910018
265	0	0.1286133	-1.913276	0.2912663	0.1120719
266	1	0.082198	-2.412851	0.305691	0.0754415
267	0	0.4719563	-0.112293	0.237487	0.2492135
268	1	0.0587276	-2.774323	0.3366356	0.0552787
269	1	0.0461117	-3.02948	0.3605287	0.0439854
270	0	0.2223552	-1.251994	0.2486203	0.1729134
271	0	0.3508707	-0.615214	0.2331465	0.2277605
272	1	0.245213	-1.124308	0.2410186	0.1850836
273	0	0.4651	-0.139828	0.2616047	0.248782
274	1	0.2515642	-1.090287	0.2406401	0.1882797
275	1	0.3193927	-0.756564	0.2326593	0.217381
276	0	0.4809728	-0.076146	0.238617	0.249638
277	1	0.1096907	-2.093904	0.2820144	0.0976586
278	0	0.4303873	-0.280271	0.2333935	0.2451541
279	0	0.6214792	0.4958313	0.2669422	0.2352428

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
280	0	0.3832228	-0.475891	0.2311175	0.2363631
281	0	0.3802371	-0.488542	0.2471245	0.2356568
282	1	0.4711491	-0.115532	0.2517009	0.2491676
283	0	0.3739571	-0.515278	0.2355622	0.2341132
284	1	0.3920435	-0.438731	0.2378704	0.2383454
285	1	0.3479705	-0.627972	0.2328879	0.226887
286	1	0.3460433	-0.636477	0.2327218	0.2262973
287	1	0.3709752	-0.528035	0.2352157	0.2333526
288	1	0.3923343	-0.437511	0.2487869	0.2384081
289	1	0.4937218	-0.025114	0.2403578	0.2499606
290	1	0.3955967	-0.423846	0.2383643	0.2391
291	1	0.206965	-1.343318	0.2453339	0.1641305
292	1	0.2916505	-0.887382	0.2301405	0.2065905
293	1	0.2116898	-1.314769	0.2361556	0.1668773
294	0	0.6703199	0.7096324	0.3215191	0.2209911
295	1	0.3261319	-0.725733	0.2322137	0.2197699
296	1	0.1726891	-1.566687	0.2663603	0.1428676
297	1	0.3950884	-0.425973	0.2382928	0.2389936
298	1	0.1771541	-1.535749	0.2517035	0.1457706
299	1	0.324056	-0.735194	0.2414784	0.2190437
300	1	0.2163394	-1.287127	0.2353796	0.1695367
301	1	0.3161659	-0.771448	0.2328985	0.216205
302	0	0.3520937	-0.609849	0.2311459	0.2281237
303	1	0.1313731	-1.888873	0.2629381	0.1141142

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Parameter Code=PPG78 Parameter=PPG ≤ 7.8 mmol/L (SMPG) Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
304	1	0.3717313	-0.524797	0.2309776	0.2335471
305	0	0.3429335	-0.650249	0.2314087	0.2253301
306	0	0.5319514	0.12798	0.2465663	0.2489791
307	0	0.2827596	-0.930814	0.239934	0.2028066
308	1	0.1468946	-1.759168	0.2552531	0.1253166
309	1	0.0777293	-2.473607	0.3066989	0.0716874
310	1	0.2788947	-0.949951	0.2399254	0.2011124
311	1	0.3717313	-0.524797	0.2309776	0.2335471
312	0	0.3503866	-0.61734	0.2331026	0.2276158
313	1	0.3157295	-0.773467	0.2409684	0.2160444
314	1	0.2670592	-1.009595	0.2388087	0.1957386
315	1	0.2194461	-1.268897	0.2435075	0.1712895
316	1	0.1890616	-1.456119	0.2595402	0.1533173
317	0	0.3675087	-0.54292	0.2348255	0.232446
318	0	0.3963971	-0.4205	0.2493773	0.2392664
319	0	0.1310152	-1.892012	0.2896006	0.1138502
320	1	0.14985	-1.735778	0.2539603	0.1273949
321	1	0.209049	-1.330667	0.2525588	0.1653475
322	0	0.1375648	-1.835665	0.2852676	0.1186407
323	0	0.2314843	-1.199949	0.233274	0.1778993
324	0	0.3027527	-0.834224	0.2303091	0.2110935
325	1	0.1225384	-1.968609	0.2680735	0.1075227
326	0	0.5457148	0.1833712	0.280874	0.2479102
327	1	0.0822664	-2.411944	0.3014913	0.0754986

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
328	0	0.4884078	-0.046377	0.2396119	0.2498656
329	1	0.2771874	-0.958456	0.2399298	0.2003546
330	1	0.2086977	-1.332794	0.2526701	0.1651429
331	0	0.260453	-1.043616	0.2399634	0.1926172
332	1	0.5448851	0.180025	0.2694411	0.2479853
333	1	0.1811963	-1.508263	0.2429919	0.1483642
334	0	0.565635	0.2640637	0.2532571	0.245692
335	1	0.318689	-0.759803	0.2308885	0.2171263
336	1	0.4651	-0.139828	0.2616047	0.248782
337	1	0.5930909	0.376758	0.2595701	0.2413341
338	1	0.3576805	-0.585446	0.2337941	0.2297452
339	1	0.3862427	-0.463134	0.2311824	0.2370593
340	1	0.3557288	-0.593951	0.2336028	0.2291858
341	0	0.6858431	0.7807565	0.2871722	0.2154623
342	1	0.245213	-1.124308	0.2410186	0.1850836
343	0	0.2473548	-1.11277	0.2316974	0.1861704
344	1	0.4751368	-0.099535	0.237876	0.2493818
345	0	0.3589759	-0.579812	0.1889809	0.2301122
346	1	0.3751473	-0.510197	0.1853078	0.2344118
347	0	0.6200716	0.4898521	0.1975933	0.2355828
348	0	0.4275643	-0.291796	0.1803223	0.2447531
349	0	0.4711466	-0.115542	0.1794615	0.2491675
350	1	0.5167159	0.0668884	0.2036471	0.2497206
351	1	0.2906934	-0.892019	0.197676	0.2061908

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Parameter Code=PPG78 Parameter=PPG <=7.8 mmol/L (SMPG) Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
352	1	0.3290293	-0.712579	0.2100814	0.220769
353	1	0.2967437	-0.862853	0.2065696	0.2086869
354	1	0.1237698	-1.957205	0.2528351	0.1084509
355	1	0.3298758	-0.708747	0.2102099	0.2210577
356	1	0.1129798	-2.060659	0.2614528	0.1002154
357	1	0.1211397	-1.981682	0.2346557	0.1064649
358	0	0.24072	-1.148736	0.2039598	0.1827739
359	1	0.4232089	-0.309614	0.2037387	0.2441031
360	1	0.2506603	-1.095094	0.2022137	0.1878297
361	0	0.4335291	-0.267467	0.205244	0.2455816
362	1	0.2786879	-0.95098	0.2052574	0.2010209
363	0	0.3018769	-0.838376	0.1970442	0.2107472
364	1	0.2635474	-1.027612	0.2046252	0.1940902
365	0	0.4046212	-0.386246	0.2013508	0.2409029
366	1	0.3106946	-0.796874	0.2075328	0.2141635
367	1	0.0635846	-2.689688	0.2857472	0.0595416
368	1	0.4347825	-0.262365	0.2320266	0.2457467
369	1	0.3384004	-0.670431	0.2115546	0.2238856
370	1	0.1378428	-1.833324	0.22221	0.1188422
371	0	0.240602	-1.149382	0.2029528	0.1827127
372	1	0.0868	-2.353348	0.2615889	0.0792658
373	1	0.2098822	-1.325636	0.2044647	0.1658317
374	1	0.323974	-0.735568	0.2093332	0.2190149
375	0	0.4722744	-0.111016	0.2421115	0.2492313

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
376	0	0.3555709	-0.59464	0.2142695	0.2291402
377	1	0.5333287	0.1335126	0.1831318	0.2488892
378	0	0.3555709	-0.59464	0.2142695	0.2291402
379	0	0.2462471	-1.118729	0.2029498	0.1856095
380	1	0.1258625	-1.938047	0.2512848	0.1100212
381	1	0.1110103	-2.080462	0.237018	0.0986871
382	1	0.2268799	-1.226014	0.2032983	0.1754054
383	1	0.2378128	-1.164708	0.2029833	0.1812579
384	1	0.1708857	-1.579363	0.2139962	0.1416838
385	0	0.3620677	-0.566401	0.188963	0.2309747
386	1	0.4152625	-0.342252	0.1910039	0.2428196
387	0	0.5036831	0.0147328	0.1806771	0.2499864
388	1	0.5209132	0.0837018	0.1819489	0.2495626
389	1	0.4405824	-0.238799	0.1934069	0.2464696
390	0	0.3736661	-0.516521	0.1983627	0.2340397
391	1	0.4678065	-0.128952	0.1794255	0.2489636
392	1	0.5285575	0.1143546	0.1826509	0.2491845
393	0	0.4692377	-0.123205	0.1794389	0.2490537
394	1	0.6606307	0.666106	0.2081674	0.2241978
395	1	0.3484655	-0.625791	0.1891631	0.2270373
396	1	0.4071736	-0.375662	0.1900885	0.2413833
397	1	0.1836616	-1.491734	0.2241967	0.14993
398	0	0.5237812	0.0951966	0.1822024	0.2494345
399	0	0.3178372	-0.763729	0.1908216	0.2168167

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
400	0	0.5599102	0.2407976	0.1864104	0.2464108
401	1	0.327187	-0.720936	0.1939272	0.2201357
402	1	0.1980644	-1.398436	0.2058226	0.1588349
403	1	0.2138285	-1.302001	0.210132	0.1681059
404	1	0.0757224	-2.501939	0.2692208	0.0699885
405	1	0.2290164	-1.213874	0.2063735	0.1765679
406	0	0.2629674	-1.030602	0.2033711	0.1938156
407	1	0.3751127	-0.510345	0.217775	0.2344032
408	1	0.1331309	-1.873555	0.2243776	0.115407
409	0	0.3233704	-0.738325	0.2094678	0.218802
410	1	0.199762	-1.387783	0.208039	0.1598571
411	0	0.4904472	-0.038216	0.247367	0.2499087
412	1	0.2378128	-1.164708	0.2029833	0.1812579
413	0	0.6124713	0.4577123	0.2272102	0.2373502
414	1	0.2990437	-0.851856	0.1927385	0.2096166
415	0	0.528187	0.1128677	0.205917	0.2492055
416	0	0.3756971	-0.507853	0.1892287	0.2345488
417	1	0.6606307	0.666106	0.2081674	0.2241978
418	0	0.6597711	0.6622744	0.2079167	0.2244732
419	1	0.0658221	-2.652711	0.3301031	0.0614896
420	0	0.5036831	0.0147328	0.1806771	0.2499864
421	1	0.3221464	-0.743925	0.1950745	0.2183681
422	0	0.0727344	-2.545426	0.3188352	0.0674441
423	1	0.4422645	-0.231977	0.1927433	0.2466666

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
424	1	0.1936295	-1.426597	0.2197816	0.1561371
425	0	0.3632016	-0.561495	0.1893187	0.2312862
426	0	0.6467538	0.6048003	0.2042637	0.2284633
427	1	0.2486952	-1.105583	0.2040024	0.1868459
428	0	0.4688673	-0.124692	0.1958529	0.2490308
429	1	0.5567089	0.2278159	0.2122141	0.2467841
430	0	0.379062	-0.493531	0.1987897	0.235374
431	0	0.4150582	-0.343093	0.190535	0.2427849
432	1	0.2535501	-1.079767	0.2017558	0.1892624
433	1	0.1587591	-1.66749	0.2176291	0.1335547
434	1	0.4238173	-0.307122	0.1805328	0.2441962
435	0	0.2657717	-1.016182	0.2000542	0.1951371
436	0	0.4308433	-0.278411	0.1916928	0.2452174
437	0	0.1290607	-1.909289	0.2612154	0.112404
438	1	0.133308	-1.872021	0.246058	0.115537
439	1	0.2280694	-1.219245	0.2065865	0.1760538
440	1	0.1190322	-2.001627	0.2655255	0.1048635
441	0	0.3902215	-0.446381	0.2207567	0.2379487
442	1	0.2306989	-1.204369	0.2251869	0.1774769
443	1	0.544304	0.1776818	0.2093614	0.2480372
444	1	0.1268254	-1.929324	0.2275447	0.1107407
445	1	0.4085931	-0.369785	0.2018252	0.2416448
446	1	0.1474218	-1.754967	0.218282	0.1256886
447	1	0.1690367	-1.592469	0.2348742	0.1404633

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
448	1	0.2764857	-0.961961	0.19886	0.2000413
449	1	0.2181385	-1.276548	0.2037892	0.1705541
450	1	0.3007258	-0.843844	0.2063487	0.2102898
451	1	0.1380452	-1.831621	0.2429521	0.1189888
452	1	0.3033823	-0.831243	0.2071908	0.2113415
453	1	0.4080773	-0.371919	0.1816587	0.2415502
454	1	0.2711907	-0.98859	0.2048876	0.1976463
455	1	0.5710852	0.2862803	0.2181853	0.2449469
456	0	0.1318522	-1.88468	0.2551362	0.1144672
457	1	0.435842	-0.258055	0.1928917	0.2458838
458	1	0.4384315	-0.24753	0.1798355	0.2462093
459	1	0.3040882	-0.827905	0.1921527	0.2116186
460	1	0.4373868	-0.251775	0.2058384	0.2460796
461	1	0.2887081	-0.901667	0.1941093	0.2053557
462	0	0.3234027	-0.738178	0.1947841	0.2188134
463	0	0.153037	-1.710977	0.2442571	0.1296167
464	1	0.2782029	-0.953393	0.1957468	0.200806
465	0	0.6502474	0.6201267	0.2052179	0.2274257
466	1	0.3389586	-0.667939	0.1894936	0.2240657
467	1	0.1992421	-1.391038	0.2204553	0.1595447
468	1	0.4106183	-0.36141	0.1906584	0.2420109
469	1	0.3055084	-0.821203	0.1919974	0.212173
470	0	0.4528932	-0.188988	0.1948806	0.2477809
471	0	0.4460482	-0.21665	0.1931297	0.2470892

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
472	1	0.4238173	-0.307122	0.1805328	0.2441962
473	1	0.4106183	-0.36141	0.1906584	0.2420109
474	1	0.2833626	-0.927842	0.205572	0.2030683
475	1	0.5190005	0.0760385	0.1817865	0.249639
476	1	0.2950434	-0.871014	0.1932416	0.2079928
477	0	0.5654085	0.2631418	0.216706	0.2457217
478	1	0.2830608	-0.929329	0.1966308	0.2029374
479	0	0.5013957	0.0055827	0.2008541	0.2499981
480	1	0.5323749	0.129681	0.1830331	0.2489519
481	0	0.3481772	-0.627061	0.1896536	0.2269498
482	1	0.2278429	-1.220531	0.2100046	0.1759305
483	1	0.4152625	-0.342252	0.1910039	0.2428196
484	1	0.2918656	-0.88634	0.1936658	0.2066801
485	1	0.1658697	-1.615187	0.236625	0.138357
486	0	0.4555342	-0.178334	0.1941806	0.2480228
487	1	0.454584	-0.182166	0.1940701	0.2479374
488	1	0.1511689	-1.725462	0.2417935	0.1283169
489	0	0.3794968	-0.491685	0.1891536	0.235479
490	0	0.3747988	-0.511684	0.1892267	0.2343247
491	0	0.5472337	0.1894998	0.2100194	0.247769
492	0	0.4748061	-0.100861	0.1979743	0.2493653
493	1	0.3389586	-0.667939	0.1894936	0.2240657
494	0	0.2619664	-1.035773	0.1987912	0.19334
495	0	0.5417405	0.1673516	0.2109228	0.2482577

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
496	1	0.3323629	-0.697517	0.1906796	0.2218978
497	1	0.2251578	-1.235858	0.210871	0.1744618
498	0	0.5207521	0.0830563	0.2063142	0.2495693
499	0	0.4797468	-0.081057	0.1796306	0.2495898
500	0	0.6132787	0.461115	0.1960661	0.2371679
501	0	0.4824552	-0.070208	0.1991917	0.2496922
502	0	0.5483913	0.1941729	0.2124853	0.2476583
503	0	0.3037069	-0.829708	0.1935284	0.211469
504	0	0.2778184	-0.955309	0.1958116	0.2006353
505	0	0.5599102	0.2407976	0.1864104	0.2464108
506	1	0.3587823	-0.580653	0.1894123	0.2300576
507	0	0.5109729	0.0438988	0.202568	0.2498796
508	0	0.3484655	-0.625791	0.1891631	0.2270373
509	0	0.6640583	0.6814324	0.2091788	0.2230849
510	1	0.3582431	-0.582998	0.1878844	0.229905
511	1	0.2424624	-1.139226	0.2033403	0.1836744
512	1	0.408921	-0.368428	0.1815884	0.2417046
513	1	0.5371412	0.1488391	0.1835397	0.2486205
514	1	0.259138	-1.050454	0.2137549	0.1919855
515	1	0.2956657	-0.868024	0.1946267	0.2082475
516	0	0.3607412	-0.572148	0.1889687	0.230607
517	1	0.4719406	-0.112356	0.1975363	0.2492127
518	0	0.3024024	-0.835884	0.2000394	0.2109552
519	0	0.3061432	-0.818213	0.1932224	0.2124195

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
520	1	0.3500159	-0.618969	0.1896964	0.2275048
521	1	0.0959055	-2.24357	0.292669	0.0867076
522	1	0.3582431	-0.582998	0.1878844	0.229905
523	1	0.1092943	-2.097969	0.2785825	0.0973491
524	0	0.4540027	-0.184511	0.1794549	0.2478843
525	1	0.5033114	0.0132459	0.2011883	0.249989
526	1	0.1988683	-1.393383	0.2407356	0.1593197
527	1	0.2267582	-1.226708	0.2269432	0.1753389
528	1	0.43038	-0.280301	0.1801786	0.2451531
529	1	0.2027616	-1.369123	0.2160834	0.1616493
530	1	0.2760295	-0.964243	0.2079089	0.1998372
531	0	0.3632016	-0.561495	0.1893187	0.2312862
532	1	0.6179136	0.480702	0.2288679	0.2360964
533	1	0.3314182	-0.701778	0.1930008	0.2215802
534	1	0.4797468	-0.081057	0.1796306	0.2495898
535	1	0.5224544	0.0898781	0.2047636	0.2494958
536	1	0.2787175	-0.950832	0.2070386	0.2010341
537	1	0.6441232	0.5933055	0.2035577	0.2292285
538	1	0.2853993	-0.917835	0.1962322	0.2039466
539	1	0.4778344	-0.088721	0.1795835	0.2495087
540	1	0.7202724	0.9458133	0.2286305	0.2014801
541	1	0.5529234	0.2124895	0.211325	0.2471991
542	0	0.3195011	-0.756066	0.1906862	0.2174201
543	1	0.3474053	-0.630464	0.1898067	0.2267149

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
544	1	0.2376604	-1.16555	0.2046929	0.1811779
545	1	0.2717104	-0.985962	0.1968872	0.1978839
546	0	0.498522	-0.005912	0.200361	0.2499978
547	1	0.3805516	-0.487208	0.1845863	0.2357321
548	0	0.2342068	-1.184708	0.204825	0.179354
549	1	0.3287337	-0.713918	0.1900317	0.2206679
550	0	0.3587823	-0.580653	0.1894123	0.2300576
551	1	0.2671851	-1.008952	0.1977422	0.1957972
552	0	0.1860684	-1.475762	0.2479603	0.1514469
553	1	0.3849251	-0.468695	0.1893113	0.2367578
554	0	0.6981552	0.8385283	0.2203059	0.2107345
555	1	0.425532	-0.300104	0.1918741	0.2444545
556	0	0.5719871	0.289963	0.2184236	0.2448179
557	1	0.5842924	0.3404194	0.1903103	0.2428948
558	0	0.4574355	-0.170671	0.1944053	0.2481883
559	1	0.0307532	-3.450527	0.4238104	0.0298074
560	1	0.313698	-0.782887	0.1911823	0.2152916
561	0	0.5398375	0.1596884	0.2104847	0.248413
562	0	0.3974997	-0.415894	0.1896645	0.2394937
563	0	0.3465372	-0.634296	0.189846	0.2264492
564	0	0.6263695	0.5166733	0.1990706	0.2340307
565	0	0.2982723	-0.855539	0.2060806	0.2093059
566	1	0.0935743	-2.270753	0.2550685	0.0848181
567	1	0.230503	-1.205473	0.2050019	0.1773714

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
568	1	0.188371	-1.46063	0.2099805	0.1528874
569	0	0.4285127	-0.287922	0.2044967	0.2448896
570	1	0.3364483	-0.679162	0.196601	0.2232508
571	1	0.2322325	-1.195748	0.2031042	0.1783006
572	1	0.1726523	-1.566945	0.2135281	0.1428435
573	0	0.4194135	-0.325182	0.227125	0.2435058
574	1	0.1156957	-2.033837	0.2591799	0.1023102
575	1	0.2462471	-1.118729	0.2029498	0.1856095
576	1	0.258982	-1.051266	0.2009533	0.1919103
577	1	0.1584213	-1.670022	0.231291	0.133324
578	0	0.457186	-0.171677	0.2091526	0.248167
579	1	0.1984949	-1.395728	0.2147206	0.1590947
580	1	0.2940291	-0.875895	0.2063363	0.207576
581	1	0.1249513	-1.946356	0.2285484	0.1093384
582	1	0.5384266	0.1540101	0.2270322	0.2485234
583	1	0.3523112	-0.608895	0.1890745	0.228188
584	1	0.4044891	-0.386795	0.2013354	0.2408777
585	1	0.1475358	-1.754061	0.2217099	0.125769
586	1	0.1766366	-1.539303	0.212526	0.1454361
587	1	0.1398388	-1.81663	0.2213402	0.1202839
588	1	0.4287973	-0.28676	0.192181	0.2449302
589	0	0.533752	0.1352135	0.2258257	0.2488608
590	1	0.3350495	-0.685434	0.2110152	0.2227913
591	1	0.0558378	-2.827846	0.3036372	0.05272

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
592	0	0.3322132	-0.698192	0.2105696	0.2218476
593	1	0.362532	-0.564391	0.2154707	0.2311026
594	0	0.5422079	0.1692344	0.2280238	0.2482185
595	1	0.3804132	-0.487795	0.198903	0.235699
596	1	0.2465344	-1.117182	0.2029058	0.1857552
597	0	0.2557513	-1.06817	0.2031136	0.1903426
598	1	0.1969691	-1.405346	0.2084698	0.1581723
599	1	0.3508589	-0.615266	0.2136772	0.2277569
600	0	0.365497	-0.551584	0.1977955	0.2319089
601	1	0.1506578	-1.729451	0.2170895	0.12796
602	1	0.2077868	-1.338318	0.2118396	0.1646115
603	1	0.1607168	-1.652904	0.2137774	0.1348869
604	1	0.1032367	-2.161767	0.2469075	0.0925789
605	1	0.2591766	-1.050253	0.2045298	0.1920041
606	1	0.4543348	-0.183171	0.2086486	0.2479147
607	1	0.3189595	-0.758558	0.2086247	0.2172243
608	1	0.1269258	-1.928418	0.2313563	0.1108156
609	1	0.632618	0.5434646	0.2559677	0.2324125
610	0	0.3395297	-0.665391	0.2117154	0.2242493
611	1	0.2141756	-1.299937	0.2040867	0.1683044
612	0	0.3615612	-0.568594	0.1975572	0.2308347
613	1	0.3503391	-0.617549	0.213403	0.2276016
614	1	0.1953176	-1.415821	0.206209	0.1571686
615	1	0.2779669	-0.954569	0.2052172	0.2007013

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG78 Parameter=PPG <=7.8 mmol/L (SMPG) Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
616	1	0.1424029	-1.795474	0.2402353	0.1221243
617	1	0.2258311	-1.232002	0.2071011	0.1748314
618	1	0.35252	-0.607981	0.2137604	0.2282496
619	0	0.4337539	-0.266551	0.2317648	0.2456115
620	1	0.2573531	-1.059772	0.201186	0.1911225
621	0	0.3198331	-0.754539	0.2087456	0.2175399
622	1	0.1582719	-1.671143	0.2410354	0.1332219
623	1	0.4705797	-0.117817	0.2116367	0.2491344
624	1	0.3721658	-0.522937	0.1892283	0.2336584
625	1	0.3759131	-0.506931	0.1985355	0.2346024
626	0	0.2205034	-1.262735	0.2097601	0.1718817
627	0	0.5263369	0.1054452	0.2239554	0.2493064
628	1	0.3789341	-0.494075	0.1891399	0.2353431
629	1	0.1209239	-1.98371	0.2679351	0.1063013
630	1	0.0779539	-2.470478	0.311088	0.0718771
631	1	0.270351	-0.992842	0.204853	0.1972613
632	1	0.3270449	-0.721581	0.2097837	0.2200865
633	1	0.2141756	-1.299937	0.2040867	0.1683044
634	1	0.415055	-0.343107	0.1909878	0.2427843
635	0	0.2900707	-0.89504	0.1954729	0.2059297
636	0	0.150929	-1.727333	0.2419444	0.1281494
637	1	0.1349062	-1.858258	0.2567143	0.1167065
638	1	0.2427908	-1.13744	0.2055759	0.1838434
639	1	0.4402911	-0.239981	0.1933744	0.2464348

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG78 Parameter=PPG ≤ 7.8 mmol/L (SMPG) Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
640	1	0.4426239	-0.23052	0.1796965	0.246708
641	1	0.1901731	-1.448886	0.2175798	0.1540073
642	1	0.1114467	-2.076048	0.2723672	0.0990264
643	1	0.2966825	-0.863146	0.1944803	0.208662
644	1	0.4470751	-0.212496	0.1932378	0.247199
645	0	0.5138512	0.0554191	0.203104	0.2498081
646	0	0.3067719	-0.815254	0.1988746	0.2126629
647	1	0.3774089	-0.500561	0.1849999	0.2349714
648	1	0.1981476	-1.397912	0.2209124	0.1588851
649	1	0.2831152	-0.929061	0.1966214	0.202961
650	1	0.2431925	-1.135255	0.2035002	0.1840499
651	1	0.1789909	-1.523199	0.2091154	0.1469531
652	1	0.1821209	-1.502044	0.2206159	0.1489529
653	1	0.1307496	-1.894347	0.2478049	0.1136541
654	1	0.1034964	-2.158965	0.2424138	0.0927849
655	1	0.1493024	-1.740083	0.2175811	0.1270112
656	1	0.1553213	-1.693461	0.2188012	0.1311966
657	1	0.1422671	-1.796587	0.223892	0.1220272
658	0	0.3163507	-0.770594	0.1965926	0.2162729
659	1	0.1005743	-2.19086	0.2446921	0.0904591
660	0	0.2404545	-1.150189	0.2046086	0.1826362
661	0	0.3113371	-0.793876	0.2076142	0.2144063
662	1	0.153952	-1.703936	0.2159408	0.1302508
663	0	0.1735654	-1.560567	0.213292	0.1434404

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG78 Parameter=PPG ≤ 7.8 mmol/L (SMPG) Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
664	1	0.1084156	-2.107028	0.2430131	0.0966617
665	0	0.5503765	0.2021922	0.2302133	0.2474622
666	1	0.1261207	-1.935703	0.2279187	0.1102142
667	0	0.3251522	-0.730194	0.1965088	0.2194282
668	1	0.2168452	-1.284147	0.2059878	0.1698234
669	1	0.1451452	-1.773197	0.2226777	0.124078
670	1	0.0857681	-2.366437	0.2626472	0.0784119
671	1	0.1851416	-1.481893	0.2106231	0.1508642
672	1	0.1885576	-1.45941	0.2072818	0.1530036
673	0	0.3909925	-0.443142	0.199877	0.2381174
674	0	0.228472	-1.216959	0.2336437	0.1762726
675	1	0.3109031	-0.795901	0.2333253	0.2142424
676	1	0.1866212	-1.472116	0.241533	0.1517937
677	1	0.2393384	-1.15631	0.2443151	0.1820555
678	1	0.380952	-0.485509	0.2364133	0.2358276
679	1	0.1080301	-2.111022	0.3075015	0.0963596
680	1	0.1392256	-1.821737	0.2652247	0.1198418
681	1	0.1561875	-1.686873	0.251353	0.1317929
682	1	0.1308886	-1.893125	0.2632044	0.1137567
683	1	0.1541177	-1.702664	0.2590409	0.1303654
684	1	0.3127175	-0.787445	0.2306267	0.2149253
685	1	0.2701825	-0.993697	0.230418	0.1971839
686	1	0.1223267	-1.970579	0.2739751	0.1073629
687	1	0.4487184	-0.20585	0.2349687	0.2473702

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG78 Parameter=PPG <=7.8 mmol/L (SMPG) Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
688	0	0.1970269	-1.404981	0.2471206	0.1582073
689	1	0.4939875	-0.024051	0.2403958	0.2499639
690	1	0.2739824	-0.974511	0.2376971	0.198916
691	1	0.2227145	-1.249917	0.234417	0.1731128
692	1	0.1869442	-1.46999	0.2414497	0.151996
693	1	0.207813	-1.338159	0.2368523	0.1646268
694	0	0.5303629	0.1216011	0.246279	0.2490781
695	1	0.1794908	-1.519801	0.2510882	0.1472738
696	1	0.3812028	-0.484446	0.2364448	0.2358872
697	1	0.3762367	-0.505553	0.2466071	0.2346826
698	1	0.299174	-0.851234	0.2302329	0.2096689
699	1	0.3127175	-0.787445	0.2306267	0.2149253
700	1	0.1036145	-2.157694	0.2864321	0.0928785
701	1	0.4004742	-0.40349	0.2499857	0.2400946
702	1	0.1167332	-2.023736	0.2773566	0.1031066
703	1	0.1141231	-2.0493	0.2252535	0.101099
704	1	0.1260508	-1.936337	0.2553117	0.110162
705	1	0.2053334	-1.353287	0.2323486	0.1631716
706	1	0.4045717	-0.386452	0.2532539	0.2408934
707	0	0.252425	-1.08572	0.2338353	0.1887066
708	1	0.1425136	-1.794568	0.2485064	0.1222035
709	1	0.1502344	-1.732764	0.2170636	0.127664
710	1	0.0542048	-2.859256	0.2655582	0.0512666
711	1	0.0715755	-2.562736	0.26044	0.0664525

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG78 Parameter=PPG ≤ 7.8 mmol/L (SMPG) Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
712	1	0.0400621	-3.176438	0.2885968	0.0384571
713	1	0.1441688	-1.781088	0.2128658	0.1233842
714	0	0.0839587	-2.389737	0.305522	0.0769096
715	1	0.1120525	-2.069945	0.2228871	0.0994967
716	1	0.0937071	-2.269189	0.2301673	0.0849261
717	1	0.0551954	-2.840098	0.2641381	0.0521489
718	1	0.1199068	-1.993313	0.2208235	0.1055291
719	1	0.1117553	-2.072936	0.2231782	0.0992661
720	1	0.1109284	-2.081293	0.2790733	0.0986233
721	1	0.0708437	-2.573802	0.2461344	0.0658248
722	1	0.1628094	-1.637472	0.2423633	0.1363025
723	1	0.2275286	-1.222319	0.2274929	0.1757594
724	1	0.2238	-1.243658	0.2320222	0.1737135
725	1	0.071106	-2.569823	0.322242	0.06605
726	1	0.0491786	-2.961868	0.2712816	0.04676
727	0	0.1179151	-2.012324	0.2736041	0.1040111
728	1	0.1879005	-1.46371	0.2207847	0.1525939
729	1	0.1317942	-1.885187	0.2194536	0.1144245
730	1	0.2521386	-1.087239	0.232991	0.1885647
731	1	0.049584	-2.953231	0.2727425	0.0471255
732	0	0.4653027	-0.139013	0.2538819	0.2487961
733	1	0.1062828	-2.129286	0.2247719	0.0949867
734	1	0.1506664	-1.729384	0.2183699	0.1279661
735	1	0.1451535	-1.77313	0.2173092	0.124084

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG78 Parameter=PPG ≤ 7.8 mmol/L (SMPG) Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
736	1	0.0768207	-2.486349	0.2399752	0.0709193
737	1	0.0732788	-2.537381	0.2427841	0.0679091
738	1	0.2097215	-1.326605	0.2215201	0.1657384
739	0	0.2062177	-1.347877	0.233494	0.163692
740	1	0.0837936	-2.391885	0.2359399	0.0767722
741	1	0.2307124	-1.204293	0.2043961	0.1774842
742	1	0.0665105	-2.64157	0.2489631	0.0620869
743	1	0.2975865	-0.858817	0.2411386	0.2090288
744	1	0.1432051	-1.78892	0.2185659	0.1226974
745	1	0.0815363	-2.421654	0.2374789	0.0748882
746	0	0.150123	-1.733636	0.2183749	0.1275861
747	1	0.0588963	-2.771275	0.2574331	0.0554275
748	1	0.083712	-2.392949	0.235994	0.0767043
749	1	0.1093659	-2.097235	0.223848	0.097405
750	1	0.1194756	-1.997406	0.2224896	0.1052012
751	1	0.1048919	-2.144014	0.225255	0.0938896
752	1	0.3789268	-0.494106	0.2295348	0.2353413
753	1	0.1021199	-2.173889	0.2325452	0.0916914
754	1	0.2672381	-1.008681	0.2210107	0.1958219
755	1	0.0707218	-2.575654	0.2449861	0.0657202
756	1	0.0366881	-3.267924	0.2991424	0.0353421
757	1	0.3013886	-0.840694	0.2127408	0.2105535
758	1	0.1054924	-2.137635	0.2250541	0.0943637
759	1	0.501392	0.0055679	0.2381754	0.2499981

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG78 Parameter=PPG ≤ 7.8 mmol/L (SMPG) Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
760	1	0.2345064	-1.183038	0.2257229	0.1795131
761	1	0.1411306	-1.805931	0.2186715	0.1212128
762	1	0.1612848	-1.6487	0.2480905	0.135272
763	1	0.1720553	-1.571131	0.2173352	0.1424523
764	0	0.0759208	-2.499107	0.2406635	0.0701568
765	1	0.0639119	-2.684203	0.2704804	0.0598272
766	1	0.1417571	-1.800772	0.2175494	0.1216621
767	1	0.1448899	-1.775256	0.2173256	0.1238968
768	0	0.0856068	-2.368496	0.2347679	0.0782783
769	1	0.161862	-1.644439	0.2084956	0.1356627
770	1	0.069612	-2.592665	0.2459903	0.0647662
771	1	0.1265857	-1.93149	0.2192246	0.1105618
772	0	0.1312348	-1.890085	0.2528553	0.1140122
773	1	0.4918243	-0.032706	0.2362338	0.2499332
774	0	0.3889832	-0.451588	0.2211852	0.2376753
775	1	0.6382961	0.5679764	0.2755041	0.2308742
776	0	0.4600412	-0.160177	0.2658849	0.2484033
777	0	0.4703173	-0.118871	0.2636654	0.2491189
778	0	0.352812	-0.606702	0.2437148	0.2283357
779	1	0.3036318	-0.830063	0.2131358	0.2114395
780	1	0.1226429	-1.967637	0.2209804	0.1076016
781	0	0.2005604	-1.382796	0.2225693	0.1603359
782	1	0.1420221	-1.798596	0.2135248	0.1218518
783	1	0.2549352	-1.072462	0.2062274	0.1899432

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG78 Parameter=PPG ≤ 7.8 mmol/L (SMPG) Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
784	1	0.1874305	-1.466793	0.2374823	0.1523003
785	1	0.0856939	-2.367383	0.2455386	0.0783505
786	1	0.115611	-2.034666	0.2218845	0.1022451
787	1	0.1805453	-1.512657	0.2179269	0.1479487
788	1	0.0916148	-2.294075	0.231262	0.0832216
789	1	0.1905277	-1.446585	0.2211224	0.1542269
790	1	0.1052919	-2.139761	0.2251207	0.0942055
791	1	0.1340546	-1.865575	0.2162459	0.116084
792	1	0.1439764	-1.782649	0.2129236	0.1232472
793	1	0.1349151	-1.858182	0.2182342	0.116713
794	1	0.402712	-0.394178	0.2225305	0.240535
795	0	0.2241744	-1.241503	0.2041336	0.1739202
796	1	0.0852038	-2.373655	0.2343109	0.0779441
797	1	0.0633482	-2.693664	0.2522654	0.0593352
798	1	0.1309935	-1.892203	0.2187578	0.1138342
799	1	0.1186897	-2.004897	0.2211082	0.1046024
800	1	0.3170787	-0.767229	0.2504279	0.2165398
801	1	0.1639061	-1.629447	0.2186499	0.1370409
802	1	0.0947632	-2.256815	0.2378791	0.0857831
803	1	0.1102852	-2.087832	0.2642215	0.0981223
804	1	0.1843574	-1.4871	0.2388528	0.1503697
805	1	0.3902356	-0.446322	0.2461586	0.2379518
806	1	0.0713423	-2.566251	0.2990533	0.0662526
807	0	0.3195914	-0.75565	0.2181656	0.2174527

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG78 Parameter=PPG <=7.8 mmol/L (SMPG) Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
808	0	0.1832335	-1.494592	0.2368515	0.149659
809	0	0.3479479	-0.628072	0.2185794	0.2268802
810	1	0.292719	-0.882215	0.2329553	0.2070346
811	1	0.3214671	-0.747038	0.2392095	0.218126
812	1	0.3717215	-0.524839	0.2469206	0.2335446
813	1	0.3532732	-0.604682	0.21879	0.2284712
814	1	0.2116732	-1.314869	0.2306869	0.1668676
815	1	0.1033048	-2.161033	0.2683152	0.0926329
816	1	0.5585591	0.2353164	0.2937029	0.2465708
817	1	0.1538019	-1.705088	0.2169676	0.1301469
818	1	0.2249063	-1.2373	0.2241421	0.1743234
819	0	0.2868453	-0.910755	0.2418897	0.2045651
820	1	0.0583098	-2.781906	0.2581633	0.0549098
821	1	0.2561487	-1.066083	0.2063512	0.1905366
822	1	0.031484	-3.426285	0.3412114	0.0304928
823	1	0.2364396	-1.172299	0.2337601	0.1805359
824	1	0.3293784	-0.710998	0.2181689	0.2208883
825	0	0.1838708	-1.490339	0.2367335	0.1500623
826	1	0.0805189	-2.435318	0.2373163	0.0740356
827	1	0.1830979	-1.495498	0.2381674	0.1495731
828	1	0.0944082	-2.260961	0.2294323	0.0854953
829	1	0.152581	-1.7145	0.2183633	0.1293
830	0	0.142535	-1.794393	0.2174888	0.1222188
831	1	0.2509175	-1.093725	0.2058378	0.1879579

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Parameter Code=PPG78 Parameter=PPG ≤ 7.8 mmol/L (SMPG) Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
832	1	0.151758	-1.720879	0.218364	0.1287275
833	1	0.115611	-2.034666	0.2218845	0.1022451
834	1	0.1818132	-1.504111	0.2397563	0.1487572
835	1	0.1118654	-2.071827	0.2265046	0.0993516
836	1	0.0942132	-2.263244	0.2299117	0.0853371
837	1	0.0926821	-2.281317	0.2306958	0.0840921
838	1	0.2148855	-1.295724	0.2039536	0.1687097
839	1	0.0717699	-2.559814	0.2602054	0.066619
840	1	0.0876254	-2.34298	0.2335272	0.0799472
841	1	0.0875529	-2.343887	0.2329437	0.0798874
842	1	0.2680733	-1.00442	0.2077135	0.19621
843	1	0.1595819	-1.661342	0.2184777	0.1341155
844	0	0.2381535	-1.16283	0.2048212	0.1814364
845	1	0.0707148	-2.575762	0.26149	0.0657142
846	1	0.1007632	-2.188773	0.2334754	0.09061
847	1	0.1123897	-2.06656	0.222787	0.0997583
848	0	0.1893585	-1.454184	0.2187781	0.1535019
849	1	0.1003882	-2.192919	0.2268888	0.0903104
850	1	0.1984977	-1.39571	0.2198857	0.1590964
851	0	0.2074481	-1.340377	0.2039859	0.1644134
852	1	0.0576624	-2.793758	0.2607682	0.0543375
853	0	0.2868453	-0.910755	0.2418897	0.2045651
854	1	0.0863711	-2.358771	0.2336204	0.0789112
855	1	0.0898606	-2.315338	0.2322284	0.0817857

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Parameter Code=PPG78 Parameter=PPG <=7.8 mmol/L (SMPG) Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
856	1	0.1725325	-1.567784	0.2192024	0.142765
857	0	0.1388269	-1.825068	0.2188167	0.119554
858	1	0.1389353	-1.824161	0.2177982	0.1196323
859	1	0.1391899	-1.822035	0.2177738	0.1198161
860	1	0.0690626	-2.601178	0.3003605	0.064293
861	1	0.052205	-2.89896	0.2894648	0.0494796
862	1	0.0922492	-2.286476	0.2304654	0.0837393
863	1	0.0727034	-2.545886	0.2432664	0.0674176
864	1	0.2418378	-1.14263	0.2050786	0.1833523
865	1	0.1689051	-1.593407	0.207226	0.1403761
866	0	0.3547338	-0.598295	0.2236778	0.2288977
867	1	0.0705125	-2.578844	0.2451732	0.0655405
868	1	0.2741543	-0.973646	0.2318324	0.1989937
869	1	0.0705017	-2.579009	0.3001012	0.0655312
870	0	0.2846754	-0.921387	0.241302	0.2036353
871	1	0.34988	-0.619567	0.2186512	0.227464
872	1	0.2971732	-0.860795	0.2365166	0.2088613
873	1	0.1195814	-1.9964	0.2587147	0.1052817
874	0	0.1777543	-1.531637	0.2196599	0.1461577
875	1	0.4106522	-0.36127	0.2501362	0.242017
876	0	0.4150714	-0.343039	0.2554664	0.2427871
877	0	0.3611089	-0.570554	0.2450792	0.2307093
878	1	0.1201474	-1.991035	0.2719527	0.105712
879	1	0.2252757	-1.235182	0.2319364	0.1745266

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
880	1	0.4830467	-0.067839	0.2668949	0.2497126
881	1	0.2416429	-1.143693	0.2050643	0.1832516
882	1	0.1418926	-1.799659	0.2135655	0.1217591
883	0	0.3445786	-0.642956	0.2184671	0.2258442
884	1	0.1331873	-1.873066	0.2184525	0.1154485
885	1	0.3905004	-0.445209	0.2213228	0.2380098
886	0	0.3552207	-0.596169	0.2237907	0.2290389
887	1	0.054794	-2.847822	0.2628054	0.0517916
888	1	0.3542454	-0.60043	0.2188327	0.2287556
889	1	0.0272514	-3.575019	0.3246176	0.0265088
890	0	0.2400787	-1.152248	0.2271566	0.1824409
891	1	0.0936744	-2.269573	0.2387318	0.0848995
892	0	0.4960763	-0.015695	0.237086	0.2499846
893	1	0.3727152	-0.520586	0.2470984	0.2337986
894	1	0.281836	-0.935373	0.23223	0.2024045
895	1	0.1129252	-2.061203	0.2774618	0.1001731
896	1	0.5778327	0.3138826	0.2567711	0.2439421
897	1	0.2154157	-1.292584	0.222452	0.1690118
898	1	0.2247282	-1.238322	0.2276626	0.1742254
899	1	0.244203	-1.129773	0.2337302	0.1845679
900	1	0.108119	-2.1101	0.2286994	0.0964293
901	1	0.285075	-0.919426	0.2324265	0.2038072
902	1	0.0983803	-2.215352	0.2351662	0.0887016
903	1	0.0843788	-2.384287	0.2348125	0.077259

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
904	1	0.188877	-1.457324	0.2048423	0.1532025
905	0	0.3172858	-0.766274	0.2156742	0.2166155
906	1	0.1924851	-1.433942	0.2361389	0.1554346
907	1	0.225119	-1.23608	0.2270006	0.1744404
908	1	0.1818304	-1.503995	0.2200761	0.1487681
909	1	0.1365548	-1.844204	0.2189897	0.1179076
910	1	0.0665663	-2.640672	0.3052405	0.0621352
911	1	0.2422279	-1.140504	0.2051077	0.1835535
912	1	0.2769231	-0.959776	0.2200853	0.2002367
913	0	0.0854405	-2.370622	0.234873	0.0781404
914	1	0.1838721	-1.490331	0.2182214	0.1500631
915	1	0.1390813	-1.822941	0.2187992	0.1197377
916	1	0.4421181	-0.23257	0.2468734	0.2466497
917	0	0.4326979	-0.270852	0.2262174	0.2454704
918	1	0.164183	-1.627428	0.20805	0.1372269
919	0	0.1547935	-1.697489	0.2183764	0.1308325
920	0	0.1683239	-1.597553	0.2188996	0.139991
921	0	0.3279727	-0.717368	0.2178116	0.2204066
922	1	0.1129252	-2.061203	0.2774618	0.1001731
923	1	0.1111233	-2.079318	0.2231683	0.0987749
924	1	0.1592815	-1.663584	0.2490122	0.1339109
925	1	0.3907437	-0.444187	0.2688897	0.2380631
926	1	0.0590646	-2.768242	0.2589531	0.055576
927	1	0.4044914	-0.386785	0.2488987	0.2408781

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG78 Parameter=PPG ≤ 7.8 mmol/L (SMPG) Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
928	1	0.064686	-2.671338	0.2508333	0.0605017
929	1	0.1869453	-1.469983	0.2375556	0.1519967
930	1	0.1193577	-1.998527	0.258838	0.1051114
931	0	0.347008	-0.632217	0.2428012	0.2265934
932	1	0.6919629	0.8093123	0.2955829	0.2131502
933	0	0.2346899	-1.182016	0.2260453	0.1796105
934	1	0.2940414	-0.875836	0.2330558	0.207581
935	1	0.1818145	-1.504102	0.2054952	0.148758
936	1	0.1781968	-1.528613	0.2378392	0.1464427
937	1	0.34988	-0.619567	0.2186512	0.227464
938	0	0.2756476	-0.966155	0.220196	0.199666
939	0	0.1649069	-1.622162	0.2170325	0.1377126
940	1	0.0587726	-2.773508	0.2781961	0.0553184
941	0	0.1631575	-1.63492	0.2169881	0.1365371
942	1	0.0583093	-2.781914	0.3155519	0.0549094
943	1	0.1086279	-2.104834	0.2239653	0.0968279
944	1	0.0497848	-2.948978	0.2724098	0.0473063
945	1	0.3824359	-0.479222	0.2304236	0.2361787
946	0	0.0714838	-2.564116	0.2455456	0.0663739
947	1	0.180074	-1.515847	0.2178879	0.1476473
948	1	0.2477538	-1.110628	0.2319543	0.1863719
949	1	0.129788	-1.902835	0.2189392	0.1129431
950	1	0.0485497	-2.9754	0.2723227	0.0461926
951	1	0.07667	-2.488476	0.2400892	0.0707917

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Parameter Code=PPG78 Parameter=PPG <=7.8 mmol/L (SMPG) Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
952	1	0.1462121	-1.764625	0.2172471	0.1248341
953	1	0.4116938	-0.356968	0.2235297	0.242202
954	1	0.1349151	-1.858182	0.2182342	0.116713
955	1	0.0890851	-2.324857	0.2425216	0.081149
956	1	0.3340921	-0.689735	0.2182241	0.2224746
957	0	0.0326754	-3.387912	0.3726994	0.0316077
958	1	0.2223222	-1.252184	0.2236659	0.1728951
959	1	0.111544	-2.075066	0.2230399	0.099102
960	1	0.1731251	-1.563639	0.2065791	0.1431528
961	1	0.31019	-0.799231	0.2143269	0.2139722
962	1	0.1147442	-2.043171	0.2221181	0.101578
963	1	0.2947056	-0.872638	0.2403641	0.2078542
964	1	0.0969842	-2.231192	0.2282814	0.0875782
965	1	0.0596611	-2.757561	0.2767988	0.0561016
966	1	0.2074481	-1.340377	0.2039859	0.1644134
967	1	0.1030005	-2.164321	0.2319538	0.0923914
968	1	0.1335741	-1.86972	0.2192636	0.1157321
969	0	0.123561	-1.959132	0.2205596	0.1082937
970	1	0.165075	-1.620942	0.218709	0.1378252
971	1	0.07363	-2.532222	0.243642	0.0682086
972	0	0.2786294	-0.951271	0.2199425	0.200995
973	0	0.1498383	-1.73587	0.2112664	0.1273868
974	1	0.2060532	-1.348882	0.2040106	0.1635953
975	1	0.1178029	-2.013403	0.2213235	0.1039254

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Parameter Code=PPG78 Parameter=PPG <=7.8 mmol/L (SMPG) Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
976	0	0.1229811	-1.964498	0.2201578	0.1078568
977	1	0.1460794	-1.765688	0.2172546	0.1247402

Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

Model Information

Data Set	WORK.ENDPOINT
Distribution	Binomial
Link Function	Logit
Dependent Variable	aval

Number of Observations Read	977
Number of Observations Used	977
Number of Events	69
Number of Trials	977

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Response Profile

Ordered Value	aval	Total Frequency
1	0	69
2	1	908

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Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

PROC GENMOD is modeling the probability that avar='0'. One way to change this to model the probability that avar='1' is to specify the DESCENDING option in the PROC statement.

Parameter Information

Parameter	Effect	TRTPN	REGION1	BOLAD1
Prm1	Intercept			
Prm2	TRTPN	2		
Prm3	TRTPN	3		
Prm4	TRTPN	4		
Prm5	REGION1		ASIA (EXCLUDING JAPAN)	
Prm6	REGION1		EUROPE	
Prm7	REGION1		JAPAN	
Prm8	REGION1		NORTH AMERICA	
Prm9	BOLAD1			BOLUS INSULIN ALGORITHM (SLIDING SCALE)
Prm10	BOLAD1			CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY
Prm11	P9PPRABL			

Criteria For Assessing Goodness Of Fit

Criterion	DF	Value	Value/DF
Log Likelihood		-226.9173	
Full Log Likelihood		-226.9173	
AIC (smaller is better)		469.8346	
AICC (smaller is better)		469.9834	
BIC (smaller is better)		508.9105	

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Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

Algorithm converged.

Analysis Of Maximum Likelihood Parameter Estimates

Parameter		DF	Estimate	Standard Error	Wald 95% Confidence Limits		Wald Chi-Square
Intercept		1	1.2406	0.6951	-0.1219	2.6030	3.18
TRTPN	2	1	-0.0412	0.2955	-0.6204	0.5380	0.02
TRTPN	3	1	-0.5629	0.3329	-1.2154	0.0896	2.86
TRTPN	4	0	0.0000	0.0000	0.0000	0.0000	.
REGION1	ASIA (EXCLUDING JAPAN)	1	-0.4423	0.5193	-1.4601	0.5755	0.73
REGION1	EUROPE	1	0.1511	0.3194	-0.4750	0.7772	0.22
REGION1	JAPAN	1	0.1235	0.3807	-0.6225	0.8696	0.11
REGION1	NORTH AMERICA	0	0.0000	0.0000	0.0000	0.0000	.
BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	1	-0.0405	0.2818	-0.5928	0.5117	0.02

Analysis Of Maximum Likelihood Parameter Estimates

Parameter		Pr > ChiSq
Intercept		0.0743
TRTPN	2	0.8891
TRTPN	3	0.0909
TRTPN	4	.
REGION1	ASIA (EXCLUDING JAPAN)	0.3944
REGION1	EUROPE	0.6363
REGION1	JAPAN	0.7455
REGION1	NORTH AMERICA	.
BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.8856

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Parameter Code=PPG7870 Parameter=PPG <=7.8 mmol/L and HbA1c <7.0% without severe hypo and with minimal weight gain

The GENMOD Procedure

Analysis Of Maximum Likelihood Parameter Estimates

Parameter	DF	Estimate	Standard Error	Wald 95% Confidence Limits	Wald Chi-Square
BOLAD1 CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY	0	0.0000	0.0000	0.0000 0.0000	.
P9PPRABL	1	-0.4144	0.0730	-0.5574 -0.2714	32.24
Scale	0	1.0000	0.0000	1.0000 1.0000	

Analysis Of Maximum Likelihood Parameter Estimates

Parameter	Pr > ChiSq
BOLAD1 CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY	.
P9PPRABL	<.0001
Scale	

NOTE: The scale parameter was held fixed.

Coefficients for TRTPN Least Squares Means Using WORK.ENDPOINT Margins

Parameter	Geographic Region Grouping Method 1
Intercept	
Planned Treatment (N) 2	
Planned Treatment (N) 3	
Planned Treatment (N) 4	
Geographic Region Grouping Method 1 ASIA (EXCLUDING JAPAN)	ASIA (EXCLUDING JAPAN)
Geographic Region Grouping Method 1 EUROPE	EUROPE
Geographic Region Grouping Method 1 JAPAN	JAPAN

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Parameter Code=PPG7870 Parameter=PPG <=7.8 mmol/L and HbA1c <7.0% without severe hypo and with minimal weight gain

The GENMOD Procedure

Coefficients for TRTPN Least Squares Means Using WORK.ENDPOINT Margins

Parameter	Geographic Region Grouping Method 1
Geographic Region Grouping Method 1 NORTH AMERICA	NORTH AMERICA
Bolus Adjustment Method at Timepoint 1 BOLUS INSULIN ALGORITHM (SLIDING SCALE)	
Bolus Adjustment Method at Timepoint 1 CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY	
PPG all meals (SMPG) (mmol/L) at Baseline	

Coefficients for TRTPN Least Squares Means Using WORK.ENDPOINT Margins

Bolus Adjustment Method at Timepoint 1	Planned Treatment (N)	Row1	Row2	Row3
	1	1	1	1
	2	1		
	3		1	
	4			1
		0.1351	0.1351	0.1351
		0.3367	0.3367	0.3367
		0.2467	0.2467	0.2467
		0.2815	0.2815	0.2815
BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.5793	0.5793	0.5793
CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0.4207	0.4207	0.4207
		9.5719	9.5719	9.5719

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The GENMOD Procedure

TRTPN Least Squares Means

Planned Treatment (N)	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
2	WORK.ENDPOINT	-2.7689	0.2347	-11.80	<.0001	0.05	-3.2290	-2.3088
3	WORK.ENDPOINT	-3.2906	0.2817	-11.68	<.0001	0.05	-3.8428	-2.7384
4	WORK.ENDPOINT	-2.7277	0.2274	-12.00	<.0001	0.05	-3.1734	-2.2821

Differences of TRTPN Least Squares Means

Planned Treatment (N)	Planned Treatment (N)	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
2	4	WORK.ENDPOINT	-0.04120	0.2955	-0.14	0.8891	0.05	-0.6204	0.5380
3	4	WORK.ENDPOINT	-0.5629	0.3329	-1.69	0.0909	0.05	-1.2154	0.08965

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) / NovoRapid (meal)	WORK.ENDPOINT	-0.04120	0.2955	-0.14	0.8891	0.05	-0.6204	0.5380

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Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
TRTPN	Faster aspart (post) / NovoRapid (meal)	WORK.ENDPOINT	-0.5629	0.3329	-1.69	0.0909	0.05	-1.2154	0.08965

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
1	1	0.0987884	-2.21076	0.3867538	0.0890293
2	1	0.0575476	-2.795873	0.39246	0.0542359
3	1	0.0249126	-3.667154	0.4472121	0.0242919
4	1	0.0080062	-4.819495	0.5771667	0.0079421
5	1	0.0300912	-3.472968	0.4308999	0.0291857
6	1	0.2655764	-1.017183	0.3960991	0.1950456
7	1	0.0198879	-3.897555	0.4427567	0.0194924
8	1	0.0126169	-4.360024	0.4815146	0.0124577
9	1	0.1151106	-2.03957	0.3902471	0.1018601
10	1	0.1324799	-1.879208	0.3268445	0.114929
11	1	0.0865585	-2.356399	0.3856167	0.0790661
12	1	0.010734	-4.523549	0.4976923	0.0106188
13	1	0.1057837	-2.134551	0.4256174	0.0945935
14	1	0.1989579	-1.39282	0.4048448	0.1593737
15	1	0.0992443	-2.20565	0.3868245	0.0893949

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Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
16	1	0.3489309	-0.623742	0.4780577	0.2271781
17	1	0.0305771	-3.45645	0.3934062	0.0296421
18	1	0.1071047	-2.120663	0.3232757	0.0956333
19	1	0.0732711	-2.537495	0.3682775	0.0679024
20	1	0.0042769	-5.450244	0.6698811	0.0042586
21	1	0.0110309	-4.495963	0.5251047	0.0109092
22	1	0.0189633	-3.946102	0.4462855	0.0186037
23	1	0.024602	-3.680019	0.4089059	0.0239967
24	1	0.0037343	-5.586462	0.625375	0.0037203
25	1	0.0169385	-4.06108	0.4551748	0.0166516
26	1	0.0191065	-3.938437	0.4457193	0.0187414
27	1	0.0076484	-4.865575	0.5338145	0.0075899
28	1	0.0602378	-2.747326	0.3909579	0.0566092
29	1	0.0493256	-2.958728	0.352862	0.0468926
30	1	0.0270426	-3.582926	0.4017743	0.0263113
31	1	0.0108204	-4.51544	0.5385136	0.0107033
32	1	0.0231068	-3.744251	0.4325346	0.0225729
33	0	0.1204899	-1.987799	0.3245557	0.1059721
34	1	0.11122	-2.07834	0.4287739	0.0988501
35	1	0.0279414	-3.549306	0.4222642	0.0271607
36	1	0.052391	-2.895206	0.3787617	0.0496462
37	1	0.0026343	-5.936508	0.6735406	0.0026273
38	1	0.0245935	-3.680374	0.4287055	0.0239886
39	1	0.0109256	-4.505664	0.4958671	0.0108062

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
40	0	0.1534424	-1.707853	0.4544496	0.1298978
41	1	0.0713586	-2.566005	0.3687856	0.0662666
42	1	0.1865734	-1.472431	0.4245511	0.1517637
43	1	0.016578	-4.082963	0.4687894	0.0163032
44	1	0.063673	-2.688205	0.3518065	0.0596187
45	1	0.0353477	-3.306534	0.3942215	0.0340983
46	1	0.0790233	-2.455692	0.3435176	0.0727786
47	1	0.0621407	-2.714199	0.3683947	0.0582792
48	1	0.0424056	-3.117143	0.36495	0.0406074
49	0	0.3238521	-0.736125	0.4236523	0.2189719
50	0	0.0389074	-3.206886	0.3856271	0.0373936
51	1	0.0458756	-3.034862	0.3738364	0.043771
52	0	0.0839612	-2.389704	0.3716448	0.0769117
53	1	0.0615915	-2.723661	0.3383855	0.057798
54	1	0.0100038	-4.594737	0.500374	0.0099037
55	1	0.0611319	-2.731641	0.3538591	0.0573948
56	1	0.0097292	-4.622843	0.5037375	0.0096346
57	1	0.0180046	-3.99896	0.4679662	0.0176804
58	1	0.0183752	-3.978205	0.4556047	0.0180376
59	1	0.0497108	-2.950544	0.3715825	0.0472396
60	0	0.279311	-0.947882	0.3868459	0.2012964
61	1	0.0334803	-3.362745	0.3993283	0.0323593
62	1	0.0123068	-4.38522	0.4761742	0.0121553
63	1	0.0251785	-3.656265	0.4175889	0.0245445

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Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
64	1	0.0212323	-3.830768	0.4211166	0.0207815
65	1	0.0229997	-3.749006	0.4143274	0.0224707
66	1	0.0481064	-2.985038	0.3724346	0.0457922
67	1	0.0243276	-3.691517	0.4097895	0.0237357
68	1	0.1282444	-1.916571	0.3428442	0.1117978
69	1	0.0669478	-2.634548	0.3494856	0.0624658
70	1	0.1805141	-1.512869	0.3591658	0.1479287
71	1	0.2136542	-1.303038	0.3563334	0.1680061
72	1	0.0220436	-3.792442	0.4178861	0.0215577
73	1	0.0685817	-2.608683	0.3329538	0.0638783
74	0	0.0214551	-3.820104	0.4469009	0.0209948
75	1	0.0409766	-3.152914	0.3679174	0.0392975
76	1	0.0134426	-4.295793	0.4663518	0.0132619
77	1	0.1933736	-1.428237	0.3476275	0.1559803
78	1	0.0174924	-4.028343	0.4715382	0.0171864
79	1	0.0501561	-2.941157	0.3658501	0.0476405
80	1	0.0695675	-2.593352	0.3323161	0.0647279
81	1	0.0647476	-2.670319	0.3510063	0.0605554
82	1	0.054083	-2.861635	0.3463566	0.051158
83	1	0.158295	-1.670969	0.334264	0.1332377
84	0	0.1634256	-1.632957	0.3528958	0.1367177
85	1	0.0409468	-3.153673	0.3779807	0.0392702
86	1	0.0531594	-2.879835	0.3619925	0.0503335
87	1	0.0224886	-3.772002	0.4161977	0.0219829

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
88	0	0.0876274	-2.342955	0.3249125	0.0799489
89	1	0.0321685	-3.40407	0.3902604	0.0311337
90	1	0.2018809	-1.37458	0.3512156	0.161125
91	1	0.0804525	-2.436215	0.3269953	0.0739799
92	1	0.0820739	-2.414497	0.3264377	0.0753378
93	1	0.0160048	-4.118734	0.473372	0.0157486
94	1	0.068725	-2.606442	0.348366	0.0640018
95	1	0.0270626	-3.582168	0.4094514	0.0263302
96	1	0.0435301	-3.089796	0.3756134	0.0416353
97	1	0.0832092	-2.399521	0.3670536	0.0762855
98	1	0.0037659	-5.577998	0.6893629	0.0037517
99	1	0.0709973	-2.57147	0.4084975	0.0659567
100	1	0.1136256	-2.054231	0.323705	0.1007148
101	1	0.0518705	-2.905741	0.3965195	0.0491799
102	1	0.0560186	-2.824422	0.4049873	0.0528805
103	0	0.0428226	-3.106923	0.3641178	0.0409888
104	1	0.0469679	-3.010185	0.38427	0.0447619
105	1	0.0851793	-2.37397	0.3670031	0.0779237
106	1	0.0399842	-3.178465	0.3700881	0.0383855
107	1	0.0132408	-4.311123	0.4680126	0.0130655
108	1	0.1245282	-1.950231	0.389602	0.1090209
109	1	0.0540487	-2.862305	0.3948063	0.0511275
110	1	0.1585884	-1.668769	0.3868456	0.1334381
111	0	0.0390975	-3.201816	0.3955889	0.0375688

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
112	1	0.0853786	-2.371415	0.3670011	0.0780891
113	1	0.0214543	-3.820145	0.4477775	0.020994
114	1	0.0085515	-4.753063	0.5685153	0.0084784
115	1	0.004531	-5.392276	0.5997206	0.0045104
116	1	0.1135899	-2.054585	0.3710045	0.1006872
117	1	0.0994729	-2.203095	0.3868606	0.0895781
118	1	0.214885	-1.295727	0.4123547	0.1687094
119	0	0.0521224	-2.900631	0.3963107	0.0494056
120	1	0.0344854	-3.332125	0.4047148	0.0332962
121	0	0.1180046	-2.011464	0.3910399	0.1040795
122	1	0.0210137	-3.841344	0.4388435	0.0205721
123	1	0.0310085	-3.441993	0.4132436	0.030047
124	1	0.0211283	-3.83579	0.4629638	0.0206818
125	1	0.0541568	-2.860194	0.4048842	0.0512238
126	1	0.0101532	-4.579761	0.5035138	0.0100501
127	1	0.0765829	-2.489707	0.4106603	0.070718
128	1	0.0249725	-3.664688	0.4077405	0.0243489
129	1	0.2556618	-1.06864	0.4495312	0.1902989
130	1	0.024168	-3.698259	0.4297514	0.0235839
131	1	0.0330438	-3.376319	0.4141982	0.0319519
132	1	0.0751384	-2.510312	0.3292253	0.0694926
133	1	0.0136185	-4.282614	0.4989244	0.013433
134	1	0.0997303	-2.200225	0.3681209	0.0897842
135	1	0.0388299	-3.208962	0.4089942	0.0373221

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Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
136	1	0.0516525	-2.910182	0.3495199	0.0489845
137	1	0.0410005	-3.152306	0.4088291	0.0393195
138	1	0.1983478	-1.396653	0.4045603	0.1590059
139	1	0.0576622	-2.793761	0.4051536	0.0543373
140	1	0.0370125	-3.258786	0.4103291	0.0356425
141	1	0.101613	-2.17943	0.3232486	0.0912878
142	1	0.0399721	-3.17878	0.3833134	0.0383744
143	1	0.0773658	-2.478688	0.3441293	0.0713803
144	1	0.0977158	-2.222866	0.3234414	0.0881675
145	1	0.054701	-2.849618	0.3696517	0.0517088
146	1	0.0437434	-3.084686	0.375438	0.0418299
147	1	0.0388237	-3.209126	0.3727479	0.0373165
148	1	0.1146271	-2.044325	0.3406198	0.1014877
149	1	0.079644	-2.447194	0.3704291	0.0733008
150	1	0.0158446	-4.128954	0.4746886	0.0155936
151	1	0.0364193	-3.275558	0.3787109	0.0350929
152	1	0.0081488	-4.801698	0.5257294	0.0080824
153	1	0.1061312	-2.130883	0.3232472	0.0948674
154	1	0.1525525	-1.71472	0.3492957	0.1292803
155	1	0.1322461	-1.881244	0.3937301	0.1147571
156	1	0.0129111	-4.336674	0.4708021	0.0127444
157	0	0.0572902	-2.800628	0.3574314	0.0540081
158	1	0.0202554	-3.878871	0.4536891	0.0198451
159	1	0.017123	-4.050061	0.4741974	0.0168298

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Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
160	1	0.0686966	-2.606886	0.3684932	0.0639773
161	1	0.008486	-4.760817	0.5206166	0.008414
162	1	0.0458197	-3.036139	0.3738749	0.0437202
163	1	0.050293	-2.938288	0.3514333	0.0477636
164	1	0.0217699	-3.805218	0.4189536	0.0212959
165	1	0.0430325	-3.101813	0.3637043	0.0411807
166	1	0.0329163	-3.380316	0.3886441	0.0318328
167	1	0.0069509	-4.96191	0.5906241	0.0069026
168	1	0.0371322	-3.255432	0.3897391	0.0357534
169	1	0.0153621	-4.160374	0.4521164	0.0151261
170	1	0.069382	-2.596222	0.3479754	0.0645681
171	1	0.0685616	-2.608997	0.348465	0.0638609
172	1	0.1525932	-1.714405	0.3323962	0.1293085
173	1	0.0321921	-3.403312	0.3909073	0.0311558
174	1	0.0492059	-2.961283	0.3530428	0.0467847
175	1	0.0139957	-4.254911	0.4619708	0.0137998
176	1	0.0041483	-5.480905	0.6745396	0.0041311
177	1	0.0499528	-2.945434	0.3714645	0.0474575
178	1	0.0364193	-3.275558	0.3787109	0.0350929
179	1	0.0157207	-4.136934	0.4849898	0.0154735
180	1	0.0357968	-3.293444	0.3803619	0.0345154
181	1	0.03273	-3.386185	0.3892305	0.0316588
182	1	0.0306909	-3.452617	0.3931695	0.029749
183	1	0.0205016	-3.86654	0.4242064	0.0200812

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Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
184	1	0.0495658	-2.953618	0.352502	0.047109
185	1	0.1315655	-1.887188	0.3435622	0.114256
186	1	0.0232406	-3.738342	0.4376884	0.0227004
187	1	0.0053471	-5.225841	0.581388	0.0053185
188	1	0.0157207	-4.136934	0.4849898	0.0154735
189	1	0.0421843	-3.122608	0.3905968	0.0404048
190	1	0.0709023	-2.572912	0.3314981	0.0658751
191	1	0.0274608	-3.567152	0.4193467	0.0267067
192	1	0.1060101	-2.132161	0.3232443	0.0947719
193	1	0.0138205	-4.267687	0.4633323	0.0136295
194	1	0.0183688	-3.978559	0.4643243	0.0180314
195	1	0.0143996	-4.226047	0.48735	0.0141923
196	1	0.0421986	-3.122253	0.3653688	0.0404179
197	1	0.0909254	-2.302388	0.3406444	0.082658
198	1	0.0394967	-3.191241	0.3711891	0.0379367
199	1	0.3258825	-0.726868	0.4095246	0.2196831
200	1	0.0228851	-3.754116	0.4147404	0.0223614
201	1	0.0697127	-2.591112	0.3477835	0.0648528
202	1	0.0188751	-3.950857	0.4317657	0.0185188
203	1	0.0333977	-3.3653	0.3995647	0.0322823
204	1	0.0460631	-3.030585	0.3719663	0.0439413
205	1	0.1017771	-2.177633	0.3784452	0.0914185
206	1	0.0372236	-3.252877	0.3895191	0.035838
207	1	0.1470609	-1.757842	0.3306949	0.125434

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
208	1	0.0025952	-5.951483	0.6850623	0.0025885
209	1	0.034387	-3.335083	0.3864143	0.0332046
210	1	0.1117261	-2.073229	0.429071	0.0992434
211	1	0.0618435	-2.719309	0.3684142	0.0580189
212	1	0.0311144	-3.438475	0.428223	0.0301463
213	1	0.0353464	-3.306574	0.4028387	0.034097
214	1	0.0095835	-4.638084	0.5538065	0.0094916
215	1	0.0345706	-3.32957	0.4045253	0.0333755
216	1	0.027528	-3.564637	0.423606	0.0267702
217	1	0.1659292	-1.614757	0.3369236	0.1383967
218	1	0.1032283	-2.161858	0.3398782	0.0925722
219	1	0.0113803	-4.464428	0.4851349	0.0112508
220	1	0.1046145	-2.146972	0.3797223	0.0936703
221	1	0.1063439	-2.128642	0.3399602	0.0950349
222	0	0.1355569	-1.852694	0.3445024	0.1171812
223	1	0.0213922	-3.823103	0.4204638	0.0209346
224	1	0.0461894	-3.027716	0.3579091	0.0440559
225	1	0.0150104	-4.183888	0.4818186	0.0147851
226	1	0.0619919	-2.716754	0.3684041	0.0581489
227	1	0.0052528	-5.243727	0.5838285	0.0052252
228	1	0.0977158	-2.222866	0.3234414	0.0881675
229	1	0.0079449	-4.827249	0.5289495	0.0078818
230	1	0.0153302	-4.162485	0.4882099	0.0150951
231	1	0.0228281	-3.756671	0.4149474	0.022307

Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
232	1	0.0435301	-3.089796	0.3756134	0.0416353
233	1	0.0195001	-3.917641	0.4287423	0.0191199
234	1	0.0770242	-2.483484	0.3283598	0.0710914
235	1	0.0054708	-5.202846	0.5782604	0.0054409
236	1	0.01328	-4.308124	0.5069365	0.0131037
237	1	0.0412664	-3.145564	0.380644	0.0395635
238	1	0.0814747	-2.422476	0.3427167	0.0748366
239	1	0.1168822	-2.022292	0.3240616	0.1032207
240	1	0.1374007	-1.837049	0.3280293	0.1185217
241	1	0.0149427	-4.188479	0.4550047	0.0147194
242	1	0.0044963	-5.399993	0.6646413	0.0044761
243	1	0.0630161	-2.699275	0.4510281	0.0590451
244	1	0.0253198	-3.650523	0.4932529	0.0246787
245	1	0.0767601	-2.487204	0.4515191	0.070868
246	1	0.0021852	-6.123838	0.7146952	0.0021805
247	1	0.0565588	-2.814254	0.4520534	0.0533599
248	1	0.0095758	-4.638894	0.5769266	0.0094841
249	1	0.0116579	-4.440042	0.5361507	0.011522
250	1	0.0551712	-2.840563	0.4880301	0.0521273
251	1	0.120604	-1.986723	0.4721087	0.1060587
252	1	0.0142642	-4.235636	0.5218387	0.0140607
253	1	0.0399275	-3.179944	0.4672993	0.0383333
254	1	0.0111116	-4.488588	0.5398468	0.0109882
255	1	0.0429534	-3.103736	0.4851556	0.0411084

Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
256	1	0.0102482	-4.570351	0.5463178	0.0101432
257	1	0.062117	-2.714606	0.4511125	0.0582585
258	1	0.0252568	-3.653078	0.4933346	0.0246189
259	1	0.0094554	-4.651669	0.5782991	0.009366
260	1	0.0299281	-3.478574	0.4751395	0.0290324
261	1	0.0200871	-3.887386	0.5025292	0.0196836
262	1	0.0000519	-9.86627	1.3522494	0.0000519
263	1	0.012056	-4.406067	0.5490261	0.0119106
264	1	0.0114478	-4.458446	0.5543418	0.0113167
265	0	0.0090801	-4.692551	0.5827276	0.0089976
266	1	0.0052334	-5.247447	0.6104127	0.005206
267	1	0.0738911	-2.528399	0.458138	0.0684312
268	1	0.0033958	-5.68181	0.6596496	0.0033843
269	1	0.0025014	-5.988419	0.6973701	0.0024951
270	1	0.0198808	-3.897921	0.5081393	0.0194855
271	1	0.0708256	-2.574076	0.4509442	0.0658093
272	1	0.0241489	-3.699069	0.4948719	0.0235658
273	1	0.0747394	-2.516068	0.4975306	0.0691534
274	1	0.0251313	-3.658188	0.4934991	0.0244997
275	1	0.0354825	-3.302588	0.4721325	0.0342235
276	1	0.0769191	-2.484963	0.4585427	0.0710025
277	1	0.007659	-4.864185	0.5719658	0.0076003
278	1	0.0612118	-2.730251	0.4579323	0.0574649
279	1	0.1421377	-1.797647	0.4813606	0.1219346

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
280	1	0.0490175	-2.965318	0.461159	0.0466148
281	1	0.0504454	-2.935101	0.4864916	0.0479007
282	1	0.1219992	-1.973633	0.4652957	0.1071154
283	0	0.0791474	-2.453988	0.4518756	0.0728831
284	1	0.0861163	-2.362005	0.4532556	0.0787003
285	1	0.0698233	-2.589407	0.4508966	0.064948
286	1	0.0691624	-2.599627	0.4508738	0.064379
287	1	0.0780373	-2.469318	0.4517017	0.0719475
288	1	0.0534651	-2.873779	0.4874253	0.0506066
289	1	0.0813876	-2.423641	0.4593304	0.0747637
290	1	0.0875343	-2.344119	0.4535906	0.0798721
291	1	0.0186654	-3.962242	0.5060775	0.018317
292	1	0.0520979	-2.901126	0.4534267	0.0493837
293	1	0.0318393	-3.414697	0.4717096	0.0308256
294	0	0.1831255	-1.495314	0.5653106	0.1495905
295	1	0.0367725	-3.265539	0.4705732	0.0354203
296	1	0.0137066	-4.276073	0.5404092	0.0135188
297	1	0.0873305	-2.346674	0.4535415	0.0797039
298	1	0.0148693	-4.193477	0.5191483	0.0146482
299	1	0.0379978	-3.23149	0.4853522	0.0365539
300	1	0.0328793	-3.381481	0.4700225	0.0317982
301	1	0.0348755	-3.320474	0.4729157	0.0336592
302	1	0.0420358	-3.126288	0.4654841	0.0402688
303	1	0.0162294	-4.104568	0.5205553	0.015966

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
304	1	0.0463496	-3.024085	0.4625414	0.0442013
305	1	0.0401238	-3.174834	0.4671185	0.0385139
306	1	0.0962438	-2.239675	0.4631983	0.0869809
307	0	0.0302789	-3.466557	0.488429	0.0293621
308	1	0.0189149	-3.948708	0.5073918	0.0185571
309	1	0.0081044	-4.807215	0.5921887	0.0080387
310	1	0.029611	-3.489553	0.4889173	0.0287341
311	1	0.0463496	-3.024085	0.4625414	0.0442013
312	1	0.0706576	-2.576631	0.4509351	0.0656651
313	1	0.0363518	-3.277481	0.4856782	0.0350304
314	1	0.0264256	-3.606642	0.4880465	0.0257273
315	1	0.0203759	-3.872814	0.5018179	0.0199608
316	1	0.0156239	-4.143209	0.5283397	0.0153798
317	0	0.0767601	-2.487204	0.4515191	0.070868
318	1	0.054509	-2.853338	0.4877893	0.0515378
319	1	0.0093129	-4.667	0.5799533	0.0092262
320	1	0.0194436	-3.920602	0.5051403	0.0190655
321	1	0.0181199	-3.992459	0.5155901	0.0177916
322	1	0.0099588	-4.59929	0.5727072	0.0098596
323	0	0.0363784	-3.276723	0.4651437	0.035055
324	1	0.0553442	-2.837249	0.452367	0.0522812
325	1	0.0147684	-4.200384	0.5291919	0.0145503
326	1	0.1064339	-2.127696	0.5170389	0.0951057
327	1	0.0087223	-4.733117	0.5838128	0.0086462

Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
328	1	0.0794977	-2.449192	0.4589715	0.0731778
329	1	0.0293187	-3.499773	0.4891448	0.0284591
330	1	0.0180745	-3.995014	0.5157974	0.0177478
331	1	0.0253939	-3.647524	0.4905927	0.0247491
332	1	0.165415	-1.618477	0.4845649	0.1380529
333	1	0.0254017	-3.647209	0.4853323	0.0247565
334	1	0.1114366	-2.07615	0.4684942	0.0990185
335	1	0.0602098	-2.747822	0.4513505	0.0565846
336	1	0.0747394	-2.516068	0.4975306	0.0691534
337	1	0.1255675	-1.940731	0.4741606	0.1098003
338	1	0.0732161	-2.538305	0.4511182	0.0678555
339	1	0.0497371	-2.949987	0.4608359	0.0472633
340	1	0.0725256	-2.548525	0.4510595	0.0672656
341	1	0.1891924	-1.455266	0.5033139	0.1533986
342	1	0.0241489	-3.699069	0.4948719	0.0235658
343	1	0.0402345	-3.171965	0.4609521	0.0386157
344	1	0.0749471	-2.513069	0.4582663	0.06933
345	1	0.0620587	-2.715607	0.3282745	0.0582074
346	1	0.0643218	-2.677373	0.311473	0.0601845
347	1	0.1860833	-1.475664	0.2912866	0.1514563
348	0	0.0820412	-2.414931	0.2944714	0.0753104
349	0	0.0994693	-2.203135	0.2855074	0.0895751
350	1	0.1938384	-1.425259	0.2976692	0.1562651
351	1	0.070634	-2.576992	0.3162468	0.0656448

Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
352	1	0.0898107	-2.315949	0.342881	0.0817447
353	1	0.120969	-1.983286	0.3064628	0.1063355
354	1	0.0206945	-3.856973	0.4323918	0.0202663
355	1	0.0901878	-2.311344	0.3430089	0.0820539
356	1	0.0183197	-3.981288	0.4481311	0.0179841
357	1	0.0346321	-3.327727	0.3740094	0.0334328
358	1	0.0528762	-2.885476	0.3341759	0.0500803
359	1	0.1327171	-1.877145	0.3089354	0.1151033
360	1	0.056199	-2.821017	0.3297711	0.0530407
361	1	0.1386559	-1.826499	0.3103048	0.1194305
362	1	0.1101526	-2.089183	0.3057324	0.098019
363	1	0.0749843	-2.512532	0.3135616	0.0693617
364	1	0.1014452	-2.181268	0.306021	0.0911541
365	1	0.1224716	-1.96923	0.3070943	0.1074723
366	1	0.0818673	-2.417242	0.340543	0.0751651
367	1	0.0090874	-4.691742	0.4976702	0.0090048
368	1	0.1449279	-1.774949	0.3699696	0.1239238
369	1	0.0940377	-2.265302	0.3443907	0.0851946
370	1	0.0250212	-3.662692	0.3851508	0.0243951
371	1	0.0551571	-2.840833	0.3408563	0.0521148
372	1	0.0224373	-3.774339	0.4242158	0.0219338
373	1	0.0451041	-3.052629	0.347078	0.0430697
374	1	0.0875779	-2.343574	0.3421527	0.079908
375	1	0.1689508	-1.593081	0.3839871	0.1404064

Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
376	0	0.1596294	-1.660988	0.3155319	0.1341479
377	1	0.1296723	-1.903859	0.2809121	0.1128574
378	1	0.1596294	-1.660988	0.3155319	0.1341479
379	1	0.0571084	-2.803999	0.3401803	0.0538471
380	1	0.0211663	-3.833952	0.4295362	0.0207183
381	1	0.0187126	-3.959666	0.4126327	0.0183625
382	1	0.0505501	-2.932918	0.3430773	0.0479948
383	1	0.0542051	-2.85925	0.34124	0.0512669
384	1	0.0549777	-2.844281	0.3323344	0.0519552
385	1	0.0630033	-2.699492	0.3278249	0.0590339
386	1	0.0809028	-2.430143	0.3239185	0.0743576
387	1	0.1143973	-2.046591	0.2818865	0.1013106
388	1	0.1230656	-1.963714	0.2810476	0.1079205
389	1	0.0906414	-2.305828	0.324447	0.0824255
390	1	0.1066168	-2.125775	0.305918	0.0952496
391	1	0.0980351	-2.21925	0.2860284	0.0884242
392	1	0.1270963	-1.92688	0.2809174	0.1109428
393	1	0.0986475	-2.212344	0.2858018	0.0889161
394	1	0.2203087	-1.263868	0.3032949	0.1717728
395	1	0.0589194	-2.770858	0.3299967	0.0554479
396	1	0.1237866	-1.95705	0.286105	0.1084635
397	1	0.0216382	-3.811418	0.4069534	0.02117
398	1	0.1245641	-1.949902	0.2809812	0.1090479
399	1	0.0503732	-2.936611	0.336801	0.0478357

Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
400	1	0.1449291	-1.77494	0.2819616	0.1239246
401	1	0.0506611	-2.930607	0.3331753	0.0480946
402	1	0.0414828	-3.14011	0.3507748	0.0397619
403	1	0.0443768	-3.069646	0.348496	0.0424075
404	1	0.0113611	-4.466134	0.4693358	0.011232
405	1	0.0490907	-2.963749	0.3399577	0.0466808
406	0	0.0630855	-2.698102	0.3389216	0.0591057
407	1	0.1736905	-1.559695	0.3204121	0.1435221
408	1	0.0238685	-3.711037	0.3892782	0.0232988
409	0	0.1378043	-1.833647	0.3094143	0.1188143
410	1	0.0682385	-2.614068	0.318628	0.063582
411	1	0.1815917	-1.505601	0.391485	0.1486162
412	1	0.0542051	-2.85925	0.34124	0.0512669
413	0	0.2777548	-0.955626	0.3303848	0.2006071
414	1	0.045542	-3.042509	0.3423824	0.0434679
415	0	0.2026185	-1.370008	0.3005233	0.1615642
416	1	0.1075613	-2.115897	0.2885166	0.0959919
417	1	0.2203087	-1.263868	0.3032949	0.1717728
418	1	0.2195189	-1.268472	0.3029901	0.1713303
419	1	0.0054509	-5.206507	0.5890894	0.0054212
420	0	0.1143973	-2.046591	0.2818865	0.1013106
421	1	0.0493489	-2.958233	0.3358164	0.0469135
422	1	0.0061963	-5.077588	0.5702627	0.0061579
423	1	0.1437618	-1.784391	0.2865744	0.1230943

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
424	1	0.0233588	-3.733146	0.3987595	0.0228132
425	0	0.1015284	-2.180357	0.2902595	0.0912204
426	1	0.2079155	-1.337536	0.2986449	0.1646867
427	1	0.0555059	-2.83416	0.3302207	0.052425
428	0	0.1603708	-1.655472	0.2890179	0.134652
429	1	0.2258524	-1.231881	0.3088864	0.1748431
430	0	0.1092768	-2.098149	0.3059454	0.0973354
431	1	0.1280943	-1.917914	0.2859282	0.1116862
432	1	0.0571838	-2.8026	0.3285738	0.0539139
433	1	0.0497281	-2.950178	0.3400799	0.0472552
434	1	0.0806648	-2.433348	0.2954606	0.074158
435	1	0.0614454	-2.726193	0.3239061	0.0576698
436	1	0.137029	-1.840189	0.2860696	0.118252
437	1	0.0218827	-3.799934	0.4406592	0.0214038
438	1	0.0228741	-3.754612	0.4198461	0.0223508
439	1	0.0487903	-2.970203	0.3404549	0.0464098
440	1	0.0118427	-4.424131	0.4800217	0.0117024
441	0	0.1849999	-1.482833	0.3247207	0.150775
442	1	0.0289861	-3.511525	0.3976526	0.0281459
443	1	0.2154934	-1.292125	0.3050286	0.169056
444	1	0.022356	-3.778051	0.3952316	0.0218562
445	1	0.1246135	-1.949449	0.3074186	0.1090849
446	1	0.0274239	-3.568535	0.3775341	0.0266718
447	1	0.0316999	-3.419227	0.3920622	0.0306951

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
448	1	0.0653119	-2.661038	0.3203189	0.0610463
449	1	0.0477139	-2.993642	0.3449515	0.0454373
450	1	0.0777238	-2.473684	0.33964	0.0716828
451	1	0.0239846	-3.706065	0.4140376	0.0234094
452	1	0.1250665	-1.945302	0.3070006	0.1094249
453	1	0.0750759	-2.511211	0.2999945	0.0694395
454	1	0.1058001	-2.134378	0.3057666	0.0946065
455	1	0.1577763	-1.674867	0.3489756	0.132883
456	1	0.0136052	-4.283602	0.4620589	0.0134201
457	1	0.0887522	-2.328967	0.3242367	0.0808752
458	1	0.0861372	-2.361739	0.291798	0.0787176
459	1	0.0468095	-3.013728	0.3407736	0.0446184
460	1	0.1409233	-1.807642	0.3108785	0.121064
461	1	0.0430099	-3.102364	0.3459423	0.04116
462	1	0.0496739	-2.951326	0.3351515	0.0472064
463	1	0.0276086	-3.561632	0.4096309	0.0268463
464	1	0.0405229	-3.164521	0.3499369	0.0388808
465	1	0.2109649	-1.319119	0.2997616	0.1664587
466	1	0.0561731	-2.821505	0.3318182	0.0530177
467	1	0.0400337	-3.177177	0.3642231	0.038431
468	1	0.0792074	-2.453164	0.3239829	0.0729336
469	1	0.0471702	-3.005675	0.3403355	0.0449451
470	0	0.0956974	-2.245973	0.3252271	0.0865394
471	0	0.1460437	-1.765974	0.2868148	0.1247149

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
472	1	0.0806648	-2.433348	0.2954606	0.074158
473	1	0.0792074	-2.453164	0.3239829	0.0729336
474	1	0.0399546	-3.179237	0.3586245	0.0383582
475	1	0.1220753	-1.972923	0.2811035	0.1071729
476	1	0.0445517	-3.06553	0.3437177	0.0425669
477	1	0.1541167	-1.702672	0.3471829	0.1303647
478	1	0.0677129	-2.622365	0.3132255	0.0631278
479	1	0.1825855	-1.498927	0.2943215	0.1492481
480	1	0.1291536	-1.908463	0.2809084	0.1124729
481	1	0.0563697	-2.817803	0.3229279	0.0531921
482	1	0.0486936	-2.972288	0.3430402	0.0463226
483	1	0.0809028	-2.430143	0.3239185	0.0743576
484	1	0.0437743	-3.083947	0.3448165	0.0418581
485	1	0.0308726	-3.446526	0.3953673	0.0299195
486	0	0.15188	-1.719932	0.2875748	0.1288125
487	1	0.1512878	-1.724536	0.2874886	0.1283998
488	1	0.0164268	-4.092278	0.4386667	0.016157
489	1	0.0685162	-2.609709	0.3257614	0.0638217
490	1	0.1071201	-2.120501	0.2886266	0.0956454
491	1	0.2179039	-1.277923	0.3059092	0.1704218
492	1	0.1052623	-2.140075	0.3274351	0.0941821
493	1	0.0561731	-2.821505	0.3318182	0.0530177
494	1	0.0368444	-3.263513	0.3569	0.0354868
495	1	0.1397007	-1.817778	0.340411	0.1201844

Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
496	1	0.0875592	-2.343808	0.2965868	0.0798926
497	1	0.0478476	-2.990705	0.3448431	0.0455582
498	1	0.1279652	-1.919071	0.3353533	0.1115901
499	1	0.1032432	-2.161697	0.2842934	0.0925841
500	1	0.1809098	-1.510196	0.2897371	0.1481814
501	1	0.1087822	-2.103241	0.3284479	0.0969486
502	1	0.1436194	-1.785548	0.3421996	0.1229929
503	0	0.0756723	-2.502654	0.3052213	0.069946
504	1	0.0404335	-3.166823	0.3500905	0.0387986
505	1	0.1449291	-1.77494	0.2819616	0.1239246
506	1	0.0994476	-2.203378	0.2909868	0.0895577
507	1	0.189558	-1.452885	0.2963517	0.1536257
508	1	0.0589194	-2.770858	0.3299967	0.0554479
509	0	0.2234886	-1.245451	0.3045327	0.1735414
510	1	0.0592532	-2.764854	0.3184317	0.0557423
511	1	0.0326781	-3.387827	0.3666324	0.0316102
512	1	0.0753678	-2.507016	0.299736	0.0696875
513	1	0.131765	-1.885442	0.2809499	0.114403
514	1	0.0346708	-3.326573	0.3753049	0.0334687
515	1	0.0725141	-2.548697	0.3081538	0.0672558
516	1	0.0625969	-2.706398	0.3280146	0.0586785
517	1	0.1039685	-2.153888	0.3270877	0.093159
518	1	0.0444155	-3.068735	0.3468622	0.0424428
519	1	0.0766441	-2.488841	0.3043781	0.0707698

Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
520	1	0.0953995	-2.24942	0.2926044	0.0862984
521	1	0.0147504	-4.201623	0.4966138	0.0145329
522	1	0.0592532	-2.764854	0.3184317	0.0557423
523	1	0.0175213	-4.026661	0.4717541	0.0172143
524	1	0.0922881	-2.286012	0.2884744	0.083771
525	1	0.1839639	-1.489719	0.2947108	0.1501212
526	1	0.0232335	-3.738653	0.4268994	0.0226937
527	1	0.02824	-3.538368	0.4010125	0.0274425
528	1	0.0830875	-2.401118	0.2937508	0.0761839
529	1	0.0249873	-3.664082	0.3917901	0.0243629
530	1	0.0383102	-3.222977	0.3634631	0.0368425
531	1	0.1015284	-2.180357	0.2902595	0.0912204
532	1	0.2833306	-0.928	0.3328495	0.2030544
533	1	0.0517798	-2.907586	0.331013	0.0490987
534	1	0.1032432	-2.161697	0.2842934	0.0925841
535	1	0.1981918	-1.397634	0.2990601	0.1589118
536	1	0.0389083	-3.206862	0.3616689	0.0373944
537	1	0.2056499	-1.351349	0.2978279	0.163358
538	1	0.0685901	-2.608552	0.3122398	0.0638855
539	1	0.1023938	-2.170906	0.2845474	0.0919093
540	1	0.2833798	-0.927758	0.3301965	0.2030757
541	1	0.2226486	-1.250298	0.3076733	0.1730762
542	1	0.0508155	-2.927402	0.3363601	0.0482333
543	1	0.0942141	-2.263233	0.2931317	0.0853378

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Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
544	1	0.0873028	-2.347021	0.3086941	0.079681
545	1	0.0390283	-3.203657	0.3526032	0.0375051
546	0	0.180533	-1.51274	0.2937533	0.1479409
547	1	0.0660046	-2.649748	0.3094024	0.061648
548	0	0.0854858	-2.370043	0.3092815	0.078178
549	1	0.0533147	-2.876756	0.3340657	0.0504722
550	1	0.0994476	-2.203378	0.2909868	0.0895577
551	1	0.0380053	-3.231283	0.3545538	0.0365609
552	1	0.0210899	-3.837645	0.4401759	0.0206451
553	1	0.0703004	-2.582083	0.3252786	0.0653583
554	1	0.257945	-1.056677	0.3188491	0.1914094
555	1	0.0847496	-2.379496	0.3239554	0.0775671
556	1	0.1583653	-1.670442	0.3492664	0.1332857
557	1	0.1604034	-1.65523	0.2845591	0.1346742
558	1	0.15307	-1.710723	0.287754	0.1296395
559	1	0.0034983	-5.651962	0.720614	0.0034861
560	1	0.0492832	-2.959632	0.3379346	0.0468544
561	1	0.1385977	-1.826986	0.3399156	0.1193884
562	1	0.1186376	-2.005395	0.2865522	0.1045627
563	1	0.0938219	-2.267837	0.2933118	0.0850194
564	1	0.1910141	-1.443434	0.2928394	0.1545277
565	0	0.0767224	-2.487737	0.3394601	0.070836
566	1	0.0247205	-3.67509	0.412291	0.0241094
567	1	0.0835551	-2.394996	0.3099768	0.0765736

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
568	1	0.0628787	-2.701605	0.3233097	0.058925
569	0	0.1357463	-1.851078	0.3096089	0.1173193
570	1	0.0893813	-2.321213	0.3079269	0.0813923
571	1	0.0523244	-2.896549	0.34211	0.0495866
572	1	0.0557581	-2.829359	0.3313129	0.0526492
573	1	0.207972	-1.337193	0.3342385	0.1647197
574	1	0.0189084	-3.949058	0.4440005	0.0185509
575	1	0.0571084	-2.803999	0.3401803	0.0538471
576	1	0.0590586	-2.768352	0.3264212	0.0555706
577	1	0.0289761	-3.511879	0.3918094	0.0281365
578	0	0.1529832	-1.711392	0.3143375	0.1295794
579	1	0.0398383	-3.182274	0.3584195	0.0382512
580	1	0.1193123	-1.998958	0.3062832	0.1050769
581	1	0.021913	-3.798518	0.3971019	0.0214328
582	1	0.2108131	-1.320031	0.3369268	0.166371
583	1	0.0600553	-2.750555	0.3293315	0.0564487
584	1	0.1224007	-1.96989	0.3070841	0.1074188
585	1	0.0450362	-3.054206	0.3484935	0.043008
586	1	0.057533	-2.796143	0.3291028	0.0542229
587	1	0.0255153	-3.642632	0.3834807	0.0248642
588	1	0.0860018	-2.363461	0.3240182	0.0786055
589	1	0.2070799	-1.342618	0.3352794	0.1641978
590	1	0.092513	-2.283331	0.3438275	0.0839543
591	1	0.0128115	-4.34452	0.4991022	0.0126473

Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
592	1	0.0912339	-2.298661	0.343371	0.0829103
593	1	0.164566	-1.62464	0.3171763	0.137484
594	0	0.2138729	-1.301737	0.3382895	0.1681313
595	1	0.1099496	-2.091256	0.3059643	0.0978607
596	1	0.0548076	-2.847559	0.3315448	0.0518038
597	0	0.0604693	-2.743245	0.3393334	0.0568128
598	1	0.0669088	-2.635173	0.319695	0.062432
599	1	0.0998392	-2.199013	0.3467036	0.0898713
600	1	0.1026696	-2.167908	0.306025	0.0921285
601	1	0.0282536	-3.537874	0.3751786	0.0274553
602	1	0.0425625	-3.113287	0.3522417	0.0407509
603	1	0.0308916	-3.445891	0.3684968	0.0299373
604	1	0.0280824	-3.544127	0.3971855	0.0272938
605	1	0.098992	-2.208475	0.3062706	0.0891926
606	1	0.1512019	-1.725205	0.3137872	0.1283399
607	1	0.0853954	-2.3712	0.3414922	0.078103
608	1	0.0368369	-3.263722	0.3676319	0.03548
609	1	0.2990045	-0.852043	0.3789247	0.2096008
610	0	0.1485517	-1.746006	0.3121646	0.1264841
611	1	0.046453	-3.021748	0.3459275	0.0442951
612	1	0.1008017	-2.188349	0.3061418	0.0906407
613	1	0.155971	-1.688516	0.3143675	0.1316441
614	1	0.04066	-3.161	0.3517517	0.0390068
615	1	0.1097305	-2.093496	0.3057267	0.0976898

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Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
616	1	0.0250227	-3.662629	0.4089221	0.0243966
617	1	0.0480837	-2.985533	0.3416484	0.0457717
618	1	0.1574907	-1.677019	0.3148453	0.1326873
619	0	0.1443056	-1.77998	0.3696137	0.1234815
620	1	0.0584932	-2.778572	0.3270534	0.0550717
621	0	0.0857733	-2.366371	0.3416028	0.0784163
622	1	0.0289231	-3.513765	0.403637	0.0280866
623	1	0.1615592	-1.646672	0.3171519	0.1354578
624	1	0.1058337	-2.134023	0.2889627	0.0946329
625	1	0.1077193	-2.114252	0.30592	0.0961159
626	1	0.0282985	-3.536242	0.3795806	0.0274976
627	1	0.2012679	-1.378389	0.332751	0.1607591
628	1	0.0683331	-2.612581	0.3258158	0.0636637
629	1	0.0200482	-3.889362	0.4527585	0.0196463
630	1	0.0067763	-4.987526	0.5572821	0.0067304
631	1	0.1053176	-2.139488	0.3057835	0.0942258
632	1	0.0889303	-2.326767	0.3425878	0.0810217
633	1	0.046453	-3.021748	0.3459275	0.0442951
634	1	0.0808265	-2.43117	0.3239203	0.0742936
635	1	0.0703607	-2.581162	0.3103323	0.0654101
636	1	0.0163905	-4.094526	0.4389338	0.0161219
637	1	0.0232344	-3.738612	0.4324983	0.0226946
638	1	0.0535329	-2.87244	0.3336452	0.0506671
639	1	0.0905244	-2.307249	0.3244326	0.0823297

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Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
640	1	0.0877599	-2.341299	0.2908444	0.0800581
641	1	0.0374654	-3.246151	0.3644074	0.0360618
642	1	0.0108406	-4.513559	0.4917594	0.0107231
643	1	0.0729093	-2.542835	0.3077702	0.0675935
644	1	0.1466675	-1.760981	0.2868862	0.1251561
645	0	0.1916938	-1.439042	0.2970027	0.1549473
646	1	0.0454796	-3.043945	0.3443194	0.0434112
647	1	0.0650222	-2.665794	0.3105975	0.0607943
648	1	0.0397174	-3.185438	0.3651262	0.03814
649	1	0.0677332	-2.622043	0.3132024	0.0631454
650	1	0.0536934	-2.869277	0.333038	0.0508104
651	1	0.0359148	-3.290031	0.3585638	0.0346249
652	1	0.0352288	-3.310028	0.3706401	0.0339877
653	1	0.022282	-3.78144	0.4230959	0.0217856
654	1	0.0170568	-4.054	0.4223445	0.0167659
655	1	0.027905	-3.550649	0.3761525	0.0271263
656	1	0.0482739	-2.981386	0.3425227	0.0459435
657	1	0.0428889	-3.105307	0.3529015	0.0410494
658	1	0.0808331	-2.431081	0.3107289	0.0742991
659	1	0.016426	-4.092326	0.4264119	0.0161562
660	1	0.0887848	-2.328564	0.3082608	0.0809021
661	1	0.0821385	-2.41364	0.3406104	0.0753918
662	1	0.0291077	-3.507213	0.3728865	0.0282604
663	1	0.0561631	-2.821694	0.330795	0.0530088

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Fast-acting insulin aspart
NN1218-4131

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
664	1	0.0299346	-3.478349	0.3898925	0.0290385
665	1	0.2206069	-1.262133	0.341325	0.1719395
666	1	0.0221891	-3.785717	0.3959293	0.0216967
667	1	0.0845142	-2.382535	0.3093447	0.0773716
668	1	0.0765952	-2.489534	0.313157	0.0707284
669	1	0.0440575	-3.077202	0.3504554	0.0421165
670	1	0.0220948	-3.790068	0.4261408	0.0216067
671	1	0.0613898	-2.727156	0.3248014	0.0576211
672	1	0.0386653	-3.213379	0.3543571	0.0371703
673	0	0.1153114	-2.037599	0.306276	0.1020147
674	1	0.0356686	-3.297163	0.4660423	0.0343964
675	1	0.0338998	-3.349857	0.4742449	0.0327506
676	1	0.0264995	-3.603773	0.4825527	0.0257973
677	1	0.0222493	-3.782943	0.4996757	0.0217543
678	1	0.0817941	-2.418216	0.4523439	0.0751038
679	1	0.0071734	-4.930173	0.609516	0.007122
680	1	0.0105907	-4.537135	0.5436523	0.0104785
681	1	0.0205962	-3.861836	0.500558	0.020172
682	1	0.016148	-4.109678	0.5210057	0.0158873
683	1	0.0121999	-4.39405	0.532752	0.0120511
684	1	0.0583575	-2.781038	0.4516643	0.0549519
685	1	0.0461381	-3.02888	0.4563712	0.0440094
686	1	0.0088716	-4.71599	0.5585785	0.0087929
687	1	0.0665569	-2.640823	0.4576829	0.0621271

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
688	1	0.0173555	-4.036339	0.5099485	0.0170543
689	1	0.0814832	-2.422364	0.4593495	0.0748437
690	1	0.0275321	-3.564484	0.4855186	0.0267741
691	1	0.0343312	-3.336767	0.4678573	0.0331525
692	1	0.0265655	-3.601218	0.4823925	0.0258598
693	1	0.0309842	-3.442803	0.4731889	0.0300242
694	1	0.0955791	-2.247341	0.4629926	0.0864437
695	1	0.0151526	-4.174314	0.517956	0.014923
696	1	0.0818901	-2.416939	0.4523622	0.0751841
697	1	0.0494753	-2.955541	0.4862333	0.0470275
698	1	0.0542852	-2.85769	0.4526759	0.0513383
699	1	0.0583575	-2.781038	0.4516643	0.0549519
700	1	0.0070979	-4.940837	0.5792303	0.0070475
701	1	0.0555721	-2.832898	0.4881795	0.0524839
702	1	0.0083272	-4.779867	0.5642398	0.0082578
703	1	0.0317165	-3.418689	0.3695017	0.0307105
704	1	0.0219515	-3.796726	0.4335115	0.0214696
705	1	0.0414266	-3.141523	0.3839436	0.0397105
706	1	0.1262747	-1.934306	0.3947087	0.1103294
707	1	0.0587133	-2.774582	0.3790227	0.055266
708	1	0.0259228	-3.626368	0.4195868	0.0252508
709	1	0.0772961	-2.479665	0.3166202	0.0713214
710	1	0.0211795	-3.833315	0.4170201	0.0207309
711	1	0.0173671	-4.035659	0.4373491	0.0170655

Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
712	1	0.0087692	-4.727696	0.487745	0.0086923
713	1	0.0432563	-3.096392	0.3425242	0.0413852
714	1	0.0122855	-4.386972	0.5262025	0.0121346
715	1	0.0529081	-2.884839	0.3322309	0.0501089
716	1	0.0421176	-3.12426	0.3480644	0.0403437
717	1	0.0216621	-3.810293	0.4143707	0.0211928
718	1	0.057717	-2.792754	0.3273854	0.0543858
719	1	0.0322433	-3.401672	0.3654223	0.0312036
720	1	0.0177	-4.01633	0.4778093	0.0173867
721	1	0.0295896	-3.490298	0.3801182	0.028714
722	1	0.031141	-3.437594	0.4061922	0.0301712
723	1	0.0847472	-2.379528	0.3571043	0.0775651
724	1	0.0793561	-2.451127	0.3492213	0.0730587
725	1	0.0099186	-4.603372	0.5560545	0.0098203
726	1	0.0113193	-4.469858	0.4572321	0.0111912
727	1	0.0192001	-3.933454	0.4675501	0.0188314
728	1	0.0647914	-2.669596	0.3502048	0.0605935
729	1	0.0400765	-3.176064	0.3558564	0.0384704
730	1	0.0982157	-2.217209	0.3640489	0.0885694
731	1	0.0189608	-3.946239	0.430333	0.0186013
732	1	0.2454197	-1.123192	0.3744234	0.1851889
733	1	0.0494468	-2.956146	0.3364724	0.0470019
734	1	0.0479325	-2.988843	0.3511483	0.0456349
735	1	0.0739068	-2.52817	0.317686	0.0684446

Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
736	1	0.0198705	-3.898451	0.3998194	0.0194756
737	1	0.0187107	-3.959773	0.4051742	0.0183606
738	1	0.1200873	-1.991604	0.3186962	0.1056663
739	1	0.0706753	-2.576362	0.3541142	0.0656803
740	1	0.036555	-3.271698	0.3599319	0.0352187
741	1	0.0829225	-2.403286	0.3127946	0.0760463
742	1	0.0165453	-4.084971	0.4167626	0.0162715
743	1	0.1931787	-1.429487	0.3484162	0.1558607
744	1	0.0447712	-3.060385	0.352591	0.0427668
745	1	0.0353158	-3.307469	0.3630326	0.0340686
746	1	0.0476998	-2.993953	0.3512365	0.0454245
747	1	0.0141913	-4.240831	0.4323276	0.0139899
748	1	0.03651	-3.272976	0.3600412	0.035177
749	1	0.0313445	-3.430871	0.3669567	0.030362
750	1	0.0336885	-3.35633	0.3637475	0.0325536
751	1	0.029682	-3.487083	0.3700937	0.028801
752	1	0.1751022	-1.54989	0.3387955	0.1444414
753	1	0.0274274	-3.568402	0.384247	0.0266752
754	1	0.0613743	-2.727426	0.3545077	0.0576075
755	1	0.0178847	-4.005764	0.4093313	0.0175648
756	1	0.0130686	-4.32439	0.4782484	0.0128978
757	1	0.1227796	-1.966368	0.317602	0.1077048
758	1	0.0299036	-3.479418	0.3696519	0.0290093
759	1	0.1811384	-1.508654	0.351308	0.1483273

Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
760	1	0.0503573	-2.936943	0.3678919	0.0478214
761	1	0.0439051	-3.080826	0.3530847	0.0419775
762	1	0.0294118	-3.496505	0.417748	0.0285468
763	1	0.0923362	-2.285438	0.3146479	0.0838102
764	1	0.0195741	-3.913781	0.4011376	0.0191909
765	1	0.015044	-4.18162	0.4557177	0.0148176
766	1	0.0716653	-2.561386	0.318546	0.0665293
767	1	0.0737321	-2.530725	0.3177484	0.0682957
768	1	0.0375578	-3.243592	0.3575546	0.0361472
769	1	0.0505852	-2.932187	0.3316834	0.0480263
770	1	0.0175292	-4.026205	0.4112166	0.0172219
771	1	0.0363644	-3.277123	0.3567923	0.035042
772	0	0.0381289	-3.227907	0.3987437	0.0366751
773	1	0.1744164	-1.554645	0.3490412	0.1439953
774	0	0.113247	-2.057996	0.3362	0.1004221
775	1	0.3030458	-0.832836	0.4023352	0.2112091
776	0	0.1594398	-1.662402	0.4112186	0.1340187
777	0	0.2498286	-1.099527	0.3830389	0.1874143
778	0	0.0998431	-2.198969	0.3837287	0.0898745
779	1	0.1241622	-1.953592	0.3180218	0.1087459
780	1	0.0348726	-3.320559	0.3605563	0.0336565
781	1	0.0709383	-2.572365	0.3517069	0.065906
782	1	0.042394	-3.11743	0.3440642	0.0405967
783	1	0.0957928	-2.244871	0.3123636	0.0866165

Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
784	1	0.0379609	-3.232498	0.3943096	0.0365199
785	1	0.0218617	-3.800914	0.4094668	0.0213838
786	1	0.0550732	-2.842445	0.3299099	0.0520401
787	1	0.0983962	-2.215173	0.314848	0.0887144
788	1	0.0409275	-3.154164	0.3503484	0.0392524
789	1	0.0660496	-2.649017	0.3504535	0.061687
790	1	0.0298295	-3.481973	0.3697987	0.0289397
791	1	0.0392442	-3.197915	0.3502548	0.0377041
792	1	0.0431788	-3.098267	0.3426601	0.0413144
793	1	0.067209	-2.630373	0.3206658	0.062692
794	1	0.1203618	-1.989009	0.3366113	0.1058748
795	0	0.0795849	-2.448	0.3133659	0.0732512
796	1	0.0226866	-3.763032	0.3887965	0.0221719
797	1	0.0155569	-4.147571	0.4228689	0.0153149
798	1	0.064691	-2.671255	0.3221317	0.0605061
799	1	0.0569646	-2.806674	0.328071	0.0537196
800	1	0.1379205	-1.83267	0.3884812	0.1188985
801	1	0.0537199	-2.868754	0.3497349	0.0508341
802	1	0.0248908	-3.66805	0.3947328	0.0242713
803	1	0.0303091	-3.465529	0.421667	0.0293905
804	1	0.0354917	-3.302319	0.3983969	0.0342321
805	1	0.1834705	-1.493009	0.3575161	0.1498091
806	1	0.017286	-4.040422	0.4876362	0.0169872
807	1	0.0814078	-2.423372	0.3413018	0.0747805

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
808	0	0.0599365	-2.752662	0.3631668	0.0563441
809	0	0.0936325	-2.270067	0.3376809	0.0848655
810	1	0.1174503	-2.0168	0.3428669	0.1036557
811	1	0.0856766	-2.367604	0.3795625	0.0783362
812	1	0.1090387	-2.100598	0.3871915	0.0971492
813	1	0.0960451	-2.241961	0.3372473	0.0868205
814	1	0.0432992	-3.095357	0.3800823	0.0414243
815	1	0.0168447	-4.066731	0.4587455	0.016561
816	1	0.2337676	-1.187158	0.4509644	0.1791203
817	1	0.0797016	-2.446408	0.3160208	0.0733493
818	1	0.1318968	-1.884291	0.3222402	0.1145001
819	1	0.1186646	-2.005138	0.3762142	0.1045833
820	1	0.0140137	-4.253607	0.4336557	0.0138173
821	1	0.0964588	-2.237206	0.3124059	0.0871545
822	1	0.0062225	-5.073343	0.5801682	0.0061838
823	1	0.0532206	-2.87862	0.3810543	0.0503882
824	1	0.0855114	-2.369715	0.3397949	0.0781992
825	1	0.060225	-2.747552	0.3628702	0.056598
826	1	0.0211006	-3.837129	0.3946876	0.0206553
827	1	0.0367211	-3.266992	0.3961027	0.0353727
828	1	0.0258914	-3.627612	0.3789555	0.025221
829	1	0.0487553	-2.970957	0.3508573	0.0463782
830	0	0.0721769	-2.553721	0.3183382	0.0669674
831	1	0.0936024	-2.270422	0.3122646	0.084841

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
832	1	0.048401	-2.978622	0.3509786	0.0460584
833	1	0.0550732	-2.842445	0.3299099	0.0520401
834	1	0.0347986	-3.322759	0.4003404	0.0335877
835	1	0.0308956	-3.445758	0.3720726	0.0299411
836	1	0.0424067	-3.117116	0.3475284	0.0406084
837	1	0.0415335	-3.138834	0.3491695	0.0398085
838	1	0.0749411	-2.513154	0.3145496	0.069325
839	1	0.0174271	-4.032148	0.4369164	0.0171234
840	1	0.038682	-3.212931	0.3550217	0.0371857
841	1	0.0234934	-3.72726	0.3860782	0.0229415
842	1	0.1031126	-2.163109	0.313115	0.0924804
843	1	0.0518047	-2.90708	0.3500478	0.0491209
844	0	0.086791	-2.353462	0.3123907	0.0792583
845	1	0.017102	-4.051311	0.4392836	0.0168095
846	1	0.0269543	-3.586287	0.3860913	0.0262278
847	1	0.0531123	-2.880771	0.3320016	0.0502914
848	1	0.104808	-2.144909	0.3155336	0.0938232
849	1	0.0280354	-3.54585	0.3736258	0.0272495
850	1	0.1115858	-2.074644	0.3167015	0.0991344
851	0	0.0713052	-2.566811	0.3158343	0.0662208
852	1	0.0228742	-3.754608	0.4080576	0.0223509
853	1	0.1186646	-2.005138	0.3762142	0.1045833
854	1	0.0230866	-3.745146	0.3874269	0.0225536
855	1	0.0399362	-3.179715	0.3523505	0.0383413

Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
856	1	0.0576136	-2.794657	0.3494989	0.0542943
857	1	0.0429499	-3.103821	0.3536831	0.0411052
858	1	0.0698178	-2.589492	0.3193555	0.0649432
859	1	0.0699839	-2.586937	0.3192789	0.0650861
860	1	0.0099949	-4.595632	0.5173543	0.009895
861	1	0.0116621	-4.439683	0.4898117	0.0115261
862	1	0.0251292	-3.658273	0.3810752	0.0244977
863	1	0.018524	-3.969993	0.4060877	0.0181808
864	1	0.0887342	-2.329189	0.312283	0.0808605
865	1	0.0536127	-2.870865	0.3281969	0.0507384
866	1	0.1577469	-1.675089	0.3308618	0.1328628
867	1	0.0178175	-4.009597	0.409683	0.0175
868	1	0.1065317	-2.126668	0.342877	0.0951827
869	1	0.0170275	-4.055752	0.4895603	0.0167375
870	1	0.117335	-2.017913	0.3753873	0.1035675
871	1	0.0945035	-2.259847	0.3375149	0.0855726
872	1	0.0755572	-2.504301	0.3778682	0.0698483
873	1	0.0337103	-3.355661	0.4106973	0.0325739
874	0	0.0600178	-2.751221	0.349587	0.0564156
875	1	0.1992792	-1.390806	0.3630481	0.159567
876	1	0.1321434	-1.882139	0.3974825	0.1146815
877	1	0.1038154	-2.155533	0.3851655	0.0930377
878	1	0.0196878	-3.907872	0.4644303	0.0193002
879	1	0.0801034	-2.440943	0.3488817	0.0736869

Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
880	1	0.2614965	-1.038205	0.3879811	0.1931161
881	1	0.088631	-2.330466	0.3122872	0.0807755
882	1	0.0423421	-3.118708	0.3441588	0.0405493
883	0	0.0921256	-2.287953	0.3379942	0.0836385
884	1	0.0660964	-2.648259	0.3212881	0.0617277
885	1	0.114019	-2.05033	0.336224	0.1010187
886	0	0.1580867	-1.672534	0.3310109	0.1330953
887	1	0.0129604	-4.332814	0.4420563	0.0127924
888	1	0.0964897	-2.236851	0.3371763	0.0871794
889	1	0.0054501	-5.206651	0.5499098	0.0054204
890	1	0.1440456	-1.782087	0.3265978	0.1232964
891	1	0.0245214	-3.68338	0.3963903	0.0239201
892	1	0.1773793	-1.534205	0.3500274	0.1459159
893	1	0.1095361	-2.095488	0.3873917	0.097538
894	1	0.1109892	-2.080677	0.3427399	0.0986706
895	1	0.0181247	-3.99219	0.4747976	0.0177962
896	1	0.242657	-1.138167	0.3754877	0.1837746
897	1	0.1244746	-1.950723	0.3199193	0.1089807
898	1	0.0472737	-3.003375	0.3727984	0.0450389
899	1	0.0558551	-2.827518	0.3799474	0.0527353
900	1	0.0295479	-3.491749	0.376539	0.0286748
901	1	0.1128941	-2.061514	0.3427392	0.1001491
902	1	0.0261292	-3.618226	0.3894264	0.0254465
903	1	0.0224051	-3.775807	0.3897874	0.0219031

Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
904	1	0.0625416	-2.70734	0.3204973	0.0586302
905	1	0.1327408	-1.87694	0.32086	0.1151207
906	1	0.0377444	-3.238442	0.3924744	0.0363198
907	1	0.0834733	-2.396065	0.3565179	0.0765055
908	1	0.0619193	-2.718005	0.3497673	0.0580853
909	1	0.0420145	-3.126817	0.3543268	0.0402493
910	1	0.0158307	-4.12985	0.4989615	0.01558
911	1	0.0889411	-2.326634	0.3122751	0.0810306
912	1	0.0648482	-2.668659	0.3513583	0.0606429
913	1	0.0374656	-3.246147	0.3577685	0.0360619
914	1	0.100802	-2.188345	0.3150526	0.090641
915	1	0.0430551	-3.101266	0.3536144	0.0412013
916	1	0.2252001	-1.235615	0.3638711	0.174485
917	1	0.1369551	-1.840814	0.3389685	0.1181984
918	1	0.0515759	-2.911747	0.3304861	0.0489159
919	0	0.0497121	-2.950517	0.3505592	0.0472408
920	0	0.0557019	-2.830428	0.349552	0.0525992
921	1	0.1396532	-1.818173	0.3234008	0.1201502
922	1	0.0181247	-3.99219	0.4747976	0.0177962
923	1	0.0523466	-2.896102	0.3328729	0.0496064
924	1	0.0289055	-3.51439	0.4196256	0.02807
925	1	0.2826719	-0.931246	0.3941469	0.2027685
926	1	0.0235696	-3.723947	0.4046409	0.023014
927	1	0.1944318	-1.421467	0.3613032	0.1566281

Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
928	1	0.0159732	-4.120742	0.4202273	0.015718
929	1	0.0378212	-3.236331	0.3945047	0.0363908
930	1	0.0336271	-3.358216	0.4109454	0.0324964
931	0	0.0971211	-2.22963	0.3828032	0.0876886
932	1	0.3675285	-0.542834	0.4325066	0.2324513
933	1	0.139691	-1.817859	0.3249659	0.1201774
934	1	0.1182472	-2.009135	0.3429069	0.1042648
935	1	0.0593258	-2.763552	0.3228751	0.0558063
936	1	0.0576741	-2.793544	0.3656107	0.0543478
937	1	0.0945035	-2.259847	0.3375149	0.0855726
938	0	0.0643849	-2.676325	0.3517534	0.0602395
939	1	0.0873237	-2.34676	0.3148708	0.0796982
940	1	0.0135339	-4.288934	0.469662	0.0133507
941	1	0.0861096	-2.36209	0.3149844	0.0786947
942	1	0.0080595	-4.812814	0.5442168	0.0079945
943	1	0.0508463	-2.926763	0.334674	0.048261
944	1	0.0190561	-3.941129	0.4297195	0.018693
945	1	0.1777006	-1.532004	0.3400305	0.1461231
946	1	0.0299256	-3.478659	0.3789721	0.02903
947	1	0.0980567	-2.219006	0.3148245	0.0884416
948	1	0.0957543	-2.245315	0.3626947	0.0865855
949	1	0.0639223	-2.68403	0.3226214	0.0598362
950	1	0.0111388	-4.486119	0.4590836	0.0110147
951	1	0.0198208	-3.901006	0.4000382	0.0194279

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
952	1	0.0746094	-2.51795	0.3174426	0.0690428
953	1	0.1251768	-1.944295	0.3371115	0.1095076
954	1	0.067209	-2.630373	0.3206658	0.062692
955	1	0.0229816	-3.749812	0.403703	0.0224534
956	1	0.0875307	-2.344164	0.3391676	0.0798691
957	1	0.0039072	-5.541011	0.6427562	0.003892
958	1	0.1298624	-1.902176	0.3215751	0.1129981
959	1	0.0526007	-2.890991	0.3325803	0.0498339
960	1	0.055457	-2.835094	0.3263111	0.0523815
961	1	0.1282475	-1.916544	0.3193255	0.1118001
962	1	0.0545437	-2.852665	0.3304555	0.0515687
963	1	0.1906033	-1.446095	0.3471701	0.1542737
964	1	0.026809	-3.591841	0.3765653	0.0260903
965	1	0.0137921	-4.269771	0.4671464	0.0136019
966	1	0.0713052	-2.566811	0.3158343	0.0662208
967	1	0.0277358	-3.556904	0.3830704	0.0269665
968	1	0.0407976	-3.157478	0.3552551	0.0391332
969	1	0.0352182	-3.310339	0.3596595	0.0339779
970	1	0.0542419	-2.858534	0.3496734	0.0512997
971	1	0.0310585	-3.440333	0.375252	0.0300938
972	1	0.0654708	-2.658439	0.3508389	0.0611844
973	1	0.0455617	-3.042056	0.3387021	0.0434858
974	1	0.0706314	-2.577031	0.3161104	0.0656426
975	1	0.056418	-2.816894	0.3285851	0.053235

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG7870 Parameter=PPG ≤ 7.8 mmol/L and HbA1c $< 7.0\%$ without severe hypo and with minimal weight gain

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
976	0	0.0596293	-2.758127	0.3257536	0.0560736
977	1	0.0745212	-2.519228	0.3174725	0.0689678

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG78W Parameter=PPG <=7.8 mmol/L (SMPG) without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Model Information

Data Set	WORK.ENDPOINT
Distribution	Binomial
Link Function	Logit
Dependent Variable	aval

Number of Observations Read	977
Number of Observations Used	977
Number of Events	207
Number of Trials	977

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Response Profile

Ordered Value	aval	Total Frequency
1	0	207
2	1	770

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Parameter Code=PPG78W Parameter=PPG <=7.8 mmol/L (SMPG) without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

PROC GENMOD is modeling the probability that aval='0'. One way to change this to model the probability that aval='1' is to specify the DESCENDING option in the PROC statement.

Parameter Information

Parameter	Effect	TRTPN	REGION1	BOLAD1
Prm1	Intercept			
Prm2	TRTPN	2		
Prm3	TRTPN	3		
Prm4	TRTPN	4		
Prm5	REGION1		ASIA (EXCLUDING JAPAN)	
Prm6	REGION1		EUROPE	
Prm7	REGION1		JAPAN	
Prm8	REGION1		NORTH AMERICA	
Prm9	BOLAD1			BOLUS INSULIN ALGORITHM (SLIDING SCALE)
Prm10	BOLAD1			CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY
Prm11	P9PPRABL			

Criteria For Assessing Goodness Of Fit

Criterion	DF	Value	Value/DF
Log Likelihood		-447.1004	
Full Log Likelihood		-447.1004	
AIC (smaller is better)		910.2009	
AICC (smaller is better)		910.3496	
BIC (smaller is better)		949.2768	

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The GENMOD Procedure

Algorithm converged.

Analysis Of Maximum Likelihood Parameter Estimates

Parameter		DF	Estimate	Standard Error	Wald 95% Confidence Limits		Wald Chi-Square
Intercept		1	1.4506	0.4602	0.5486	2.3525	9.94
TRTPN	2	1	0.3014	0.2009	-0.0924	0.6952	2.25
TRTPN	3	1	-0.0587	0.2101	-0.4705	0.3530	0.08
TRTPN	4	0	0.0000	0.0000	0.0000	0.0000	.
REGION1	ASIA (EXCLUDING JAPAN)	1	0.0227	0.2962	-0.5579	0.6033	0.01
REGION1	EUROPE	1	0.5077	0.2084	0.0993	0.9161	5.94
REGION1	JAPAN	1	-0.5699	0.2784	-1.1155	-0.0242	4.19
REGION1	NORTH AMERICA	0	0.0000	0.0000	0.0000	0.0000	.
BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	1	0.3641	0.1884	-0.0051	0.7333	3.74

Analysis Of Maximum Likelihood Parameter Estimates

Parameter		Pr > ChiSq
Intercept		0.0016
TRTPN	2	0.1336
TRTPN	3	0.7798
TRTPN	4	.
REGION1	ASIA (EXCLUDING JAPAN)	0.9389
REGION1	EUROPE	0.0148
REGION1	JAPAN	0.0407
REGION1	NORTH AMERICA	.
BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.0533

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Parameter Code=PPG78W Parameter=PPG <=7.8 mmol/L (SMPG) without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Analysis Of Maximum Likelihood Parameter Estimates

Parameter	DF	Estimate	Standard Error	Wald 95% Confidence Limits	Wald Chi-Square
BOLAD1 CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY	0	0.0000	0.0000	0.0000 0.0000	.
P9PPRABL	1	-0.3481	0.0459	-0.4381 -0.2581	57.47
Scale	0	1.0000	0.0000	1.0000 1.0000	

Analysis Of Maximum Likelihood Parameter Estimates

Parameter	Pr > ChiSq
BOLAD1 CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY	.
P9PPRABL	<.0001
Scale	

NOTE: The scale parameter was held fixed.

Coefficients for TRTPN Least Squares Means Using WORK.ENDPOINT Margins

Parameter	Geographic Region Grouping Method 1
Intercept	
Planned Treatment (N) 2	
Planned Treatment (N) 3	
Planned Treatment (N) 4	
Geographic Region Grouping Method 1 ASIA (EXCLUDING JAPAN)	ASIA (EXCLUDING JAPAN)
Geographic Region Grouping Method 1 EUROPE	EUROPE
Geographic Region Grouping Method 1 JAPAN	JAPAN

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG78W Parameter=PPG <=7.8 mmol/L (SMPG) without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Coefficients for TRTPN Least Squares Means Using WORK.ENDPOINT Margins

Parameter	Geographic Region Grouping Method 1
Geographic Region Grouping Method 1 NORTH AMERICA	NORTH AMERICA
Bolus Adjustment Method at Timepoint 1 BOLUS INSULIN ALGORITHM (SLIDING SCALE)	
Bolus Adjustment Method at Timepoint 1 CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY	
PPG all meals (SMPG) (mmol/L) at Baseline	

Coefficients for TRTPN Least Squares Means Using WORK.ENDPOINT Margins

Bolus Adjustment Method at Timepoint 1	Planned Treatment (N)	Row1	Row2	Row3
	1	1	1	1
	2	1		
	3		1	
	4			1
		0.1351	0.1351	0.1351
		0.3367	0.3367	0.3367
		0.2467	0.2467	0.2467
		0.2815	0.2815	0.2815
BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.5793	0.5793	0.5793
CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0.4207	0.4207	0.4207
		9.5719	9.5719	9.5719

Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG78W Parameter=PPG <=7.8 mmol/L (SMPG) without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

TRTPN Least Squares Means

Planned Treatment (N)	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
2	WORK.ENDPOINT	-1.3355	0.1444	-9.25	<.0001	0.05	-1.6186	-1.0525
3	WORK.ENDPOINT	-1.6957	0.1583	-10.71	<.0001	0.05	-2.0059	-1.3854
4	WORK.ENDPOINT	-1.6369	0.1531	-10.69	<.0001	0.05	-1.9370	-1.3368

Differences of TRTPN Least Squares Means

Planned Treatment (N)	Planned Treatment (N)	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
2	4	WORK.ENDPOINT	0.3014	0.2009	1.50	0.1336	0.05	-0.09242	0.6952
3	4	WORK.ENDPOINT	-0.05874	0.2101	-0.28	0.7798	0.05	-0.4705	0.3530

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) / NovoRapid (meal)	WORK.ENDPOINT	0.3014	0.2009	1.50	0.1336	0.05	-0.09242	0.6952

Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG78W Parameter=PPG <=7.8 mmol/L (SMPG) without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
TRTPN	Faster aspart (post) / NovoRapid (meal)	WORK.ENDPOINT	-0.05874	0.2101	-0.28	0.7798	0.05	-0.4705	0.3530

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
1	1	0.143529	-1.786284	0.2856716	0.1229284
2	1	0.0929793	-2.277789	0.2840239	0.0843341
3	1	0.0469904	-3.009681	0.3079797	0.0447823
4	1	0.0183849	-3.977667	0.3771457	0.0180469
5	1	0.0548593	-2.846561	0.3001273	0.0518498
6	1	0.4047889	-0.385551	0.2927277	0.2409348
7	1	0.0420829	-3.125121	0.3007297	0.0403119
8	1	0.0289276	-3.513603	0.3207621	0.0280908
9	1	0.1621278	-1.642481	0.2889161	0.1358424
10	1	0.1906717	-1.445651	0.2523693	0.154316
11	1	0.1291356	-1.908623	0.2838816	0.1124596
12	1	0.0253088	-3.650967	0.3294652	0.0246683
13	1	0.1618989	-1.644167	0.3019097	0.1356877
14	1	0.1922921	-1.435185	0.305429	0.1553158
15	1	0.1440575	-1.781991	0.2857507	0.1233049

Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG78W Parameter=PPG ≤ 7.8 mmol/L (SMPG) without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
16	1	0.3123522	-0.789146	0.3478879	0.2147883
17	1	0.0865524	-2.356476	0.260894	0.0790611
18	1	0.1613148	-1.648478	0.2484364	0.1352923
19	1	0.0834222	-2.396732	0.2808859	0.076463
20	1	0.0161524	-4.1094	0.4169745	0.0158915
21	1	0.0172612	-4.041879	0.3590177	0.0169633
22	1	0.0404693	-3.165901	0.3024873	0.0388315
23	1	0.0728118	-2.544279	0.2679604	0.0675102
24	1	0.0105207	-4.543832	0.4016668	0.01041
25	1	0.0368808	-3.262485	0.3069859	0.0355206
26	1	0.0407201	-3.159462	0.3022041	0.0390619
27	1	0.0281907	-3.540167	0.3348604	0.027396
28	1	0.096476	-2.237009	0.2835977	0.0871683
29	0	0.0868698	-2.352468	0.2568893	0.0793235
30	1	0.0785134	-2.462719	0.26463	0.0723491
31	1	0.0236085	-3.722256	0.3557648	0.0230512
32	1	0.0475914	-2.996342	0.2957539	0.0453264
33	0	0.1769908	-1.53687	0.2502545	0.1456651
34	1	0.1684086	-1.596948	0.3040192	0.1400472
35	1	0.0374467	-3.246671	0.3049046	0.0360444
36	1	0.0631378	-2.697216	0.2846021	0.0591515
37	1	0.0078616	-4.837877	0.4298762	0.0077998
38	1	0.0500834	-2.942685	0.2939456	0.0475751
39	1	0.0256821	-3.635943	0.3284758	0.0250225

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG78W Parameter=PPG ≤ 7.8 mmol/L (SMPG) without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
40	0	0.216576	-1.285733	0.3206139	0.1696708
41	1	0.1667988	-1.608487	0.2556569	0.1389769
42	1	0.3340628	-0.689866	0.2977866	0.2224649
43	1	0.0356796	-3.296844	0.3143373	0.0344066
44	1	0.1431662	-1.789238	0.2495207	0.1226696
45	1	0.0904095	-2.308645	0.2664043	0.0822356
46	1	0.1688326	-1.593924	0.2478185	0.1403282
47	1	0.1502077	-1.732973	0.25389	0.1276453
48	1	0.0768782	-2.485539	0.2621786	0.0709679
49	0	0.4627053	-0.149456	0.3104293	0.2486091
50	0	0.0975332	-2.224939	0.2625507	0.0880205
51	1	0.118958	-2.002335	0.2536887	0.104807
52	0	0.1884074	-1.460392	0.259102	0.1529101
53	1	0.1038643	-2.155007	0.2511049	0.0930765
54	1	0.0351395	-3.312658	0.3160328	0.0339047
55	1	0.1387483	-1.825725	0.2501317	0.1194972
56	1	0.0343478	-3.336267	0.3179067	0.033168
57	1	0.0526354	-2.890295	0.3030992	0.0498649
58	1	0.0388342	-3.208846	0.3073091	0.0373261
59	1	0.1265839	-1.931507	0.2532591	0.1105604
60	0	0.339994	-0.663321	0.2910288	0.2243981
61	1	0.0866008	-2.355864	0.2687539	0.0791011
62	1	0.0416201	-3.13666	0.3027083	0.0398879
63	1	0.0502871	-2.93841	0.2875735	0.0477583

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG78W Parameter=PPG ≤ 7.8 mmol/L (SMPG) without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
64	1	0.0647118	-2.670911	0.2738895	0.0605242
65	1	0.0689951	-2.602229	0.2705619	0.0642348
66	1	0.1234149	-1.960482	0.2533933	0.1081836
67	1	0.0721624	-2.553937	0.2683806	0.066955
68	0	0.2421273	-1.141052	0.254084	0.1835017
69	1	0.1487846	-1.744165	0.2488923	0.1266478
70	0	0.3096118	-0.801935	0.2675568	0.2137523
71	1	0.2765463	-0.961658	0.2723495	0.2000684
72	1	0.0666879	-2.638716	0.2722972	0.0622406
73	1	0.113204	-2.058423	0.2492199	0.1003889
74	0	0.0606509	-2.740053	0.2921359	0.0569723
75	1	0.0747727	-2.515587	0.2635202	0.0691817
76	1	0.0447219	-3.061539	0.2973913	0.0427218
77	1	0.2560069	-1.066827	0.2668387	0.1904674
78	1	0.0514181	-2.914978	0.3049858	0.0487743
79	1	0.1190222	-2.001723	0.2543409	0.1048559
80	1	0.1145033	-2.045545	0.2490168	0.1013923
81	1	0.1450191	-1.774214	0.2492956	0.1239886
82	1	0.0935612	-2.270908	0.2541927	0.0848075
83	1	0.2191328	-1.270727	0.2579509	0.1711136
84	0	0.2884731	-0.902812	0.2628267	0.2052564
85	1	0.1088891	-2.102139	0.2548748	0.0970323
86	1	0.1245303	-1.950211	0.2528957	0.1090225
87	1	0.0677646	-2.621546	0.2714714	0.0631725

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG78W Parameter=PPG ≤ 7.8 mmol/L (SMPG) without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
88	0	0.1376192	-1.835207	0.2473318	0.1186801
89	1	0.0900949	-2.312477	0.2595526	0.0819778
90	1	0.2646857	-1.021755	0.2691268	0.1946272
91	1	0.1285829	-1.913547	0.2475976	0.1120493
92	1	0.130641	-1.895303	0.2474972	0.1135739
93	1	0.03466	-3.326893	0.3167989	0.0334587
94	1	0.1517996	-1.720556	0.2486193	0.1287565
95	1	0.0533443	-2.876167	0.2834725	0.0504987
96	1	0.114206	-2.048481	0.2541531	0.101163
97	1	0.092723	-2.280831	0.2809378	0.0841254
98	1	0.0145327	-4.216715	0.4284421	0.0143215
99	1	0.1180335	-2.011186	0.2895852	0.1041016
100	1	0.1690081	-1.592674	0.2492384	0.1404443
101	1	0.0854829	-2.37008	0.2853609	0.0781756
102	1	0.0976449	-2.22367	0.2859749	0.0881104
103	0	0.0774897	-2.476954	0.2618051	0.071485
104	1	0.0576601	-2.7938	0.2869514	0.0543355
105	1	0.0945444	-2.259368	0.2810387	0.0856058
106	1	0.0733013	-2.53705	0.2645106	0.0679282
107	1	0.0441749	-3.074417	0.2982862	0.0422235
108	1	0.2513874	-1.091226	0.273637	0.1881918
109	1	0.0883788	-2.333593	0.2847709	0.080568
110	1	0.1588264	-1.666987	0.294745	0.1336005
111	0	0.0495114	-2.954773	0.2920624	0.04706

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG78W Parameter=PPG ≤ 7.8 mmol/L (SMPG) without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
112	0	0.0947283	-2.257222	0.2810503	0.0857549
113	1	0.0300559	-3.47418	0.3178021	0.0291525
114	1	0.0194196	-3.921863	0.3723188	0.0190425
115	1	0.0123617	-4.380713	0.3868086	0.0122089
116	1	0.1201427	-1.99108	0.2846823	0.1057084
117	1	0.1443223	-1.779845	0.2857907	0.1234934
118	1	0.2052783	-1.353625	0.3098189	0.1631391
119	0	0.085819	-2.365788	0.2852873	0.0784541
120	1	0.0446069	-3.064235	0.2963577	0.0426171
121	0	0.1653606	-1.618871	0.2895641	0.1380165
122	1	0.044028	-3.077902	0.2988028	0.0420896
123	1	0.0408349	-3.156526	0.300471	0.0391674
124	1	0.0410386	-3.151337	0.3158315	0.0393545
125	1	0.0950292	-2.253719	0.2856827	0.0859986
126	1	0.0241698	-3.698186	0.3326323	0.0235856
127	1	0.1253731	-1.942504	0.2913198	0.1096546
128	1	0.073686	-2.531401	0.2674085	0.0682564
129	1	0.3043046	-0.826883	0.3281174	0.2117033
130	1	0.0493734	-2.957709	0.2944359	0.0469357
131	1	0.0637285	-2.687274	0.2875791	0.0596672
132	0	0.1217683	-1.97579	0.2481156	0.1069408
133	1	0.0205796	-3.862662	0.3447839	0.020156
134	1	0.1077994	-2.113419	0.2824772	0.0961787
135	1	0.0726492	-2.54669	0.2857142	0.0673713

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
136	1	0.0901596	-2.311688	0.2554879	0.0820309
137	1	0.0706203	-2.577199	0.2902037	0.0656331
138	0	0.1917925	-1.438405	0.3052622	0.1550082
139	1	0.0999379	-2.197915	0.2862689	0.0899503
140	1	0.0698794	-2.588543	0.2861451	0.0649963
141	1	0.1547472	-1.697843	0.247907	0.1308005
142	1	0.0996312	-2.201329	0.2615378	0.0897048
143	1	0.1661392	-1.61324	0.2478681	0.138537
144	1	0.1500345	-1.73433	0.2476251	0.1275242
145	1	0.1362576	-1.846728	0.2531975	0.1176914
146	1	0.1146409	-2.044188	0.2541038	0.1014984
147	1	0.0715709	-2.562806	0.2657341	0.0664485
148	1	0.2229829	-1.248368	0.2513329	0.1732615
149	1	0.1811339	-1.508684	0.2578211	0.1483244
150	1	0.0343739	-3.335478	0.3175078	0.0331924
151	1	0.0679503	-2.61861	0.2685134	0.063333
152	1	0.0296985	-3.486509	0.3302709	0.0288165
153	1	0.1601567	-1.657063	0.2483321	0.1345065
154	1	0.2745829	-0.971493	0.259947	0.1991871
155	1	0.2624495	-1.033276	0.2766286	0.1935698
156	1	0.0432775	-3.09588	0.299793	0.0414046
157	0	0.1319673	-1.883675	0.2512887	0.1145519
158	1	0.0578987	-2.789419	0.2956364	0.0545464
159	0	0.0505355	-2.933221	0.306395	0.0479817

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
160	1	0.1620806	-1.642828	0.2550651	0.1358105
161	1	0.0307043	-3.452168	0.3273802	0.0297615
162	1	0.1188455	-2.003408	0.2536979	0.1047213
163	1	0.0882416	-2.335297	0.2562864	0.080455
164	1	0.0660231	-2.649448	0.2728217	0.061664
165	1	0.0777971	-2.472661	0.26162	0.0717447
166	1	0.0625845	-2.706609	0.2732417	0.0586677
167	1	0.0173753	-4.035175	0.382206	0.0170734
168	1	0.0940022	-2.265719	0.2643775	0.0851658
169	1	0.0498413	-2.947785	0.2897995	0.0473571
170	1	0.1529083	-1.711971	0.2485296	0.1295273
171	1	0.1515234	-1.722702	0.2486425	0.1285641
172	1	0.2129534	-1.307214	0.2566255	0.1676042
173	1	0.0614608	-2.725926	0.2743345	0.0576833
174	1	0.0866997	-2.354614	0.2569659	0.0791829
175	1	0.0462122	-3.027199	0.2950396	0.0440766
176	0	0.0157482	-4.135155	0.4197117	0.0155002
177	1	0.1270592	-1.927214	0.2532441	0.1109152
178	1	0.0679503	-2.61861	0.2685134	0.063333
179	1	0.0471467	-3.006196	0.3121538	0.0449239
180	0	0.0670049	-2.633634	0.2692911	0.0625152
181	1	0.0913341	-2.297453	0.2591228	0.0829922
182	1	0.0868072	-2.353257	0.2607917	0.0792717
183	1	0.0629168	-2.700959	0.2754265	0.0589583

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG78W Parameter=PPG ≤ 7.8 mmol/L (SMPG) without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
184	1	0.0872109	-2.348175	0.2567368	0.0796052
185	0	0.2466853	-1.116369	0.2548238	0.1858317
186	1	0.0646839	-2.671372	0.2874401	0.0604999
187	1	0.0209838	-3.842797	0.3622487	0.0205435
188	1	0.0471467	-3.006196	0.3121538	0.0449239
189	1	0.0527381	-2.888237	0.2897722	0.0499568
190	1	0.1162558	-2.028375	0.2487637	0.1027404
191	1	0.073948	-2.527569	0.2783077	0.0684797
192	1	0.1600124	-1.658136	0.2483195	0.1344084
193	1	0.0457414	-3.03793	0.2957691	0.0436492
194	1	0.0264099	-3.607251	0.3263904	0.0257124
195	1	0.0317672	-3.417038	0.3243623	0.0307581
196	1	0.0765741	-2.489831	0.262367	0.0707105
197	1	0.1876817	-1.465145	0.2481572	0.1524573
198	1	0.0725756	-2.547782	0.2650158	0.0673084
199	1	0.3828036	-0.477665	0.3046473	0.236265
200	1	0.0687199	-2.606522	0.2707622	0.0639975
201	1	0.1534651	-1.707678	0.2484867	0.1299136
202	1	0.0588679	-2.771788	0.2792384	0.0554025
203	1	0.0864312	-2.35801	0.2688637	0.0789608
204	1	0.111368	-2.076843	0.2567564	0.0989651
205	1	0.2171678	-1.282248	0.2651007	0.170006
206	1	0.0941851	-2.263572	0.264279	0.0853143
207	0	0.206902	-1.343702	0.2553839	0.1640936

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG78W Parameter=PPG ≤ 7.8 mmol/L (SMPG) without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
208	1	0.011517	-4.452349	0.4235031	0.0113843
209	1	0.0949597	-2.254527	0.2579747	0.0859424
210	1	0.1690107	-1.592655	0.3042166	0.1404461
211	1	0.1496606	-1.737266	0.2538478	0.1272623
212	1	0.0563812	-2.817586	0.298873	0.0532024
213	1	0.0455306	-3.042772	0.2954648	0.0434575
214	1	0.0213467	-3.825279	0.3641651	0.020891
215	1	0.0446984	-3.062089	0.2962673	0.0427005
216	1	0.0369853	-3.259549	0.3055705	0.0356174
217	1	0.2273197	-1.223508	0.2597886	0.1756454
218	1	0.2063452	-1.347098	0.2494855	0.1637669
219	1	0.0390456	-3.203196	0.3076075	0.0375211
220	1	0.2215783	-1.256492	0.2661285	0.1724814
221	1	0.2109521	-1.319196	0.2499402	0.1664513
222	0	0.2521093	-1.087394	0.2557424	0.1885502
223	1	0.0651026	-2.664472	0.2735665	0.0608643
224	1	0.0823817	-2.410418	0.2590598	0.075595
225	1	0.0328747	-3.381624	0.3213598	0.031794
226	1	0.1499339	-1.735119	0.2538687	0.1274537
227	1	0.0206774	-3.857821	0.3636688	0.0202498
228	1	0.1500345	-1.73433	0.2476251	0.1275242
229	1	0.0290862	-3.507972	0.3320962	0.0282402
230	1	0.0461919	-3.027659	0.3138836	0.0440582
231	1	0.0685826	-2.608668	0.2708627	0.0638791

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
232	1	0.114206	-2.048481	0.2541531	0.101163
233	1	0.0604329	-2.743886	0.2777054	0.0567808
234	1	0.124199	-1.953254	0.2478968	0.1087736
235	1	0.0213843	-3.82348	0.3604306	0.0209271
236	1	0.0410913	-3.149999	0.3240398	0.0394028
237	1	0.1021622	-2.173427	0.2603837	0.0917251
238	1	0.1727843	-1.566022	0.2477931	0.1429299
239	1	0.1728096	-1.565845	0.2497004	0.1429464
240	1	0.1961966	-1.410237	0.2533396	0.1577035
241	1	0.048735	-2.971394	0.2913279	0.0463599
242	1	0.0343802	-3.33529	0.3741453	0.0331982
243	1	0.2560427	-1.06664	0.2468156	0.1904848
244	1	0.1897526	-1.451619	0.2572523	0.1537465
245	0	0.2914203	-0.888496	0.2495868	0.2064945
246	1	0.0284914	-3.529247	0.3946208	0.0276797
247	1	0.238082	-1.163224	0.2462394	0.181399
248	1	0.0862767	-2.359969	0.3099617	0.078833
249	1	0.1076639	-2.114829	0.280074	0.0960724
250	0	0.3162113	-0.771238	0.2636373	0.2162217
251	1	0.4670234	-0.132098	0.2690327	0.2489125
252	0	0.1253051	-1.943124	0.2716583	0.1096037
253	1	0.2433454	-1.134425	0.2483272	0.1841284
254	1	0.1038083	-2.155609	0.282303	0.0930321
255	0	0.2704564	-0.992308	0.2581806	0.1973097

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
256	0	0.0975903	-2.22429	0.2862465	0.0880664
257	1	0.2535973	-1.079518	0.2467009	0.1892857
258	1	0.1894228	-1.453765	0.2572815	0.1535418
259	1	0.0854344	-2.3707	0.3108189	0.0781354
260	1	0.1517084	-1.721264	0.2556337	0.1286929
261	1	0.112578	-2.064674	0.2713602	0.0999042
262	1	0.0008352	-7.087041	0.8147086	0.0008345
263	1	0.0758319	-2.500375	0.3000966	0.0700814
264	1	0.0728053	-2.544375	0.3034527	0.0675047
265	0	0.0827891	-2.405041	0.3135893	0.0759351
266	1	0.0577002	-2.793063	0.3268218	0.0543709
267	0	0.3572969	-0.587116	0.2513613	0.2296358
268	1	0.0407797	-3.157936	0.3587447	0.0391167
269	1	0.0318148	-3.415493	0.3833218	0.0308026
270	0	0.1496259	-1.737539	0.2684555	0.127238
271	1	0.2765839	-0.96147	0.2481865	0.2000852
272	1	0.183562	-1.492399	0.2578587	0.149867
273	0	0.3778564	-0.498657	0.274512	0.2350809
274	1	0.1887646	-1.458058	0.2573407	0.1531325
275	1	0.2248805	-1.237448	0.2500936	0.1743093
276	0	0.3657186	-0.550629	0.2522979	0.2319685
277	1	0.077908	-2.471116	0.3022406	0.0718384
278	1	0.3193687	-0.756675	0.2481901	0.2173723
279	0	0.5066818	0.0267289	0.2780016	0.2499554

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG78W Parameter=PPG ≤ 7.8 mmol/L (SMPG) without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
280	1	0.278054	-0.954135	0.2470111	0.20074
281	0	0.2992962	-0.850652	0.261316	0.209718
282	1	0.387677	-0.457087	0.2649535	0.2373835
283	0	0.2972153	-0.860594	0.250218	0.2088784
284	1	0.3136034	-0.783327	0.2522382	0.2152563
285	1	0.2740146	-0.974348	0.2479773	0.1989306
286	1	0.2723101	-0.982934	0.2478443	0.1981573
287	1	0.2945324	-0.873472	0.2499201	0.2077831
288	1	0.3102095	-0.79914	0.2627765	0.2139796
289	1	0.3777481	-0.499117	0.2537696	0.2350545
290	1	0.3168464	-0.768302	0.2526769	0.2164548
291	1	0.1527144	-1.713469	0.2630431	0.1293927
292	1	0.2250984	-1.236198	0.2462407	0.1744291
293	1	0.1587435	-1.667607	0.2538195	0.133544
294	0	0.5887486	0.3587944	0.3326041	0.2421237
295	1	0.2303517	-1.206327	0.2494833	0.1772898
296	1	0.1135288	-2.055193	0.287465	0.10064
297	1	0.316382	-0.770449	0.2526133	0.2162844
298	1	0.1292384	-1.90771	0.2701262	0.1125358
299	1	0.2498104	-1.099624	0.2566869	0.1874052
300	1	0.1625053	-1.639705	0.2529492	0.1360973
301	1	0.2222725	-1.252472	0.2504118	0.1728674
302	0	0.2517402	-1.089353	0.247785	0.1883671
303	1	0.095599	-2.247111	0.2823269	0.0864598

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
304	1	0.2682538	-1.0035	0.2471448	0.1962937
305	1	0.2441366	-1.130133	0.2482695	0.1845339
306	1	0.4146967	-0.344583	0.2592055	0.2427233
307	0	0.2146561	-1.297084	0.2559692	0.1685789
308	1	0.1075336	-2.116186	0.2742872	0.0959701
309	1	0.0553391	-2.837346	0.3275497	0.0522767
310	1	0.2114177	-1.316401	0.2560412	0.1667202
311	1	0.2682538	-1.0035	0.2471448	0.1962937
312	0	0.2761546	-0.963617	0.2481508	0.1998933
313	1	0.2426405	-1.138257	0.2563385	0.1837661
314	1	0.183493	-1.492859	0.2575313	0.1498233
315	1	0.16269	-1.638348	0.2609277	0.136222
316	1	0.1252546	-1.943584	0.2802195	0.1095659
317	0	0.2914203	-0.888496	0.2495868	0.2064945
318	0	0.3138955	-0.78197	0.2633005	0.2153651
319	0	0.0844336	-2.383578	0.311853	0.0773045
320	1	0.1098205	-2.092576	0.2729286	0.0977599
321	1	0.1398	-1.816952	0.272729	0.120256
322	1	0.0889356	-2.326701	0.3073305	0.0810261
323	0	0.17484	-1.551706	0.2505392	0.144271
324	0	0.2345957	-1.18254	0.2462031	0.1795606
325	1	0.088863	-2.327597	0.2876726	0.0809664
326	0	0.4570021	-0.172417	0.2928486	0.2481512
327	1	0.0586845	-2.775103	0.3221933	0.0552406

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Parameter Code=PPG78W Parameter=PPG ≤ 7.8 mmol/L (SMPG) without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
328	0	0.3727165	-0.52058	0.2531353	0.2337989
329	1	0.2099899	-1.324986	0.2560813	0.1658941
330	1	0.1395421	-1.819098	0.2728491	0.1200701
331	0	0.1784037	-1.5272	0.2588496	0.1465758
332	1	0.4603956	-0.15875	0.2818801	0.2484315
333	1	0.134363	-1.862921	0.2612853	0.1163096
334	1	0.4483798	-0.207219	0.2652618	0.2473354
335	1	0.2483523	-1.10742	0.2464922	0.1866734
336	1	0.3778564	-0.498657	0.274512	0.2350809
337	1	0.4766509	-0.093465	0.2710926	0.2494548
338	1	0.2826363	-0.931422	0.2487189	0.202753
339	1	0.2806465	-0.941257	0.2470045	0.201884
340	1	0.2808989	-0.940007	0.2485604	0.2019947
341	1	0.5779429	0.3143345	0.2973272	0.2439249
342	1	0.183562	-1.492399	0.2578587	0.149867
343	0	0.187901	-1.463707	0.2486483	0.1525942
344	1	0.3602595	-0.574238	0.2516817	0.2304726
345	0	0.3363322	-0.679682	0.1921743	0.2232128
346	1	0.3261464	-0.725666	0.1899409	0.2197749
347	0	0.5704754	0.2837908	0.199671	0.2450332
348	0	0.376317	-0.50521	0.1840623	0.2347025
349	0	0.4188982	-0.327298	0.1825865	0.2434225
350	1	0.4975366	-0.009854	0.2066373	0.2499939
351	1	0.2612558	-1.039452	0.2022936	0.1930012

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
352	1	0.3225515	-0.742071	0.2131286	0.218512
353	1	0.2938593	-0.876713	0.2093132	0.207506
354	1	0.1076802	-2.114659	0.2611012	0.0960852
355	1	0.3233972	-0.738203	0.2132612	0.2188115
356	1	0.0980496	-2.219086	0.2701184	0.0884359
357	1	0.1185673	-2.006068	0.2385816	0.1045091
358	0	0.2144033	-1.298584	0.2093105	0.1684346
359	1	0.3889879	-0.451569	0.2074479	0.2376763
360	1	0.2236645	-1.244437	0.2073988	0.1736387
361	0	0.399146	-0.409025	0.2089358	0.2398285
362	1	0.2757445	-0.965669	0.2079284	0.1997095
363	0	0.2718405	-0.985305	0.2015301	0.1979432
364	1	0.2605672	-1.043022	0.2072575	0.1926719
365	0	0.3707684	-0.528922	0.2051088	0.2332992
366	1	0.3042461	-0.827159	0.2105029	0.2116804
367	1	0.0607806	-2.737779	0.2927128	0.0570863
368	1	0.4285863	-0.287621	0.2358621	0.2449001
369	1	0.3319172	-0.699526	0.2146496	0.2217482
370	1	0.1331536	-1.873359	0.2263372	0.1154237
371	0	0.2345163	-1.182983	0.2058877	0.1795184
372	1	0.0846152	-2.38123	0.2666403	0.0774555
373	1	0.2040949	-1.360895	0.2075599	0.1624402
374	1	0.3175018	-0.765277	0.2123569	0.2166944
375	0	0.4663387	-0.134849	0.2463257	0.2488669

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Parameter Code=PPG78W Parameter=PPG ≤ 7.8 mmol/L (SMPG) without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
376	0	0.3529773	-0.605978	0.2174048	0.2283843
377	1	0.4810339	-0.075901	0.1856101	0.2496403
378	0	0.3529773	-0.605978	0.2174048	0.2283843
379	0	0.2401164	-1.152042	0.2058687	0.1824605
380	1	0.1095525	-2.095321	0.2594772	0.0975507
381	1	0.1068983	-2.122822	0.2418715	0.0954711
382	1	0.2209161	-1.260336	0.2062886	0.1721122
383	1	0.2317504	-1.198454	0.2059275	0.1780422
384	1	0.1679866	-1.599964	0.2170177	0.1397671
385	0	0.3393604	-0.666146	0.1921344	0.2241949
386	1	0.3917676	-0.439888	0.1939162	0.2382858
387	0	0.4512063	-0.195798	0.183428	0.2476192
388	1	0.4684967	-0.12618	0.1845332	0.2490075
389	1	0.4169124	-0.335461	0.1962698	0.2430964
390	0	0.3406448	-0.660422	0.2022547	0.2246059
391	1	0.4156067	-0.340835	0.1825932	0.2428778
392	1	0.4762082	-0.095239	0.1851685	0.249434
393	0	0.4170164	-0.335033	0.1825882	0.2431137
394	1	0.6134181	0.4617028	0.2102672	0.2371363
395	1	0.3260524	-0.726094	0.1924368	0.2197422
396	1	0.3878004	-0.456568	0.1928328	0.2374113
397	1	0.167956	-1.600184	0.2300721	0.1397468
398	0	0.471387	-0.114577	0.1847611	0.2491813
399	0	0.296227	-0.86533	0.1943825	0.2084766

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG78W Parameter=PPG ≤ 7.8 mmol/L (SMPG) without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
400	0	0.5080977	0.0323935	0.188702	0.2499344
401	1	0.2812262	-0.938387	0.1995053	0.202138
402	1	0.1924171	-1.43438	0.2090171	0.1553928
403	1	0.1894957	-1.453291	0.2159841	0.1535871
404	1	0.0725432	-2.548264	0.2755032	0.0672807
405	1	0.2035367	-1.364335	0.2119325	0.1621095
406	0	0.2567202	-1.063086	0.2062646	0.1908149
407	1	0.3726443	-0.520889	0.2210811	0.2337805
408	1	0.1285356	-1.913969	0.2286153	0.1120142
409	0	0.3206002	-0.751015	0.2123627	0.2178157
410	1	0.1967738	-1.406582	0.2107974	0.1580539
411	0	0.4846638	-0.061364	0.2517788	0.2497648
412	1	0.2317504	-1.198454	0.2059275	0.1780422
413	0	0.5949934	0.3846468	0.2309615	0.2409763
414	1	0.2780237	-0.954286	0.1965162	0.2007265
415	0	0.5091385	0.0365581	0.2089741	0.2499165
416	0	0.3566345	-0.590002	0.1920528	0.2294463
417	1	0.6134181	0.4617028	0.2102672	0.2371363
418	0	0.6125005	0.4578352	0.2100146	0.2373436
419	1	0.0588516	-2.772082	0.3405457	0.0553881
420	0	0.4512063	-0.195798	0.183428	0.2476192
421	1	0.2765594	-0.961593	0.2007584	0.2000743
422	0	0.0651443	-2.663788	0.3288494	0.0609005
423	1	0.4227412	-0.311531	0.195483	0.2440311

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Parameter Code=PPG78W Parameter=PPG ≤ 7.8 mmol/L (SMPG) without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
424	1	0.1773459	-1.534434	0.2254158	0.1458944
425	0	0.3443093	-0.644149	0.1921956	0.2257604
426	0	0.5986445	0.3998204	0.2063407	0.2402693
427	1	0.2326594	-1.193355	0.2079943	0.178529
428	0	0.4493651	-0.203236	0.1986438	0.2474361
429	1	0.5380731	0.1525877	0.2154669	0.2485504
430	0	0.3458761	-0.637216	0.2026534	0.2262458
431	0	0.3956335	-0.423692	0.1932708	0.2391076
432	1	0.2263623	-1.228967	0.2068946	0.1751224
433	1	0.1559179	-1.68892	0.2208118	0.1316075
434	1	0.3726931	-0.520681	0.1843314	0.2337929
435	0	0.2377992	-1.164783	0.2050069	0.1812507
436	0	0.4113465	-0.358402	0.1944247	0.2421406
437	0	0.1187185	-2.004622	0.2679648	0.1046244
438	1	0.1162251	-2.028673	0.2539971	0.1027168
439	1	0.2026593	-1.369756	0.212163	0.1615885
440	1	0.1076596	-2.114873	0.2733743	0.096069
441	0	0.3878582	-0.456324	0.2242056	0.2374242
442	1	0.1936652	-1.426368	0.2330161	0.156159
443	1	0.5254734	0.1019819	0.212524	0.2493511
444	1	0.1223607	-1.970263	0.2319409	0.1073886
445	1	0.3746533	-0.512305	0.2055708	0.2342882
446	1	0.1425506	-1.794265	0.222204	0.1222299
447	1	0.1564581	-1.684822	0.2404549	0.1319789

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Parameter Code=PPG78W Parameter=PPG ≤ 7.8 mmol/L (SMPG) without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
448	1	0.2478611	-1.110053	0.2036615	0.186426
449	1	0.2122618	-1.311345	0.2068282	0.1672067
450	1	0.2943041	-0.874571	0.2092868	0.2076892
451	1	0.1204799	-1.987894	0.2507369	0.1059645
452	1	0.3005235	-0.844806	0.2099675	0.2102091
453	1	0.3575331	-0.586087	0.1857124	0.2297032
454	1	0.2682277	-1.003633	0.2075367	0.1962816
455	1	0.5484864	0.1945571	0.2214358	0.2476491
456	0	0.1195366	-1.996826	0.2625238	0.1052476
457	1	0.4121951	-0.354898	0.1957605	0.2422903
458	1	0.3868605	-0.460528	0.1834106	0.2371995
459	1	0.2829025	-0.93011	0.1958691	0.2028687
460	1	0.4029509	-0.393185	0.2095254	0.2405815
461	1	0.2680448	-1.004565	0.1980198	0.1961968
462	0	0.2777216	-0.955792	0.2004415	0.2005923
463	1	0.1413109	-1.804444	0.2502672	0.1213422
464	1	0.2579256	-1.056779	0.1998024	0.1914
465	0	0.6023559	0.415291	0.2072991	0.2395233
466	1	0.3167737	-0.768638	0.1928479	0.2164281
467	1	0.1852017	-1.481495	0.225337	0.150902
468	1	0.3871694	-0.459226	0.1935848	0.2372693
469	1	0.2842769	-0.923345	0.1956969	0.2034635
470	0	0.4291838	-0.285182	0.1977355	0.2449851
471	0	0.4265209	-0.29606	0.1958739	0.2446008

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG78W Parameter=PPG ≤ 7.8 mmol/L (SMPG) without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
472	1	0.3726931	-0.520681	0.1843314	0.2337929
473	1	0.3871694	-0.459226	0.1935848	0.2372693
474	1	0.2409935	-1.14724	0.2121118	0.1829156
475	1	0.4665711	-0.133916	0.1843881	0.2488825
476	1	0.2741587	-0.973624	0.1970694	0.1989957
477	0	0.542696	0.1712009	0.2199197	0.2481771
478	1	0.265916	-1.015443	0.2001602	0.1952047
479	1	0.4820736	-0.071736	0.2037663	0.2496786
480	1	0.4800685	-0.079768	0.1855191	0.2496027
481	0	0.3007709	-0.84363	0.1948041	0.2103078
482	1	0.2125898	-1.309385	0.2143371	0.1673954
483	1	0.3917676	-0.439888	0.1939162	0.2382858
484	1	0.2710909	-0.989095	0.1975346	0.1976006
485	1	0.1534554	-1.707753	0.2422871	0.1299068
486	0	0.436007	-0.257383	0.1969403	0.2459049
487	1	0.4350562	-0.261251	0.1968279	0.2457823
488	1	0.137512	-1.83611	0.2485595	0.1186024
489	0	0.3564682	-0.590726	0.192216	0.2293986
490	0	0.3557476	-0.593869	0.1920542	0.2291912
491	0	0.528447	0.1139111	0.2132026	0.2491908
492	1	0.4511003	-0.196226	0.2008397	0.2476088
493	1	0.3167737	-0.768638	0.1928479	0.2164281
494	0	0.2423327	-1.139933	0.2030918	0.1836075
495	0	0.5186188	0.0745096	0.2140013	0.2496533

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG78W Parameter=PPG ≤ 7.8 mmol/L (SMPG) without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
496	1	0.3140074	-0.78145	0.1937414	0.2154068
497	1	0.2100116	-1.324855	0.2152509	0.1659067
498	0	0.4973553	-0.010579	0.2092981	0.249993
499	0	0.4273946	-0.292489	0.1826494	0.2447284
500	0	0.5633535	0.2547834	0.1981532	0.2459863
501	0	0.4587726	-0.165285	0.202068	0.2483003
502	0	0.525374	0.1015832	0.2155988	0.2493562
503	0	0.2860014	-0.914884	0.1968351	0.2042046
504	1	0.2575556	-1.058712	0.1998727	0.1912207
505	0	0.5080977	0.0323935	0.188702	0.2499344
506	1	0.3399568	-0.663487	0.1923109	0.2243862
507	0	0.4917358	-0.03306	0.2055274	0.2499317
508	0	0.3260524	-0.726094	0.1924368	0.2197422
509	0	0.6170802	0.4771734	0.2112867	0.2362922
510	1	0.310207	-0.799152	0.1928374	0.2139786
511	1	0.223678	-1.24436	0.2079697	0.1736462
512	1	0.358343	-0.582563	0.1856281	0.2299333
513	1	0.484897	-0.06043	0.1859878	0.2497719
514	1	0.2190852	-1.271005	0.2208681	0.1710869
515	1	0.2781693	-0.953561	0.1980154	0.2007911
516	0	0.338061	-0.671947	0.1921495	0.2237758
517	1	0.448229	-0.207829	0.2003986	0.2473198
518	0	0.2583779	-1.054417	0.2061498	0.1916187
519	0	0.2883767	-0.903281	0.1965054	0.2052156

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG78W Parameter=PPG ≤ 7.8 mmol/L (SMPG) without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
520	1	0.3313327	-0.702163	0.1926426	0.2215514
521	1	0.0876999	-2.342048	0.3007013	0.0800087
522	1	0.310207	-0.799152	0.1928374	0.2139786
523	1	0.1001934	-2.195077	0.2860519	0.0901547
524	0	0.4020536	-0.396916	0.182807	0.2404065
525	1	0.4840052	-0.064001	0.2041096	0.2497442
526	1	0.1655969	-1.61716	0.2494329	0.1381746
527	1	0.1901683	-1.448917	0.2348756	0.1540043
528	1	0.3790442	-0.493607	0.1838752	0.2353697
529	1	0.185969	-1.476419	0.2215081	0.1513845
530	1	0.2343368	-1.183983	0.214619	0.1794231
531	0	0.3443093	-0.644149	0.1921956	0.2257604
532	1	0.6005729	0.4078527	0.2326758	0.2398851
533	1	0.2851517	-0.919049	0.198491	0.2038402
534	1	0.4273946	-0.292489	0.1826494	0.2447284
535	1	0.503338	0.0133522	0.2077864	0.2499889
536	1	0.2367743	-1.170446	0.2136859	0.1807122
537	1	0.5958535	0.3882174	0.2056322	0.2408121
538	1	0.2681871	-1.00384	0.1997344	0.1962628
539	1	0.4255026	-0.300225	0.1826254	0.2444501
540	1	0.677879	0.7440414	0.2310124	0.2183591
541	1	0.5342257	0.137117	0.2145495	0.2488286
542	0	0.2978422	-0.857594	0.1942294	0.2091322
543	1	0.3287671	-0.713766	0.1927684	0.2206793

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

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The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
544	1	0.2346465	-1.182258	0.2073137	0.1795875
545	1	0.2516835	-1.089654	0.2010378	0.1883389
546	0	0.4791773	-0.083339	0.20326	0.2495664
547	1	0.331267	-0.70246	0.1891203	0.2215292
548	0	0.2311914	-1.201596	0.2074501	0.1777419
549	1	0.3068154	-0.81505	0.1934811	0.2126797
550	1	0.3399568	-0.663487	0.1923109	0.2243862
551	1	0.2473382	-1.112859	0.2019613	0.186162
552	1	0.1544242	-1.700315	0.2570314	0.1305774
553	1	0.3618091	-0.567521	0.1923446	0.2309033
554	0	0.6537915	0.6357471	0.2225477	0.2263482
555	1	0.4019507	-0.397344	0.194761	0.2403863
556	0	0.5494069	0.1982745	0.2216801	0.247559
557	1	0.5331892	0.1329524	0.19248	0.2488985
558	0	0.4379101	-0.249648	0.1971687	0.2461448
559	1	0.0276428	-3.560358	0.4365954	0.0268787
560	1	0.2922114	-0.884668	0.1947882	0.2068239
561	0	0.5166874	0.0667743	0.2135536	0.2497215
562	0	0.3782041	-0.497178	0.1924254	0.2351658
563	0	0.3279142	-0.717634	0.192813	0.2203865
564	0	0.5770962	0.3108644	0.2011429	0.2440562
565	0	0.2918583	-0.886376	0.2090121	0.206677
566	1	0.0913005	-2.297859	0.2598528	0.0829647
567	1	0.2274868	-1.222557	0.2076333	0.1757365

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG78W Parameter=PPG ≤ 7.8 mmol/L (SMPG) without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
568	1	0.1854102	-1.480114	0.2128241	0.1510332
569	0	0.3942046	-0.429672	0.2081961	0.2388073
570	1	0.3047895	-0.824593	0.2007487	0.2118929
571	1	0.226219	-1.229785	0.20607	0.175044
572	1	0.1697458	-1.58743	0.2165289	0.1409322
573	0	0.4172715	-0.333984	0.2308729	0.243156
574	1	0.1004701	-2.192012	0.2677417	0.0903759
575	1	0.2401164	-1.152042	0.2058687	0.1824605
576	1	0.2314401	-1.200198	0.2060076	0.1778756
577	1	0.138862	-1.824774	0.2384651	0.1195794
578	0	0.4225453	-0.312333	0.2128295	0.2440008
579	1	0.1753898	-1.5479	0.2208965	0.1446282
580	1	0.2911348	-0.889879	0.2090673	0.2063753
581	1	0.1205264	-1.987454	0.2329943	0.1059998
582	1	0.5041042	0.0164172	0.2308974	0.2499832
583	1	0.3298111	-0.70904	0.1923177	0.2210357
584	1	0.3706392	-0.529475	0.2050938	0.2332658
585	1	0.14476	-1.776305	0.2250728	0.1238045
586	1	0.1737144	-1.559528	0.2154823	0.1435377
587	1	0.1351106	-1.856508	0.2254225	0.1168557
588	1	0.405193	-0.383874	0.1950613	0.2410116
589	0	0.4993609	-0.002556	0.2296708	0.2499996
590	1	0.3285676	-0.714671	0.2140925	0.2206109
591	1	0.0541569	-2.860192	0.3103437	0.0512239

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG78W Parameter=PPG ≤ 7.8 mmol/L (SMPG) without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
592	0	0.3257329	-0.727549	0.2136324	0.219631
593	1	0.3599815	-0.575444	0.2186649	0.2303948
594	0	0.5079455	0.0317848	0.231906	0.2499369
595	1	0.3471874	-0.631425	0.20276	0.2266483
596	1	0.219817	-1.266733	0.2081584	0.1714975
597	0	0.2495513	-1.101007	0.2060142	0.1872755
598	1	0.1939868	-1.42431	0.211247	0.1563559
599	1	0.3443784	-0.643843	0.2168437	0.2257819
600	0	0.3327408	-0.695815	0.2017345	0.2220244
601	1	0.1457278	-1.768509	0.2209478	0.1244912
602	1	0.1839293	-1.48995	0.2178159	0.1500993
603	1	0.1556126	-1.691242	0.2174542	0.1313973
604	1	0.1008471	-2.187847	0.2513528	0.090677
605	1	0.2561881	-1.065876	0.207155	0.1905557
606	1	0.4197168	-0.323936	0.2123256	0.2435546
607	1	0.3124946	-0.788482	0.2116266	0.2148417
608	1	0.1243025	-1.952303	0.2351401	0.1088514
609	1	0.6009765	0.4095354	0.2604579	0.2398038
610	0	0.3368432	-0.677394	0.2147239	0.2233798
611	1	0.208341	-1.334955	0.2071514	0.164935
612	0	0.3289396	-0.712985	0.2015206	0.2207383
613	1	0.3477142	-0.629102	0.2164955	0.226809
614	1	0.1897049	-1.451929	0.2094299	0.153717
615	1	0.2750216	-0.969292	0.2078859	0.1993847

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG78W Parameter=PPG ≤ 7.8 mmol/L (SMPG) without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
616	1	0.1244001	-1.951406	0.2478825	0.1089247
617	1	0.2005863	-1.382634	0.2127194	0.1603514
618	1	0.349908	-0.619444	0.2168705	0.2274724
619	0	0.4275516	-0.291848	0.2355905	0.2447512
620	1	0.2299165	-1.208783	0.2062654	0.1770549
621	0	0.3133668	-0.784426	0.2117513	0.215168
622	1	0.1462607	-1.764235	0.2469	0.1248685
623	1	0.4358635	-0.257967	0.2153199	0.2458865
624	1	0.3531487	-0.605227	0.1920661	0.2284347
625	1	0.3428223	-0.650742	0.2024155	0.2252952
626	0	0.2027766	-1.36903	0.2148073	0.1616582
627	0	0.4918496	-0.032605	0.2277708	0.2499336
628	1	0.355915	-0.593139	0.1922054	0.2292395
629	1	0.1110814	-2.079743	0.2749669	0.0987423
630	1	0.069906	-2.588135	0.3208029	0.0650191
631	1	0.2673859	-1.007926	0.2075	0.1958907
632	1	0.320569	-0.751158	0.2128215	0.2178045
633	1	0.208341	-1.334955	0.2071514	0.164935
634	1	0.3915621	-0.440751	0.1939008	0.2382412
635	0	0.2727268	-0.980832	0.1989222	0.1983469
636	0	0.1372881	-1.837999	0.2487176	0.1184401
637	1	0.1242146	-1.953111	0.2632714	0.1087853
638	1	0.226968	-1.225511	0.2096594	0.1754535
639	1	0.4166223	-0.336655	0.1962376	0.2430482

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Parameter Code=PPG78W Parameter=PPG ≤ 7.8 mmol/L (SMPG) without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
640	1	0.3909412	-0.443358	0.18321	0.2381062
641	1	0.167764	-1.601558	0.2239439	0.1396193
642	1	0.1006526	-2.189994	0.2805107	0.0905217
643	1	0.279159	-0.948637	0.1978583	0.2012292
644	1	0.4275471	-0.291866	0.1959834	0.2447506
645	0	0.4946425	-0.021431	0.2060787	0.2499713
646	0	0.2623881	-1.033593	0.2048891	0.1935406
647	1	0.3282878	-0.715939	0.1895914	0.2205149
648	1	0.1841569	-1.488434	0.2258171	0.1502431
649	1	0.2659688	-1.015173	0.2001501	0.1952294
650	1	0.2167042	-1.284977	0.2088087	0.1697435
651	1	0.1736011	-1.560317	0.2125215	0.1434638
652	1	0.1604053	-1.655215	0.2271711	0.1346754
653	1	0.1139302	-2.05121	0.2558295	0.1009501
654	1	0.0995653	-2.202064	0.2475185	0.089652
655	1	0.1443969	-1.779241	0.2214658	0.1235464
656	1	0.1524988	-1.715135	0.2220358	0.1292429
657	1	0.1395261	-1.819231	0.2273508	0.1200586
658	1	0.2855931	-0.916885	0.2009246	0.2040297
659	1	0.0967159	-2.234259	0.2499012	0.087362
660	0	0.2374424	-1.166753	0.2072269	0.1810635
661	0	0.3048871	-0.824133	0.2105866	0.211931
662	1	0.1489635	-1.742754	0.2197369	0.1267734
663	0	0.1706552	-1.580991	0.2162823	0.141532

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Parameter Code=PPG78W Parameter=PPG ≤ 7.8 mmol/L (SMPG) without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
664	1	0.1059691	-2.132593	0.2472947	0.0947397
665	0	0.5162574	0.0650526	0.2341347	0.2497357
666	1	0.1216709	-1.976701	0.2323334	0.1068671
667	0	0.2939856	-0.876105	0.2007558	0.2075581
668	1	0.2138336	-1.301971	0.2086585	0.1681088
669	1	0.1423848	-1.795622	0.2260832	0.1221114
670	1	0.0835975	-2.394443	0.2677416	0.0766089
671	1	0.1821904	-1.501577	0.2134951	0.148997
672	1	0.1830337	-1.495928	0.2105734	0.1495323
673	0	0.3574721	-0.586353	0.2036856	0.2296858
674	0	0.1723766	-1.568876	0.2509691	0.1426629
675	1	0.2180349	-1.277155	0.2509676	0.1704957
676	1	0.1386637	-1.826434	0.2597128	0.1194361
677	1	0.1623352	-1.640955	0.2637258	0.1359825
678	1	0.3035297	-0.830545	0.2509564	0.2113994
679	1	0.0688399	-2.604648	0.3304624	0.0641009
680	1	0.1000753	-2.196388	0.2846162	0.0900602
681	1	0.1147402	-2.043211	0.2701817	0.1015749
682	1	0.0952285	-2.251403	0.2826044	0.08616
683	1	0.1114322	-2.076195	0.2780419	0.099015
684	1	0.2431804	-1.135322	0.2463384	0.1840437
685	1	0.2069328	-1.343514	0.2469252	0.1641116
686	1	0.087334	-2.34663	0.2938321	0.0797068
687	1	0.3359146	-0.681554	0.2493527	0.223076

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NN1218-4131

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG78W Parameter=PPG ≤ 7.8 mmol/L (SMPG) without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
688	0	0.1448335	-1.775712	0.2650639	0.1238567
689	1	0.3780004	-0.498044	0.2538021	0.2351161
690	1	0.1888584	-1.457445	0.2562485	0.1531909
691	1	0.1676822	-1.602144	0.251858	0.1395648
692	1	0.1389202	-1.824287	0.2596228	0.1196214
693	1	0.155616	-1.691216	0.2545951	0.1313996
694	0	0.4131347	-0.351022	0.2589493	0.2424544
695	1	0.1310607	-1.891612	0.2694537	0.1138838
696	1	0.3037567	-0.829472	0.2509839	0.2114886
697	1	0.2957077	-0.867822	0.2608667	0.2082646
698	1	0.2315266	-1.199711	0.246193	0.1779221
699	1	0.2431804	-1.135322	0.2463384	0.1840437
700	1	0.0734063	-2.535506	0.3068443	0.0680178
701	1	0.3176052	-0.764799	0.2638429	0.2167321
702	1	0.0831507	-2.400288	0.2973744	0.0762367
703	1	0.1064701	-2.127316	0.2302132	0.0951342
704	1	0.1225324	-1.968664	0.2597039	0.1075182
705	1	0.1829656	-1.496383	0.2380326	0.1494892
706	1	0.4003039	-0.404199	0.2565798	0.2400607
707	0	0.2478624	-1.110046	0.2366764	0.1864266
708	1	0.1387679	-1.825561	0.2525063	0.1195114
709	1	0.1578247	-1.674503	0.2175283	0.1329161
710	1	0.0567009	-2.811593	0.2679631	0.0534859
711	1	0.0662619	-2.645581	0.2672401	0.0618713

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG78W Parameter=PPG ≤ 7.8 mmol/L (SMPG) without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
712	1	0.0411384	-3.148804	0.292946	0.0394461
713	1	0.1351022	-1.85658	0.217009	0.1168496
714	0	0.0729264	-2.542583	0.315292	0.0676081
715	1	0.1176519	-2.014857	0.2234486	0.1038099
716	1	0.0983251	-2.215975	0.2310125	0.0886573
717	1	0.0577442	-2.792255	0.2664802	0.0544098
718	1	0.1259224	-1.937504	0.2213187	0.1100659
719	1	0.115585	-2.03492	0.2243725	0.1022251
720	1	0.0969803	-2.231237	0.2875864	0.0875751
721	1	0.0742303	-2.523453	0.2476757	0.0687202
722	1	0.1588263	-1.666987	0.2459808	0.1336005
723	1	0.2357179	-1.176301	0.2290568	0.180155
724	1	0.2222809	-1.252424	0.2345246	0.1728721
725	1	0.061551	-2.724362	0.3327475	0.0577625
726	1	0.0505838	-2.932215	0.2748418	0.0480251
727	0	0.1032505	-2.161619	0.2818379	0.0925898
728	1	0.1946673	-1.419963	0.2219393	0.156772
729	1	0.1364133	-1.845405	0.2204664	0.1178047
730	1	0.2611596	-1.03995	0.234872	0.1929552
731	1	0.0518356	-2.906451	0.2754636	0.0491486
732	0	0.4503994	-0.199057	0.257976	0.2475398
733	1	0.1115747	-2.074756	0.2254016	0.0991258
734	1	0.1560211	-1.688136	0.2193456	0.1316785
735	1	0.1524841	-1.715249	0.2177584	0.1292327

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG78W Parameter=PPG ≤ 7.8 mmol/L (SMPG) without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
736	1	0.0792761	-2.452223	0.2420231	0.0729914
737	1	0.0755968	-2.503734	0.2449726	0.0698819
738	1	0.2201961	-1.264524	0.2225452	0.1717098
739	0	0.2046269	-1.357623	0.2360855	0.1627547
740	1	0.0878779	-2.339825	0.2370315	0.0801554
741	1	0.218512	-1.274359	0.2074478	0.1707645
742	1	0.0685676	-2.608904	0.2514574	0.0638661
743	1	0.3116674	-0.792335	0.2435508	0.2145308
744	1	0.1482702	-1.748233	0.2195433	0.1262862
745	1	0.085499	-2.369874	0.2386376	0.0781889
746	0	0.1554567	-1.692429	0.2193502	0.1312899
747	1	0.0606637	-2.739829	0.2603389	0.0569836
748	1	0.0877919	-2.340899	0.237088	0.0800845
749	1	0.1131012	-2.059448	0.2250761	0.1003093
750	1	0.1115572	-2.074933	0.2272807	0.0991122
751	1	0.1084505	-2.106667	0.2265546	0.096689
752	1	0.3641282	-0.557491	0.2328986	0.2315388
753	1	0.0950844	-2.253077	0.237926	0.0860434
754	1	0.2407569	-1.148534	0.2255732	0.182793
755	1	0.0729409	-2.542368	0.2472841	0.0676205
756	1	0.0382686	-3.224105	0.3030009	0.0368041
757	1	0.2875445	-0.90734	0.2157272	0.2048627
758	1	0.1090747	-2.100228	0.2263435	0.0971774
759	1	0.4688543	-0.124744	0.2414883	0.2490299

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG78W Parameter=PPG ≤ 7.8 mmol/L (SMPG) without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
760	1	0.2100653	-1.324532	0.2308237	0.1659379
761	1	0.1461149	-1.765403	0.2196523	0.1247653
762	1	0.1425129	-1.794574	0.2548786	0.1222029
763	1	0.1807389	-1.511349	0.2179369	0.1480723
764	0	0.0783412	-2.465101	0.242746	0.0722039
765	1	0.0590675	-2.768191	0.2777447	0.0555785
766	1	0.1489131	-1.743151	0.2179922	0.126738
767	1	0.152207	-1.717395	0.2177742	0.12904
768	0	0.0897888	-2.316216	0.2358087	0.0817268
769	1	0.1520458	-1.718645	0.2122855	0.1289278
770	1	0.0717883	-2.559538	0.2483381	0.0666347
771	1	0.1183241	-2.008397	0.2238083	0.1043235
772	0	0.1295513	-1.904932	0.2564603	0.1127677
773	1	0.4592462	-0.163378	0.2395285	0.2483391
774	0	0.357507	-0.586201	0.2246131	0.2296957
775	1	0.6089629	0.4429549	0.2795692	0.2381271
776	0	0.4561641	-0.175795	0.2696719	0.2480784
777	0	0.4707695	-0.117055	0.2675473	0.2491456
778	0	0.3483	-0.62652	0.2467196	0.2269871
779	1	0.289748	-0.896608	0.2161278	0.2057941
780	1	0.1145703	-2.044884	0.2256769	0.1014439
781	0	0.2077918	-1.338288	0.2238366	0.1646144
782	1	0.1330504	-1.874253	0.2177167	0.115348
783	1	0.242084	-1.141288	0.2091966	0.1834794

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG78W Parameter=PPG ≤ 7.8 mmol/L (SMPG) without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
784	1	0.1832169	-1.494703	0.2407577	0.1496485
785	1	0.0795563	-2.448391	0.2516098	0.0732271
786	1	0.1213993	-1.979245	0.2224124	0.1066615
787	1	0.1896439	-1.452326	0.218607	0.1536791
788	1	0.0961204	-2.241095	0.232153	0.0868812
789	1	0.1973917	-1.402677	0.2222986	0.1584282
790	1	0.1088663	-2.102374	0.2264135	0.0970144
791	1	0.1254435	-1.941862	0.2206306	0.1097074
792	1	0.1349182	-1.858155	0.2170712	0.1167153
793	1	0.141717	-1.801101	0.2186751	0.1216333
794	1	0.370925	-0.528251	0.2259025	0.2333396
795	0	0.2121658	-1.311919	0.2072208	0.1671515
796	1	0.0879867	-2.338468	0.2360727	0.0802451
797	1	0.0652845	-2.661488	0.2549212	0.0610224
798	1	0.1375912	-1.835442	0.2192046	0.1186599
799	1	0.124641	-1.949197	0.2216118	0.1091056
800	1	0.3280692	-0.716931	0.2532548	0.2204398
801	1	0.1697698	-1.58726	0.2196574	0.140948
802	1	0.0881221	-2.336783	0.243551	0.0803566
803	1	0.1086564	-2.104539	0.2683767	0.0968502
804	1	0.1636312	-1.631454	0.2450254	0.136856
805	1	0.3899346	-0.447587	0.249251	0.2378856
806	1	0.0699499	-2.587459	0.3047821	0.0650569
807	0	0.2904657	-0.893123	0.2220878	0.2060954

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG78W Parameter=PPG ≤ 7.8 mmol/L (SMPG) without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
808	0	0.1815742	-1.505718	0.2396313	0.148605
809	0	0.3177037	-0.764345	0.2222546	0.2167681
810	1	0.2916093	-0.887581	0.2354531	0.2065733
811	1	0.3168736	-0.768177	0.242086	0.2164647
812	1	0.3672837	-0.543887	0.2500285	0.2323864
813	1	0.3228434	-0.740735	0.222426	0.2186155
814	1	0.1888342	-1.457603	0.2362351	0.1531758
815	1	0.1001577	-2.195473	0.2734027	0.0901261
816	1	0.5556235	0.2234187	0.2985375	0.246906
817	1	0.1615735	-1.646567	0.2174473	0.1354675
818	1	0.2360644	-1.174379	0.2253802	0.180338
819	0	0.296962	-0.861807	0.244263	0.2087756
820	1	0.060055	-2.75056	0.2611042	0.0564484
821	1	0.2432674	-1.134849	0.2093182	0.1840884
822	1	0.0288253	-3.517254	0.3513939	0.0279944
823	1	0.2319311	-1.197439	0.2366567	0.1781391
824	1	0.2998419	-0.848051	0.2219984	0.2099367
825	0	0.182213	-1.501426	0.2395068	0.1490114
826	1	0.0831185	-2.400711	0.2392304	0.0762098
827	1	0.1789205	-1.523678	0.2414945	0.146908
828	1	0.097553	-2.224714	0.2309454	0.0880364
829	1	0.1580097	-1.673112	0.2193409	0.1330426
830	0	0.149731	-1.736712	0.2179327	0.1273117
831	1	0.2381678	-1.162751	0.2088158	0.1814439

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG78W Parameter=PPG ≤ 7.8 mmol/L (SMPG) without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
832	1	0.1571549	-1.679551	0.2193407	0.1324573
833	1	0.1213993	-1.979245	0.2224124	0.1066615
834	1	0.1612949	-1.648625	0.2459925	0.1352789
835	1	0.1043262	-2.150054	0.2315387	0.0934423
836	1	0.0988584	-2.209974	0.2307463	0.0890854
837	1	0.097245	-2.228217	0.2315631	0.0877884
838	1	0.2031616	-1.36665	0.2071018	0.161887
839	1	0.0664446	-2.642632	0.2669945	0.0620297
840	1	0.0919161	-2.29046	0.2345146	0.0834676
841	1	0.090428	-2.30842	0.234636	0.0822508
842	1	0.2549079	-1.072606	0.2106666	0.1899298
843	1	0.1652801	-1.619454	0.2194703	0.1379626
844	0	0.2257431	-1.232506	0.2078397	0.1747832
845	1	0.065453	-2.658729	0.2683396	0.0611689
846	1	0.0937995	-2.268101	0.2389078	0.0850012
847	1	0.118007	-2.01144	0.2233451	0.1040814
848	0	0.1988811	-1.393302	0.2195513	0.1593274
849	1	0.1037689	-2.156032	0.2282719	0.0930009
850	1	0.2084525	-1.334279	0.2207663	0.165
851	0	0.1959625	-1.411723	0.2071927	0.1575612
852	1	0.0603425	-2.745478	0.262961	0.0567013
853	0	0.296962	-0.861807	0.244263	0.2087756
854	1	0.0891998	-2.323444	0.2353471	0.0812432
855	1	0.0942717	-2.262558	0.2331604	0.0853846

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG78W Parameter=PPG ≤ 7.8 mmol/L (SMPG) without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
856	1	0.178724	-1.525017	0.220251	0.1467817
857	0	0.1437213	-1.78472	0.2198028	0.1230655
858	1	0.1459457	-1.76676	0.2182384	0.1246455
859	1	0.1462134	-1.764614	0.2182142	0.124835
860	1	0.066623	-2.63976	0.3069893	0.0621844
861	1	0.0481096	-2.984969	0.2975632	0.0457951
862	1	0.095309	-2.25047	0.2320313	0.0862252
863	1	0.074999	-2.51232	0.245479	0.0693742
864	1	0.2293269	-1.212116	0.2080834	0.1767361
865	1	0.1588067	-1.667134	0.2108973	0.1335871
866	1	0.3401423	-0.66266	0.2268881	0.2244455
867	1	0.0727235	-2.545587	0.2474805	0.0674348
868	1	0.2729171	-0.979872	0.2342863	0.1984334
869	1	0.0691167	-2.600337	0.3058752	0.0643396
870	0	0.2947264	-0.872538	0.2436434	0.2078628
871	1	0.3195676	-0.75576	0.2223119	0.2174442
872	1	0.2925556	-0.883004	0.2393368	0.2069668
873	1	0.117923	-2.012248	0.2626062	0.1040171
874	0	0.1841426	-1.488529	0.2207403	0.1502341
875	1	0.4105397	-0.361735	0.2534098	0.2419969
876	0	0.4108681	-0.360378	0.2588713	0.2420555
877	0	0.3566273	-0.590033	0.2481271	0.2294443
878	1	0.1052571	-2.14013	0.2801004	0.0941781
879	1	0.2237633	-1.243868	0.2344333	0.1736933

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG78W Parameter=PPG ≤ 7.8 mmol/L (SMPG) without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
880	1	0.4836199	-0.065544	0.2709198	0.2497317
881	1	0.2291373	-1.213189	0.2080697	0.1766334
882	1	0.1329267	-1.875326	0.2177604	0.1152572
883	0	0.3144559	-0.779369	0.2221683	0.2155734
884	1	0.1398994	-1.816126	0.2188954	0.1203276
885	1	0.3589873	-0.579762	0.2247439	0.2301154
886	0	0.3406241	-0.660514	0.2270039	0.2245993
887	1	0.0564073	-2.817096	0.2659678	0.0532255
888	1	0.3237825	-0.736443	0.2224618	0.2189474
889	1	0.0278918	-3.551134	0.3305219	0.0271139
890	0	0.2518959	-1.088526	0.2286232	0.1884444
891	1	0.0870928	-2.349661	0.2444492	0.0795076
892	0	0.4635131	-0.146207	0.2403881	0.2486687
893	1	0.3682819	-0.539595	0.2502121	0.2326503
894	1	0.2806502	-0.941239	0.2346986	0.2018857
895	1	0.0987707	-2.210958	0.2858935	0.0890151
896	1	0.5464831	0.1864708	0.2603947	0.2478393
897	1	0.2261494	-1.230183	0.2235548	0.1750059
898	1	0.200955	-1.380336	0.2329473	0.1605721
899	1	0.2396658	-1.154513	0.2365962	0.1822261
900	1	0.100771	-2.188687	0.2338618	0.0906162
901	1	0.2839115	-0.925141	0.2349028	0.2033057
902	1	0.0915438	-2.29493	0.2406916	0.0831635
903	1	0.0871294	-2.3492	0.2365998	0.0795379

Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG78W Parameter=PPG ≤ 7.8 mmol/L (SMPG) without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
904	1	0.1780274	-1.52977	0.2082367	0.1463336
905	0	0.3031761	-0.832219	0.2187082	0.2112604
906	1	0.1711078	-1.577797	0.2421147	0.1418299
907	1	0.2332246	-1.190192	0.2285355	0.1788309
908	1	0.1883714	-1.460627	0.2211843	0.1528876
909	1	0.1413603	-1.804037	0.2199826	0.1213776
910	1	0.0652179	-2.66258	0.3112352	0.0609645
911	1	0.2297064	-1.20997	0.2081111	0.1769414
912	1	0.2498956	-1.099169	0.22451	0.1874478
913	0	0.0896136	-2.318362	0.2359184	0.081583
914	1	0.1931315	-1.42979	0.2189353	0.1558317
915	1	0.1439856	-1.782574	0.2197846	0.1232537
916	1	0.4271485	-0.293495	0.2507479	0.2446927
917	0	0.4004082	-0.403765	0.2295103	0.2400815
918	1	0.1542728	-1.701475	0.2117996	0.1304727
919	0	0.1603075	-1.655942	0.2193575	0.134609
920	0	0.1743559	-1.555065	0.2199264	0.1439559
921	0	0.3137052	-0.782854	0.2208873	0.2152942
922	1	0.0987707	-2.210958	0.2858935	0.0890151
923	1	0.1166733	-2.024318	0.2237397	0.1030606
924	1	0.1406867	-1.809598	0.2558581	0.120894
925	1	0.407622	-0.373805	0.2729131	0.2414663
926	1	0.0618196	-2.719722	0.2610653	0.0579979
927	1	0.4043216	-0.387491	0.2521159	0.2408456

Fast-acting insulin aspart
NN1218-4131

Clinical Trial Report
Statistical document

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Novo Nordisk

Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG78W Parameter=PPG ≤ 7.8 mmol/L (SMPG) without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
928	1	0.0666732	-2.638952	0.2534193	0.0622279
929	1	0.1827356	-1.497923	0.2408367	0.1493433
930	1	0.1176999	-2.014394	0.2627354	0.1038466
931	0	0.3424768	-0.652276	0.2457779	0.2251864
932	1	0.6652015	0.6865612	0.3001873	0.2227085
933	0	0.2462758	-1.118575	0.2274293	0.185624
934	1	0.2929412	-0.881142	0.2355577	0.2071267
935	1	0.1712224	-1.576989	0.208978	0.1419053
936	1	0.1765266	-1.540059	0.2406726	0.145365
937	1	0.3195676	-0.75576	0.2223119	0.2174442
938	0	0.2486906	-1.105608	0.2246382	0.1868436
939	0	0.1732365	-1.562861	0.2175781	0.1432256
940	1	0.054252	-2.858336	0.2858055	0.0513087
941	0	0.1713998	-1.575739	0.2175215	0.1420219
942	1	0.0561365	-2.822196	0.3228566	0.0529852
943	1	0.114045	-2.050073	0.2245652	0.1010387
944	1	0.052047	-2.902159	0.2751163	0.0493381
945	1	0.3676139	-0.542467	0.2338118	0.2324739
946	0	0.0749049	-2.513677	0.2470607	0.0692942
947	1	0.1891496	-1.455545	0.2185633	0.153372
948	1	0.2566297	-1.06356	0.2337764	0.1907709
949	1	0.1363228	-1.846174	0.219389	0.1177389
950	1	0.0499319	-2.945874	0.2759313	0.0474387
951	1	0.0791196	-2.454369	0.2421429	0.0728597

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Fast-acting insulin aspart
NN1218-4131

Clinical Trial Report
Statistical document

Date: 14 February 2018
Version: 1.0

Status:
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Novo Nordisk

Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG78W Parameter=PPG ≤ 7.8 mmol/L (SMPG) without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
952	1	0.1535969	-1.706664	0.2176989	0.1300049
953	1	0.379731	-0.49069	0.226872	0.2355354
954	1	0.141717	-1.801101	0.2186751	0.1216333
955	1	0.0827569	-2.405465	0.248438	0.0759082
956	1	0.304367	-0.826588	0.2220118	0.2117277
957	0	0.0312528	-3.433895	0.3823582	0.0302761
958	1	0.2333658	-1.189403	0.2248665	0.1789062
959	1	0.1171164	-2.020025	0.2236068	0.1034001
960	1	0.162862	-1.637085	0.2101848	0.136338
961	1	0.2961943	-0.865487	0.2173374	0.2084632
962	1	0.1204866	-1.98783	0.2226536	0.1059696
963	1	0.3086824	-0.806286	0.2427272	0.2133976
964	1	0.1002305	-2.194666	0.2297356	0.0901844
965	1	0.0550839	-2.842239	0.2843464	0.0520497
966	1	0.1959625	-1.411723	0.2071927	0.1575612
967	1	0.0959187	-2.243418	0.2373014	0.0867183
968	1	0.138263	-1.829793	0.2202681	0.1191463
969	0	0.1154441	-2.036299	0.2252294	0.1021168
970	1	0.1709833	-1.578674	0.2197211	0.141748
971	1	0.0771666	-2.481482	0.2450725	0.0712119
972	0	0.2515083	-1.090584	0.2243438	0.1882519
973	0	0.140525	-1.810937	0.2152873	0.1207777
974	1	0.1946133	-1.420308	0.2072294	0.156739
975	1	0.1237073	-1.957782	0.2218336	0.1084038

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Subjects achieving postprandial glucose targets 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=PPG78W Parameter=PPG ≤ 7.8 mmol/L (SMPG) without severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	aval	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
976	0	0.1291588	-1.908417	0.2206346	0.1124768
977	1	0.1534575	-1.707737	0.217706	0.1299083

30: Hypoglycaemic episodes - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=HYCNFSEX Parameter=Severe or BG confirmed hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Model Information

Data Set	WORK.ENDPOINT	
Distribution	Negative Binomial	
Link Function	Log	
Dependent Variable	AVAL	Analysis Value
Offset Variable	log_offset	

Number of Observations Read	1025
Number of Observations Used	1025

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Parameter Information

Parameter	Effect	TRTPN	REGION1	BOLAD1
Prm1	Intercept			
Prm2	TRTPN	2		
Prm3	TRTPN	3		
Prm4	TRTPN	4		
Prm5	REGION1		ASIA (EXCLUDING JAPAN)	
Prm6	REGION1		EUROPE	

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Hypoglycaemic episodes - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=HYCNFSEX Parameter=Severe or BG confirmed hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Parameter Information

Parameter	Effect	TRTPN	REGION1	BOLAD1
Prm7	REGION1		JAPAN	
Prm8	REGION1		NORTH AMERICA	
Prm9	BOLAD1			BOLUS INSULIN ALGORITHM (SLIDING SCALE)
Prm10	BOLAD1			CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Criteria For Assessing Goodness Of Fit

Criterion	DF	Value	Value/DF
Deviance	1018	1211.7277	1.1903
Scaled Deviance	1018	1211.7277	1.1903
Pearson Chi-Square	1018	779.6331	0.7658
Scaled Pearson X2	1018	779.6331	0.7658
Log Likelihood		45683.4302	
Full Log Likelihood		-4019.0912	
AIC (smaller is better)		8054.1824	
AICC (smaller is better)		8054.3241	
BIC (smaller is better)		8093.6420	

Algorithm converged.

Hypoglycaemic episodes - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=HYCNFSEX Parameter=Severe or BG confirmed hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Analysis Of Maximum Likelihood Parameter Estimates

Parameter		DF	Estimate	Standard Error	Wald 95% Confidence Limits	Wald Chi-Square
Intercept		1	8.3449	0.0926	8.1634 8.5264	8118.06
TRTPN	2	1	-0.1708	0.0925	-0.3520 0.0105	3.41
TRTPN	3	1	-0.0296	0.0927	-0.2113 0.1521	0.10
TRTPN	4	0	0.0000	0.0000	0.0000 0.0000	.
REGION1	ASIA (EXCLUDING JAPAN)	1	-0.1588	0.1378	-0.4289 0.1113	1.33
REGION1	EUROPE	1	-0.1180	0.0966	-0.3073 0.0713	1.49
REGION1	JAPAN	1	-0.1121	0.1093	-0.3262 0.1021	1.05
REGION1	NORTH AMERICA	0	0.0000	0.0000	0.0000 0.0000	.
BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	1	0.0627	0.0851	-0.1042 0.2296	0.54
BOLAD1	CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY	0	0.0000	0.0000	0.0000 0.0000	.
Dispersion		1	1.4051	0.0636	1.2859 1.5353	

Analysis Of Maximum Likelihood Parameter Estimates

Parameter		Pr > ChiSq
Intercept		<.0001
TRTPN	2	0.0648
TRTPN	3	0.7497
TRTPN	4	.
REGION1	ASIA (EXCLUDING JAPAN)	0.2493
REGION1	EUROPE	0.2220
REGION1	JAPAN	0.3051
REGION1	NORTH AMERICA	.
BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.4615
BOLAD1	CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY	.
Dispersion		

NOTE: The negative binomial dispersion parameter was estimated by maximum likelihood.

Hypoglycaemic episodes - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=HYCNFSEX Parameter=Severe or BG confirmed hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Coefficients for TRTPN Least Squares Means Using WORK.ENDPOINT Margins

Parameter	Geographic Region Grouping Method 1
Intercept	
Planned Treatment (N) 2	
Planned Treatment (N) 3	
Planned Treatment (N) 4	
Geographic Region Grouping Method 1 ASIA (EXCLUDING JAPAN)	ASIA (EXCLUDING JAPAN)
Geographic Region Grouping Method 1 EUROPE	EUROPE
Geographic Region Grouping Method 1 JAPAN	JAPAN
Geographic Region Grouping Method 1 NORTH AMERICA	NORTH AMERICA
Bolus Adjustment Method at Timepoint 1 BOLUS INSULIN ALGORITHM (SLIDING SCALE)	
Bolus Adjustment Method at Timepoint 1 CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY	

Coefficients for TRTPN Least Squares Means Using WORK.ENDPOINT Margins

Bolus Adjustment Method at Timepoint 1	Planned Treatment (N)	Row1	Row2	Row3
	1	1	1	1
	2	1		
	3		1	
	4			1
		0.1307	0.1307	0.1307
		0.3366	0.3366	0.3366
		0.239	0.239	0.239
		0.2937	0.2937	0.2937
BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.5824	0.5824	0.5824
CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0.4176	0.4176	0.4176

Hypoglycaemic episodes - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=HYCNFSEX Parameter=Severe or BG confirmed hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

TRTPN Least Squares Means

Planned Treatment (N)	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
2	WORK.ENDPOINT	8.1234	0.06550	124.01	<.0001	0.05	7.9950	8.2518
3	WORK.ENDPOINT	8.2646	0.06558	126.03	<.0001	0.05	8.1361	8.3931
4	WORK.ENDPOINT	8.2942	0.06534	126.94	<.0001	0.05	8.1661	8.4222

Differences of TRTPN Least Squares Means

Planned Treatment (N)	Planned Treatment (N)	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
2	4	WORK.ENDPOINT	-0.1708	0.09248	-1.85	0.0648	0.05	-0.3520	0.01047
3	4	WORK.ENDPOINT	-0.02958	0.09272	-0.32	0.7497	0.05	-0.2113	0.1521

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) / NovoRapid (meal)	WORK.ENDPOINT	-0.1708	0.09248	-1.85	0.0648	0.05	-0.3520	0.01047

Hypoglycaemic episodes - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=HYCNFSEX Parameter=Severe or BG confirmed hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
TRTPN	Faster aspart (post) / NovoRapid (meal)	WORK.ENDPOINT	-0.02958	0.09272	-0.32	0.7497	0.05	-0.2113	0.1521

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
1	27	15.978556	2.7712476	0.1134401	1.1313006
2	10	15.978556	2.7712476	0.1134401	0.437294
3	4	15.978556	2.7712476	0.1134401	0.1923505
4	11	15.978556	2.7712476	0.1134401	0.4781179
5	22	15.978556	2.7712476	0.1134401	0.927181
6	68	17.104857	2.8393624	0.0975357	2.635153
7	20	18.401706	2.9124434	0.1129811	0.742508
8	19	18.901752	2.9392546	0.1129811	0.689321
9	17	16.586436	2.8085853	0.1134401	0.6987441
10	5	3.399991	1.2237728	0.0969867	0.8175314
11	11	15.804876	2.7603185	0.1134401	0.4829193
12	37	18.901752	2.9392546	0.1129811	1.3187833
13	4	18.401706	2.9124434	0.1129811	0.1689133
14	51	18.748195	2.9310975	0.1122382	1.8220933
15	27	15.978556	2.7712476	0.1134401	1.1313006
16	31	19.057231	2.9474466	0.1122382	1.1005666

Hypoglycaemic episodes - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=HYCNFSEX Parameter=Severe or BG confirmed hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
17	45	17.012398	2.8339424	0.0975357	1.7618459
18	1	20.44417	3.0176978	0.0954976	0.055647
19	6	20.180592	3.0047213	0.0969867	0.2208504
20	10	18.748195	2.9310975	0.1122382	0.3774336
21	20	17.012398	2.8339424	0.0975357	0.7982821
22	0	3.399398	1.2235984	0.1122382	0.1018806
23	1	18.401706	2.9124434	0.1129811	0.0613643
24	39	19.59233	2.9751382	0.0954976	1.3432086
25	1	19.101771	2.949781	0.1129811	0.059277
26	3	18.401706	2.9124434	0.1129811	0.1330636
27	9	20.501901	3.0205176	0.1129811	0.314894
28	35	19.59233	2.9751382	0.0954976	1.2079126
29	11	16.065396	2.7766677	0.1134401	0.4757528
30	41	20.838654	3.0368097	0.0969867	1.3320549
31	24	19.59233	2.9751382	0.0954976	0.8358487
32	7	15.978556	2.7712476	0.1134401	0.3148223
33	4	18.401706	2.9124434	0.1129811	0.1689133
34	0	20.070915	2.9992717	0.0969867	0.0235382
35	4	19.701826	2.9807113	0.1129811	0.1585449
36	1	18.954219	2.9420266	0.1122382	0.0597051
37	7	18.954219	2.9420266	0.1122382	0.2689871
38	17	18.401706	2.9124434	0.1129811	0.634959
39	2	18.401706	2.9124434	0.1129811	0.0972139
40	4	18.101678	2.8960046	0.1129811	0.1715012
41	16	18.401706	2.9124434	0.1129811	0.5991093

Hypoglycaemic episodes - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=HYCNFSEX Parameter=Severe or BG confirmed hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
42	56	19.80529	2.9859491	0.0954976	1.8990217
43	52	19.59233	2.9751382	0.0954976	1.7829204
44	38	20.180592	3.0047213	0.0969867	1.273818
45	13	17.012398	2.8339424	0.0975357	0.5284843
46	0	17.752067	2.876502	0.0975357	0.0263764
47	14	17.012398	2.8339424	0.0975357	0.5670268
48	15	19.91177	2.991311	0.0954976	0.5234957
49	76	20.070915	2.9992717	0.0969867	2.5370658
50	15	17.197315	2.8447533	0.0975357	0.5995755
51	32	17.197315	2.8447533	0.0975357	1.2483136
52	20	19.59233	2.9751382	0.0954976	0.7005527
53	0	19.80529	2.9859491	0.0954976	0.023832
54	0	20.399946	3.0155323	0.0969867	0.0231842
55	6	19.37937	2.9642091	0.0954976	0.2293348
56	23	17.197315	2.8447533	0.0975357	0.904864
57	81	21.828411	3.0832124	0.0954976	2.4986051
58	50	17.382233	2.8554486	0.0975357	1.9162452
59	30	20.290269	3.0101414	0.0969867	1.0054838
60	47	19.59233	2.9751382	0.0954976	1.6138005
61	62	20.509623	3.0208942	0.0969867	2.0326598
62	12	17.382233	2.8554486	0.0975357	0.4803379
63	32	19.37937	2.9642091	0.0954976	1.1177381
64	4	20.180592	3.0047213	0.0969867	0.15504
65	58	20.12473	3.0019494	0.0954976	1.9369189
66	51	19.91177	2.991311	0.0954976	1.7229733

Hypoglycaemic episodes - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=HYCNFSEX Parameter=Severe or BG confirmed hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
67	11	19.59233	2.9751382	0.0954976	0.3961368
68	22	19.37937	2.9642091	0.0954976	0.7760445
69	11	16.735022	2.8175036	0.0975357	0.4582707
70	14	17.012398	2.8339424	0.0975357	0.5670268
71	31	17.844526	2.8816968	0.0975357	1.1696302
72	0	20.180592	3.0047213	0.0969867	0.023419
73	66	19.59233	2.9751382	0.0954976	2.2564563
74	8	20.180592	3.0047213	0.0969867	0.2866609
75	22	17.104857	2.8393624	0.0975357	0.8710136
76	32	20.180592	3.0047213	0.0969867	1.0763865
77	12	19.59233	2.9751382	0.0954976	0.4299608
78	24	20.180592	3.0047213	0.0969867	0.8131447
79	11	17.012398	2.8339424	0.0975357	0.4513992
80	48	17.104857	2.8393624	0.0975357	1.8681359
81	2	20.180592	3.0047213	0.0969867	0.0892295
82	5	17.012398	2.8339424	0.0975357	0.2201439
83	0	20.180592	3.0047213	0.0969867	0.023419
84	2	19.85156	2.9882826	0.0969867	0.0906061
85	7	17.012398	2.8339424	0.0975357	0.297229
86	0	19.48585	2.9696885	0.0954976	0.0241952
87	43	17.012398	2.8339424	0.0975357	1.6847608
88	3	19.59233	2.9751382	0.0954976	0.1255449
89	27	20.509623	3.0208942	0.0969867	0.8982131
90	2	19.27289	2.9586994	0.0954976	0.0931329
91	17	20.070915	2.9992717	0.0969867	0.5857747

Hypoglycaemic episodes - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=HYCNFSEX Parameter=Severe or BG confirmed hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
92	50	20.180592	3.0047213	0.0969867	1.6686808
93	63	19.85156	2.9882826	0.0969867	2.128792
94	4	20.070915	2.9992717	0.0969867	0.1558292
95	1	17.012398	2.8339424	0.0975357	0.0659737
96	9	19.85156	2.9882826	0.0969867	0.3244963
97	4	19.59233	2.9751382	0.0954976	0.1593689
98	12	18.954219	2.9420266	0.1122382	0.4433887
99	12	17.012398	2.8339424	0.0975357	0.4899417
100	11	18.101678	2.8960046	0.1129811	0.4262936
101	21	20.180592	3.0047213	0.0969867	0.714429
102	1	15.891716	2.765798	0.1134401	0.0702279
103	17	18.701734	2.9286162	0.1129811	0.6255196
104	48	20.180592	3.0047213	0.0969867	1.6028703
105	22	18.748195	2.9310975	0.1122382	0.8002608
106	3	18.645183	2.9255878	0.1122382	0.1314538
107	70	20.180592	3.0047213	0.0969867	2.3267855
108	52	19.69881	2.9805582	0.0954976	1.7739552
109	36	19.37937	2.9642091	0.0954976	1.2544155
110	9	15.978556	2.7712476	0.1134401	0.3964701
111	23	18.748195	2.9310975	0.1122382	0.8354964
112	36	18.954219	2.9420266	0.1122382	1.2805167
113	4	18.954219	2.9420266	0.1122382	0.1643461
114	3	18.954219	2.9420266	0.1122382	0.1294657
115	27	15.978556	2.7712476	0.1134401	1.1313006
116	43	18.401706	2.9124434	0.1129811	1.5670503

Hypoglycaemic episodes - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=HYCNFSEX Parameter=Severe or BG confirmed hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
117	1	19.057231	2.9474466	0.1122382	0.0594056
118	3	15.978556	2.7712476	0.1134401	0.1515266
119	26	18.954219	2.9420266	0.1122382	0.9317134
120	13	15.978556	2.7712476	0.1134401	0.5597658
121	0	18.954219	2.9420266	0.1122382	0.0248247
122	4	15.978556	2.7712476	0.1134401	0.1923505
123	39	18.101678	2.8960046	0.1129811	1.4454633
124	17	18.954219	2.9420266	0.1122382	0.6177904
125	42	15.978556	2.7712476	0.1134401	1.7436594
126	28	18.301697	2.9069938	0.1129811	1.0345089
127	29	18.401706	2.9124434	0.1129811	1.065155
128	0	18.701734	2.9286162	0.1129811	0.0251353
129	14	19.59233	2.9751382	0.0954976	0.4976088
130	70	16.586436	2.8085853	0.1134401	2.7896452
131	2	17.936985	2.8868648	0.0975357	0.0995405
132	3	18.401706	2.9124434	0.1129811	0.1330636
133	0	21.802021	3.0820027	0.1129811	0.0217876
134	20	20.728977	3.0315326	0.0969867	0.6646915
135	1	19.057231	2.9474466	0.1122382	0.0594056
136	19	21.220485	3.054967	0.1122382	0.6188981
137	21	11.901103	2.4766311	0.1129811	1.1560084
138	13	22.15478	3.0980533	0.0969867	0.4134888
139	25	16.152236	2.7820585	0.1134401	1.0393191
140	34	18.748195	2.9310975	0.1122382	1.2230881
141	10	19.101771	2.949781	0.1129811	0.3709493

Hypoglycaemic episodes - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=HYCNFSEX Parameter=Severe or BG confirmed hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
142	14	18.201687	2.9015143	0.1129811	0.5327696
143	22	20.180592	3.0047213	0.0969867	0.7473342
144	43	17.012398	2.8339424	0.0975357	1.6847608
145	20	17.012398	2.8339424	0.0975357	0.7982821
146	19	20.728977	3.0315326	0.0969867	0.632599
147	41	21.083051	3.0484694	0.0954976	1.3176223
148	24	25.555213	3.2408413	0.0954976	0.6514298
149	28	20.290269	3.0101414	0.0969867	0.9400049
150	7	16.735022	2.8175036	0.0975357	0.3017536
151	36	19.59233	2.9751382	0.0954976	1.2417366
152	24	20.180592	3.0047213	0.0969867	0.8131447
153	4	19.85156	2.9882826	0.0969867	0.1574319
154	0	19.48585	2.9696885	0.0954976	0.0241952
155	19	19.961237	2.9937923	0.0969867	0.6552555
156	2	12.112088	2.4942039	0.0975357	0.1421454
157	4	16.184968	2.7840829	0.0954976	0.1901041
158	11	19.59233	2.9751382	0.0954976	0.3961368
159	35	17.197315	2.8447533	0.0975357	1.3627967
160	15	17.289774	2.8501152	0.0975357	0.5966228
161	19	17.012398	2.8339424	0.0975357	0.7597396
162	3	19.59233	2.9751382	0.0954976	0.1255449
163	13	19.59233	2.9751382	0.0954976	0.4637848
164	10	19.59233	2.9751382	0.0954976	0.3623128
165	32	13.709641	2.6180993	0.0969867	1.5346916
166	9	19.37937	2.9642091	0.0954976	0.3318429

Hypoglycaemic episodes - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=HYCNFSEX Parameter=Severe or BG confirmed hypoglycaemic episodes Study Identifier=NN1218-4131

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
167	29	20.180592	3.0047213	0.0969867	0.9776708
168	24	20.399946	3.0155323	0.0969867	0.8049908
169	31	19.961237	2.9937923	0.0969867	1.0541587
170	17	16.919939	2.8284928	0.0975357	0.6860837
171	9	19.48585	2.9696885	0.0954976	0.3301574
172	10	17.289774	2.8501152	0.0975357	0.4067572
173	2	17.104857	2.8393624	0.0975357	0.1039964
174	48	19.85156	2.9882826	0.0969867	1.6275987
175	2	20.399946	3.0155323	0.0969867	0.0883347
176	6	20.070915	2.9992717	0.0969867	0.2219746
177	26	20.33769	3.0124758	0.0954976	0.8726248
178	10	17.289774	2.8501152	0.0975357	0.4067572
179	5	19.59233	2.9751382	0.0954976	0.1931929
180	25	20.070915	2.9992717	0.0969867	0.8503565
181	35	16.735022	2.8175036	0.0975357	1.3973733
182	1	19.961237	2.9937923	0.0969867	0.0569006
183	28	19.59233	2.9751382	0.0954976	0.9711447
184	5	19.59233	2.9751382	0.0954976	0.1931929
185	38	19.91177	2.991311	0.0954976	1.2898286
186	9	20.070915	2.9992717	0.0969867	0.3211928
187	0	17.012398	2.8339424	0.0975357	0.0274312
188	4	17.104857	2.8393624	0.0975357	0.1806982
189	1	10.648005	2.3653726	0.0954976	0.1005235
190	20	16.735022	2.8175036	0.0975357	0.8104342
191	41	18.233135	2.9032405	0.1122382	1.5081374

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Parameter Code=HYCNFSEX Parameter=Severe or BG confirmed hypoglycaemic episodes Study Identifier=NN1218-4131

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
192	21	19.961237	2.9937923	0.0969867	0.7217394
193	13	17.012398	2.8339424	0.0975357	0.5284843
194	15	20.180592	3.0047213	0.0969867	0.5169975
195	50	20.01825	2.9966444	0.0954976	1.6812842
196	62	19.263255	2.9581994	0.1122382	2.1548148
197	0	20.180592	3.0047213	0.0969867	0.023419
198	3	19.85156	2.9882826	0.0969867	0.124019
199	5	17.012398	2.8339424	0.0975357	0.2201439
200	0	20.290269	3.0101414	0.0969867	0.023301
201	14	17.197315	2.8447533	0.0975357	0.5614145
202	4	6.3612735	1.8502286	0.0969867	0.4264038
203	13	10.222085	2.3245506	0.0954976	0.8344358
204	41	17.012398	2.8339424	0.0975357	1.6076757
205	64	19.69881	2.9805582	0.0954976	2.1778021
206	4	17.659609	2.87128	0.0975357	0.1754619
207	2	17.012398	2.8339424	0.0975357	0.1045163
208	31	19.69881	2.9805582	0.0954976	1.0672231
209	12	16.735022	2.8175036	0.0975357	0.4974
210	48	20.180592	3.0047213	0.0969867	1.6028703
211	9	19.101771	2.949781	0.1129811	0.3363191
212	6	19.37937	2.9642091	0.0954976	0.2293348
213	5	19.59233	2.9751382	0.0954976	0.1931929
214	7	18.401706	2.9124434	0.1129811	0.2764623
215	0	0.7453604	-0.293887	0.0954976	0.1778329
216	8	15.978556	2.7712476	0.1134401	0.3556462

Hypoglycaemic episodes - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=HYCNFSEX Parameter=Severe or BG confirmed hypoglycaemic episodes Study Identifier=NN1218-4131

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
217	1	18.748195	2.9310975	0.1122382	0.0603132
218	0	16.065396	2.7766677	0.1134401	0.0289111
219	4	19.057231	2.9474466	0.1122382	0.1635217
220	12	18.748195	2.9310975	0.1122382	0.4479048
221	2	20.070915	2.9992717	0.0969867	0.0896837
222	54	17.012398	2.8339424	0.0975357	2.1087288
223	45	19.59233	2.9751382	0.0954976	1.5461525
224	1	20.33769	3.0124758	0.0954976	0.0559186
225	14	17.012398	2.8339424	0.0975357	0.5670268
226	47	17.012398	2.8339424	0.0975357	1.838931
227	10	19.59233	2.9751382	0.0954976	0.3623128
228	7	20.180592	3.0047213	0.0969867	0.2537557
229	19	20.948332	3.042059	0.0969867	0.6264103
230	9	19.59233	2.9751382	0.0954976	0.3284888
231	0	19.69881	2.9805582	0.0954976	0.0239519
232	4	20.6193	3.0262275	0.0969867	0.1519614
233	10	19.59233	2.9751382	0.0954976	0.3623128
234	4	17.289774	2.8501152	0.0975357	0.1789184
235	18	19.59233	2.9751382	0.0954976	0.6329047
236	17	19.69881	2.9805582	0.0954976	0.5960683
237	0	19.59233	2.9751382	0.0954976	0.0240729
238	9	20.180592	3.0047213	0.0969867	0.3195661
239	4	19.59233	2.9751382	0.0954976	0.1593689
240	0	17.012398	2.8339424	0.0975357	0.0274312
241	0	17.012398	2.8339424	0.0975357	0.0274312

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
242	5	17.012398	2.8339424	0.0975357	0.2201439
243	12	20.180592	3.0047213	0.0969867	0.4182818
244	2	19.412852	2.9659353	0.0969867	0.0925089
245	2	20.33769	3.0124758	0.0954976	0.0885869
246	20	19.259469	2.9580029	0.1153648	0.7117976
247	11	19.259469	2.9580029	0.1153648	0.4024954
248	3	18.698058	2.9284197	0.1214184	0.1311093
249	28	21.248219	3.0562731	0.1153648	0.900375
250	24	18.698058	2.9284197	0.1214184	0.8728956
251	2	19.259469	2.9580029	0.1153648	0.0931931
252	14	16.853554	2.8245616	0.1162053	0.571938
253	5	19.104538	2.9499259	0.1214184	0.1977715
254	0	18.799678	2.9338397	0.1214184	0.0250139
255	12	16.235885	2.7872239	0.1162053	0.511408
256	5	18.901298	2.9392306	0.1214184	0.1997437
257	4	16.235885	2.7872239	0.1162053	0.189558
258	1	18.698058	2.9284197	0.1214184	0.060463
259	20	19.307777	2.960508	0.1214184	0.7101434
260	0	18.799678	2.9338397	0.1214184	0.0250139
261	1	19.259469	2.9580029	0.1153648	0.0588262
262	0	18.698058	2.9284197	0.1214184	0.0251399
263	29	16.235885	2.7872239	0.1162053	1.1953392
264	32	19.36414	2.9634229	0.1153648	1.1185548
265	1	19.36414	2.9634229	0.1153648	0.0585308
266	43	19.259469	2.9580029	0.1153648	1.5022367

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Hypoglycaemic episodes - treatment emergent - statistical analysis - on-treatment - full analysis set

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The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
267	6	19.259469	2.9580029	0.1153648	0.2306608
268	17	19.887496	2.9900912	0.1153648	0.5908039
269	1	16.588839	2.8087301	0.1162053	0.0675197
270	10	18.698058	2.9284197	0.1214184	0.3783714
271	20	16.235885	2.7872239	0.1162053	0.833258
272	5	18.901298	2.9392306	0.1214184	0.1997437
273	7	18.393199	2.911981	0.1214184	0.2765806
274	1	16.5006	2.8033968	0.1162053	0.0678509
275	5	21.038877	3.046372	0.1153648	0.1807801
276	4	18.799678	2.9338397	0.1214184	0.1655985
277	1	18.901298	2.9392306	0.1214184	0.0598601
278	1	18.698058	2.9284197	0.1214184	0.060463
279	2	16.5006	2.8033968	0.1162053	0.1074901
280	1	16.324123	2.792644	0.1162053	0.0685231
281	29	18.799678	2.9338397	0.1214184	1.0442523
282	45	16.324123	2.792644	0.1162053	1.8299291
283	6	15.971169	2.7707852	0.1162053	0.2741143
284	19	16.235885	2.7872239	0.1162053	0.7930267
285	0	18.494818	2.9174906	0.1214184	0.0253957
286	0	19.36414	2.9634229	0.1153648	0.0243365
287	1	19.36414	2.9634229	0.1153648	0.0585308
288	1	19.468812	2.9688138	0.1153648	0.0582383
289	4	19.36414	2.9634229	0.1153648	0.1611138
290	0	19.259469	2.9580029	0.1153648	0.0244593
291	0	19.573483	2.9741757	0.1153648	0.0240945

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
292	0	18.698058	2.9284197	0.1214184	0.0251399
293	2	16.235885	2.7872239	0.1162053	0.1090955
294	0	19.259469	2.9580029	0.1153648	0.0244593
295	0	18.799678	2.9338397	0.1214184	0.0250139
296	0	18.945456	2.9415641	0.1153648	0.0248354
297	9	19.154798	2.9525533	0.1153648	0.3354547
298	40	18.698058	2.9284197	0.1214184	1.4380661
299	1	11.382767	2.4321005	0.1162053	0.0947999
300	58	16.235885	2.7872239	0.1162053	2.3620453
301	18	19.259469	2.9580029	0.1153648	0.6430638
302	20	18.698058	2.9284197	0.1214184	0.731603
303	0	18.901298	2.9392306	0.1214184	0.0248892
304	27	19.468812	2.9688138	0.1153648	0.942848
305	59	16.941793	2.8297835	0.1162053	2.3102596
306	4	16.235885	2.7872239	0.1162053	0.189558
307	28	19.050127	2.9470738	0.1153648	0.9967953
308	12	16.235885	2.7872239	0.1162053	0.511408
309	19	16.324123	2.792644	0.1162053	0.7890983
310	60	16.324123	2.792644	0.1162053	2.4304084
311	3	18.901298	2.9392306	0.1214184	0.1298019
312	10	19.468812	2.9688138	0.1153648	0.3644494
313	14	19.259469	2.9580029	0.1153648	0.5055961
314	55	19.307777	2.960508	0.1214184	1.9101899
315	1	16.059408	2.7762948	0.1162053	0.0695568
316	40	19.468812	2.9688138	0.1153648	1.3851529

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
317	58	18.799678	2.9338397	0.1214184	2.0634906
318	9	16.147646	2.7817743	0.1162053	0.3926691
319	18	18.596438	2.9229701	0.1214184	0.6643022
320	21	16.412362	2.7980348	0.1162053	0.8648778
321	0	19.573483	2.9741757	0.1153648	0.0240945
322	0	19.104538	2.9499259	0.1214184	0.0246434
323	0	16.941793	2.8297835	0.1162053	0.0275363
324	14	19.573483	2.9741757	0.1153648	0.4980543
325	18	16.235885	2.7872239	0.1162053	0.7527955
326	17	16.412362	2.7980348	0.1162053	0.7055393
327	1	19.573483	2.9741757	0.1153648	0.0579487
328	3	19.259469	2.9580029	0.1153648	0.1275601
329	42	19.36414	2.9634229	0.1153648	1.460498
330	29	18.799678	2.9338397	0.1214184	1.0442523
331	32	19.259469	2.9580029	0.1153648	1.1242006
332	1	16.412362	2.7980348	0.1162053	0.0681854
333	1	19.002918	2.9445925	0.1214184	0.0595631
334	7	16.853554	2.8245616	0.1162053	0.2998034
335	1	16.235885	2.7872239	0.1162053	0.0688643
336	3	2.4074337	0.8785613	0.1153648	0.6536739
337	30	19.259469	2.9580029	0.1153648	1.0554668
338	5	16.324123	2.792644	0.1162053	0.2286509
339	0	19.992167	2.9953405	0.1153648	0.0236246
340	0	19.002918	2.9445925	0.1214184	0.0247657
341	3	16.588839	2.8087301	0.1162053	0.1464111

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
342	48	19.259469	2.9580029	0.1153648	1.6740713
343	43	16.235885	2.7872239	0.1162053	1.7585766
344	63	19.573483	2.9741757	0.1153648	2.1569138
345	65	16.235885	2.7872239	0.1162053	2.6436641
346	3	18.698058	2.9284197	0.1214184	0.1311093
347	29	19.573483	2.9741757	0.1153648	1.0058684
348	40	16.412362	2.7980348	0.1162053	1.6217355
349	16	19.371095	2.963782	0.0913458	0.571255
350	0	16.820295	2.8225862	0.0948174	0.027719
351	0	16.636467	2.8115971	0.0948174	0.0280002
352	6	16.91221	2.8280358	0.0948174	0.2600952
353	1	16.91221	2.8280358	0.0948174	0.066333
354	0	16.820295	2.8225862	0.0948174	0.027719
355	93	20.061745	2.9988148	0.0944006	3.1006217
356	0	20.061745	2.9988148	0.0944006	0.0235483
357	51	15.884456	2.765341	0.096383	2.1225082
358	60	18.293336	2.9065368	0.094514	2.1884227
359	0	19.047406	2.9469309	0.0951125	0.024712
360	4	15.884456	2.765341	0.096383	0.1933923
361	21	18.989278	2.9438745	0.094514	0.7560146
362	14	15.884456	2.765341	0.096383	0.6038425
363	13	18.637784	2.9251909	0.0951125	0.485792
364	30	16.143442	2.7815139	0.096383	1.2420483
365	1	15.884456	2.765341	0.096383	0.0702572
366	9	15.711799	2.754412	0.096383	0.4026182

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
367	20	15.625471	2.7489023	0.096383	0.8629756
368	17	18.842595	2.93612	0.0951125	0.6211838
369	35	15.625471	2.7489023	0.096383	1.4879667
370	4	19.457028	2.9682083	0.0951125	0.1603989
371	4	15.625471	2.7489023	0.096383	0.1963185
372	3	18.392756	2.9119569	0.094514	0.1331235
373	23	19.287539	2.9594592	0.094514	0.8137969
374	29	18.392756	2.9119569	0.094514	1.0656347
375	6	15.884456	2.765341	0.096383	0.2754823
376	24	18.293336	2.9065368	0.094514	0.8907618
377	15	18.293336	2.9065368	0.094514	0.5663465
378	0	18.293336	2.9065368	0.094514	0.0256544
379	8	18.842595	2.93612	0.0951125	0.3055365
380	0	18.492176	2.9173477	0.094514	0.025399
381	0	18.293336	2.9065368	0.094514	0.0256544
382	4	18.293336	2.9065368	0.094514	0.169839
383	0	18.842595	2.93612	0.0951125	0.0249611
384	0	16.91221	2.8280358	0.0948174	0.0275805
385	1	18.842595	2.93612	0.0951125	0.060033
386	0	18.193915	2.9010872	0.094514	0.0257841
387	0	15.884456	2.765341	0.096383	0.0292122
388	13	18.293336	2.9065368	0.094514	0.4942542
389	2	18.293336	2.9065368	0.094514	0.0977467
390	1	18.492176	2.9173477	0.094514	0.0610863
391	0	18.842595	2.93612	0.0951125	0.0249611

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Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
392	1	19.476948	2.9692316	0.0913458	0.0582157
393	13	20.112066	3.0013199	0.0913458	0.4526193
394	0	16.820295	2.8225862	0.0948174	0.027719
395	5	17.831351	2.8809582	0.0948174	0.21081
396	21	19.582801	2.9746517	0.0913458	0.734709
397	1	15.711799	2.754412	0.096383	0.0709624
398	14	17.004124	2.8334559	0.0948174	0.5672806
399	1	16.91221	2.8280358	0.0948174	0.066333
400	2	17.463695	2.8601241	0.0948174	0.102027
401	7	17.096038	2.8388467	0.0948174	0.2958911
402	0	19.476948	2.9692316	0.0913458	0.0242055
403	0	20.170777	3.0042349	0.0944006	0.0234296
404	56	19.794507	2.9854045	0.0913458	1.8999844
405	0	17.004124	2.8334559	0.0948174	0.0274434
406	13	19.688654	2.9800425	0.0913458	0.4616741
407	6	17.004124	2.8334559	0.0948174	0.2588022
408	0	16.91221	2.8280358	0.0948174	0.0275805
409	0	18.094495	2.8956078	0.094514	0.025915
410	2	15.625471	2.7489023	0.096383	0.1129863
411	0	18.193915	2.9010872	0.094514	0.0257841
412	41	15.970785	2.7707611	0.096383	1.7035933
413	0	18.790437	2.9333481	0.094514	0.0250253
414	0	19.047406	2.9469309	0.0951125	0.024712
415	1	18.094495	2.8956078	0.094514	0.0623273
416	7	18.74019	2.9306704	0.0951125	0.2718344

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
417	1	18.842595	2.93612	0.0951125	0.060033
418	3	18.293336	2.9065368	0.094514	0.1337929
419	6	18.094495	2.8956078	0.094514	0.2443887
420	123	20.061745	2.9988148	0.0944006	4.093226
421	13	19.476948	2.9692316	0.0913458	0.4663386
422	25	20.170777	3.0042349	0.0944006	0.8464335
423	48	20.170777	3.0042349	0.0944006	1.6035971
424	14	17.004124	2.8334559	0.0948174	0.5672806
425	5	16.728381	2.8171068	0.0948174	0.2235766
426	12	19.688654	2.9800425	0.0913458	0.4280041
427	0	17.004124	2.8334559	0.0948174	0.0274434
428	18	17.004124	2.8334559	0.0948174	0.7215198
429	26	20.006213	2.9960429	0.0913458	0.88609
430	0	21.37012	3.0619937	0.0944006	0.0221996
431	0	20.006213	2.9960429	0.0913458	0.0236091
432	0	20.061745	2.9988148	0.0944006	0.0235483
433	0	16.91221	2.8280358	0.0948174	0.0275805
434	12	20.279808	3.0096257	0.0944006	0.4163742
435	0	20.061745	2.9988148	0.0944006	0.0235483
436	6	19.952714	2.9933652	0.0944006	0.223199
437	10	15.884456	2.765341	0.096383	0.4396624
438	1	20.49787	3.020321	0.0944006	0.055511
439	7	15.970785	2.7707611	0.096383	0.3149624
440	5	18.945001	2.9415401	0.0951125	0.1993163
441	0	17.187952	2.8442087	0.0948174	0.0271733

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Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
442	59	15.884456	2.765341	0.096383	2.4508683
443	11	20.061745	2.9988148	0.0944006	0.3875032
444	4	20.388839	3.0149876	0.0944006	0.1535633
445	15	15.884456	2.765341	0.096383	0.6448875
446	44	15.970785	2.7707611	0.096383	1.8261196
447	26	19.476948	2.9692316	0.0913458	0.9084717
448	13	17.995075	2.8900981	0.094514	0.5018231
449	5	18.842595	2.93612	0.0951125	0.2003207
450	17	16.91221	2.8280358	0.0948174	0.686372
451	36	20.061745	2.9988148	0.0944006	1.2146734
452	14	21.261089	3.0568786	0.0944006	0.4610857
453	18	18.392756	2.9119569	0.094514	0.6711107
454	27	16.575085	2.8079007	0.096383	1.0939408
455	48	20.480582	3.0194772	0.094514	1.5809695
456	14	21.152058	3.0517372	0.0944006	0.4633077
457	69	15.711799	2.754412	0.096383	2.8900371
458	0	18.591597	2.9227097	0.094514	0.0252732
459	0	18.989278	2.9438745	0.094514	0.0247822
460	10	19.952714	2.9933652	0.0944006	0.3562197
461	36	23.005588	3.1357372	0.0944006	1.0685903
462	14	16.143442	2.7815139	0.096383	0.5949735
463	53	18.842595	2.93612	0.0951125	1.8837732
464	6	16.91221	2.8280358	0.0948174	0.2600952
465	17	18.74019	2.9306704	0.0951125	0.6243299
466	0	21.594007	3.0724158	0.0913458	0.0219841

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
467	1	20.715933	3.0309031	0.0944006	0.0549655
468	13	19.688654	2.9800425	0.0913458	0.4616741
469	0	19.476948	2.9692316	0.0913458	0.0242055
470	13	18.293336	2.9065368	0.094514	0.4942542
471	7	18.382837	2.9114174	0.0948174	0.2767249
472	12	20.112066	3.0013199	0.0913458	0.4196096
473	19	16.488756	2.8026787	0.096383	0.7818716
474	2	19.90036	2.9907378	0.0913458	0.0903992
475	3	19.371095	2.963782	0.0913458	0.1268771
476	25	17.096038	2.8388467	0.0948174	0.9865342
477	9	20.49787	3.020321	0.0944006	0.3149518
478	0	19.688654	2.9800425	0.0913458	0.0239634
479	0	16.728381	2.8171068	0.0948174	0.0278589
480	4	19.794507	2.9854045	0.0913458	0.1578541
481	37	20.388839	3.0149876	0.0944006	1.2290935
482	37	19.582801	2.9746517	0.0913458	1.2761377
483	24	19.265242	2.9583025	0.0913458	0.849029
484	0	19.371095	2.963782	0.0913458	0.0243284
485	1	19.843683	2.9878857	0.0944006	0.0572143
486	1	16.636467	2.8115971	0.0948174	0.0673422
487	18	19.371095	2.963782	0.0913458	0.6396209
488	3	16.91221	2.8280358	0.0948174	0.1438378
489	35	17.004124	2.8334559	0.0948174	1.3770363
490	3	19.794507	2.9854045	0.0913458	0.1243516
491	2	19.582801	2.9746517	0.0913458	0.0917624

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492	1	19.952714	2.9933652	0.0944006	0.0569232
493	13	20.279808	3.0096257	0.0944006	0.4491294
494	34	16.360725	2.7948836	0.0948174	1.3867281
495	20	16.91221	2.8280358	0.0948174	0.8026293
496	55	20.388839	3.0149876	0.0944006	1.8157463
497	40	19.476948	2.9692316	0.0913458	1.384615
498	1	19.476948	2.9692316	0.0913458	0.0582157
499	5	20.388839	3.0149876	0.0944006	0.1861551
500	0	20.061745	2.9988148	0.0944006	0.0235483
501	49	19.843683	2.9878857	0.0944006	1.6616253
502	27	19.688654	2.9800425	0.0913458	0.9330549
503	0	16.91221	2.8280358	0.0948174	0.0275805
504	0	19.265242	2.9583025	0.0913458	0.0244525
505	0	20.388839	3.0149876	0.0944006	0.023196
506	0	20.388839	3.0149876	0.0944006	0.023196
507	1	19.265242	2.9583025	0.0913458	0.0588099
508	0	3.1755893	1.1554932	0.0913458	0.1064475
509	20	19.159389	2.9527929	0.0913458	0.7152495
510	22	19.476948	2.9692316	0.0913458	0.7724307
511	23	20.061745	2.9988148	0.0944006	0.7845449
512	13	19.476948	2.9692316	0.0913458	0.4663386
513	61	20.061745	2.9988148	0.0944006	2.0418437
514	53	19.582801	2.9746517	0.0913458	1.8175665
515	56	16.91221	2.8280358	0.0948174	2.197717
516	1	16.91221	2.8280358	0.0948174	0.066333

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
517	36	19.476948	2.9692316	0.0913458	1.2485741
518	5	19.582801	2.9746517	0.0913458	0.1932803
519	58	20.279808	3.0096257	0.0944006	1.923112
520	5	19.794507	2.9854045	0.0913458	0.1913566
521	7	16.91221	2.8280358	0.0948174	0.2988476
522	10	20.061745	2.9988148	0.0944006	0.3544164
523	0	20.061745	2.9988148	0.0944006	0.0235483
524	6	19.476948	2.9692316	0.0913458	0.2282669
525	12	17.004124	2.8334559	0.0948174	0.490161
526	0	17.004124	2.8334559	0.0948174	0.0274434
527	20	19.688654	2.9800425	0.0913458	0.6973645
528	1	17.004124	2.8334559	0.0948174	0.0660032
529	8	16.91221	2.8280358	0.0948174	0.3376
530	18	17.279866	2.849542	0.0948174	0.7109174
531	0	20.170777	3.0042349	0.0944006	0.0234296
532	7	17.371781	2.8548471	0.0948174	0.2915642
533	43	19.476948	2.9692316	0.0913458	1.4866457
534	90	19.265242	2.9583025	0.0913458	3.1166143
535	28	16.91221	2.8280358	0.0948174	1.1126488
536	34	20.061745	2.9988148	0.0944006	1.1484998
537	12	20.170777	3.0042349	0.0944006	0.4184715
538	0	20.170777	3.0042349	0.0944006	0.0234296
539	0	17.004124	2.8334559	0.0948174	0.0274434
540	3	20.388839	3.0149876	0.0944006	0.1209714
541	0	16.820295	2.8225862	0.0948174	0.027719

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542	2	20.279808	3.0096257	0.0944006	0.0888226
543	0	19.62562	2.9768359	0.0944006	0.0240349
544	3	17.279866	2.849542	0.0948174	0.1410197
545	0	17.371781	2.8548471	0.0948174	0.0269084
546	11	16.91221	2.8280358	0.0948174	0.4538573
547	27	17.096038	2.8388467	0.0948174	1.0632723
548	112	19.582801	2.9746517	0.0913458	3.8140849
549	41	16.820295	2.8225862	0.0948174	1.6245463
550	50	20.061745	2.9988148	0.0944006	1.6778888
551	45	20.061745	2.9988148	0.0944006	1.5124547
552	23	16.91221	2.8280358	0.0948174	0.9188866
553	14	17.004124	2.8334559	0.0948174	0.5672806
554	9	20.279808	3.0096257	0.0944006	0.3181087
555	36	16.91221	2.8280358	0.0948174	1.4226683
556	1	17.371781	2.8548471	0.0948174	0.0647163
557	12	20.170777	3.0042349	0.0944006	0.4184715
558	3	17.004124	2.8334559	0.0948174	0.1431228
559	64	16.91221	2.8280358	0.0948174	2.5077365
560	51	20.388839	3.0149876	0.0944006	1.685379
561	76	19.476948	2.9692316	0.0913458	2.6089836
562	33	20.170777	3.0042349	0.0944006	1.1097948
563	93	18.842595	2.93612	0.0951125	3.2866502
564	64	19.688654	2.9800425	0.0913458	2.1788471
565	1	20.388839	3.0149876	0.0944006	0.0557878
566	2	16.91221	2.8280358	0.0948174	0.1050854

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
567	36	19.047406	2.9469309	0.0951125	1.2747033
568	6	19.476948	2.9692316	0.0913458	0.2282669
569	18	19.734652	2.9823761	0.0944006	0.6286582
570	34	19.582801	2.9746517	0.0913458	1.1746198
571	9	17.004124	2.8334559	0.0948174	0.3744816
572	20	20.112066	3.0013199	0.0913458	0.6836871
573	34	17.279866	2.849542	0.0948174	1.3188082
574	40	19.794507	2.9854045	0.0913458	1.3639443
575	51	19.476948	2.9692316	0.0913458	1.7587277
576	18	17.279866	2.849542	0.0948174	0.7109174
577	12	20.170777	3.0042349	0.0944006	0.4184715
578	93	19.952714	2.9933652	0.0944006	3.116398
579	68	19.476948	2.9692316	0.0913458	2.3369017
580	53	19.476948	2.9692316	0.0913458	1.8267481
581	27	20.170777	3.0042349	0.0944006	0.9122738
582	11	20.061745	2.9988148	0.0944006	0.3875032
583	44	16.91221	2.8280358	0.0948174	1.7326878
584	0	18.094495	2.8956078	0.094514	0.025915
585	29	18.945001	2.9415401	0.0951125	1.0368222
586	8	19.457028	2.9682083	0.0951125	0.2965693
587	31	18.842595	2.93612	0.0951125	1.1121908
588	4	15.884456	2.765341	0.096383	0.1933923
589	2	16.057114	2.776152	0.096383	0.110207
590	12	18.293336	2.9065368	0.094514	0.4582081
591	39	18.842595	2.93612	0.0951125	1.3927662

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
592	90	18.842595	2.93612	0.0951125	3.1814344
593	23	18.293336	2.9065368	0.094514	0.8547156
594	35	15.970785	2.7707611	0.096383	1.4585408
595	10	18.293336	2.9065368	0.094514	0.3861158
596	9	17.093056	2.8386723	0.096383	0.372689
597	31	15.884456	2.765341	0.096383	1.3016078
598	20	15.884456	2.765341	0.096383	0.8501126
599	2	15.625471	2.7489023	0.096383	0.1129863
600	22	18.74019	2.9306704	0.0951125	0.8005777
601	21	18.492176	2.9173477	0.094514	0.7748319
602	36	15.711799	2.754412	0.096383	1.5219567
603	3	19.582801	2.9746517	0.0913458	0.1256017
604	8	15.625471	2.7489023	0.096383	0.3629828
605	13	18.842595	2.93612	0.0951125	0.4808961
606	28	18.842595	2.93612	0.0951125	1.006975
607	21	18.193915	2.9010872	0.094514	0.786578
608	1	19.794507	2.9854045	0.0913458	0.0573466
609	0	15.884456	2.765341	0.096383	0.0292122
610	37	18.492176	2.9173477	0.094514	1.3458284
611	13	19.354622	2.9629313	0.0951125	0.4690769
612	141	18.293336	2.9065368	0.094514	5.1081599
613	31	18.945001	2.9415401	0.0951125	1.1066143
614	6	15.970785	2.7707611	0.096383	0.2741203
615	32	15.798128	2.7598914	0.096383	1.3493572
616	36	15.884456	2.765341	0.096383	1.5068329

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
617	38	17.995075	2.8900981	0.094514	1.4167767
618	11	18.945001	2.9415401	0.0951125	0.4086928
619	17	18.293336	2.9065368	0.094514	0.6384388
620	11	16.229771	2.7868473	0.096383	0.4713393
621	113	18.889858	2.9386251	0.094514	3.9788352
622	26	15.798128	2.7598914	0.096383	1.1018574
623	5	18.293336	2.9065368	0.094514	0.2058851
624	15	18.842595	2.93612	0.0951125	0.55104
625	0	18.637784	2.9251909	0.0951125	0.0252152
626	15	15.884456	2.765341	0.096383	0.6448875
627	2	11.035654	2.4011313	0.094514	0.154335
628	0	19.559433	2.9734577	0.0951125	0.0241106
629	24	16.143442	2.7815139	0.096383	0.9993952
630	4	18.945001	2.9415401	0.0951125	0.1644202
631	26	18.094495	2.8956078	0.094514	0.9726342
632	0	15.970785	2.7707611	0.096383	0.0290678
633	13	18.74019	2.9306704	0.0951125	0.4833317
634	97	18.591597	2.9227097	0.094514	3.469793
635	28	18.842595	2.93612	0.0951125	1.006975
636	24	16.143442	2.7815139	0.096383	0.9993952
637	26	15.798128	2.7598914	0.096383	1.1018574
638	28	20.685893	3.0294519	0.0951125	0.9232234
639	13	18.193915	2.9010872	0.094514	0.4967517
640	54	15.711799	2.754412	0.096383	2.2681824
641	13	18.293336	2.9065368	0.094514	0.4942542

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
642	1	20.170777	3.0042349	0.0944006	0.0563498
643	6	15.970785	2.7707611	0.096383	0.2741203
644	26	19.952714	2.9933652	0.0944006	0.8883022
645	16	15.884456	2.765341	0.096383	0.6859325
646	11	19.476948	2.9692316	0.0913458	0.3983181
647	8	15.884456	2.765341	0.096383	0.3575724
648	15	19.476948	2.9692316	0.0913458	0.5343591
649	53	20.715933	3.0309031	0.0944006	1.7247588
650	30	19.688654	2.9800425	0.0913458	1.0340651
651	9	18.842595	2.93612	0.0951125	0.3406084
652	4	18.293336	2.9065368	0.094514	0.169839
653	45	18.293336	2.9065368	0.094514	1.6477307
654	31	19.794507	2.9854045	0.0913458	1.0624218
655	30	19.843683	2.9878857	0.0944006	1.026546
656	2	19.688654	2.9800425	0.0913458	0.0913035
657	17	20.279808	3.0096257	0.0944006	0.5801501
658	5	19.952714	2.9933652	0.0944006	0.1899439
659	32	21.69986	3.0773058	0.0913458	1.0058178
660	8	16.91221	2.8280358	0.0948174	0.3376
661	15	16.057114	2.776152	0.096383	0.638542
662	2	15.560388	2.7447284	0.0913458	0.1134176
663	2	27.693931	3.3212133	0.0944006	0.0662403
664	4	20.49787	3.020321	0.0944006	0.1528013
665	33	21.261089	3.0568786	0.0944006	1.0565723
666	13	17.371781	2.8548471	0.0948174	0.5184121

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
667	25	17.096038	2.8388467	0.0948174	0.9865342
668	1	11.993435	2.4843594	0.0944006	0.0905146
669	25	18.208215	2.9018728	0.0944006	0.9308147
670	9	16.316099	2.7921523	0.096383	0.388954
671	0	18.094495	2.8956078	0.094514	0.025915
672	12	16.229771	2.7868473	0.096383	0.5115845
673	25	15.884456	2.765341	0.096383	1.0553377
674	4	18.293336	2.9065368	0.094514	0.169839
675	35	18.293336	2.9065368	0.094514	1.2872693
676	20	18.842595	2.93612	0.0951125	0.7263996
677	26	18.637784	2.9251909	0.0951125	0.9463688
678	11	17.093056	2.8386723	0.096383	0.4494394
679	13	18.193915	2.9010872	0.094514	0.4967517
680	41	18.842595	2.93612	0.0951125	1.46291
681	41	18.392756	2.9119569	0.094514	1.4960244
682	35	18.293336	2.9065368	0.094514	1.2872693
683	1	19.457028	2.9682083	0.0951125	0.0582711
684	19	18.432974	2.9141411	0.0951125	0.7055487
685	1	15.884456	2.765341	0.096383	0.0702572
686	1	18.591597	2.9227097	0.094514	0.0607837
687	0	16.575085	2.8079007	0.096383	0.0280953
688	5	18.535379	2.9196813	0.0951125	0.2033955
689	7	18.842595	2.93612	0.0951125	0.2704646
690	44	18.842595	2.93612	0.0951125	1.5681258
691	0	18.637784	2.9251909	0.0951125	0.0252152

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
692	12	18.392756	2.9119569	0.094514	0.4559159
693	8	15.884456	2.765341	0.096383	0.3575724
694	33	19.259469	2.9580029	0.1153648	1.1585676
695	21	19.678154	2.9795091	0.1153648	0.7313974
696	31	16.235885	2.7872239	0.1162053	1.2758017
697	47	18.840785	2.936024	0.1153648	1.6734906
698	21	16.059408	2.7762948	0.1162053	0.8822735
699	87	18.945456	2.9415641	0.1153648	3.0607264
700	55	16.853554	2.8245616	0.1162053	2.1658696
701	41	18.698058	2.9284197	0.1214184	1.4733892
702	4	19.259469	2.9580029	0.1153648	0.161927
703	20	18.526772	2.9192168	0.1153648	0.7378665
704	65	18.698058	2.9284197	0.1214184	2.321145
705	13	19.154798	2.9525533	0.1153648	0.4736198
706	41	19.050127	2.9470738	0.1153648	1.4481212
707	1	18.494818	2.9174906	0.1214184	0.0610782
708	29	16.412362	2.7980348	0.1162053	1.1835547
709	4	19.259469	2.9580029	0.1153648	0.161927
710	0	18.698058	2.9284197	0.1214184	0.0251399
711	29	15.971169	2.7707852	0.1162053	1.2134616
712	38	15.971169	2.7707852	0.1162053	1.5810323
713	35	19.259469	2.9580029	0.1153648	1.2273014
714	25	18.945456	2.9415641	0.1153648	0.8972178
715	31	18.108088	2.8963587	0.1153648	1.1538943
716	22	16.235885	2.7872239	0.1162053	0.9137205

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
717	47	18.596438	2.9229701	0.1214184	1.6938587
718	5	19.154798	2.9525533	0.1153648	0.1972897
719	0	18.698058	2.9284197	0.1214184	0.0251399
720	3	19.259469	2.9580029	0.1153648	0.1275601
721	49	19.259469	2.9580029	0.1153648	1.7084382
722	53	18.596438	2.9229701	0.1214184	1.9068704
723	4	18.596438	2.9229701	0.1214184	0.1672749
724	21	18.698058	2.9284197	0.1214184	0.7669261
725	28	18.55322	2.9206434	0.0912	1.0215207
726	50	22.511077	3.1140075	0.1039167	1.5065361
727	29	20.374181	3.0142685	0.1032873	0.9690085
728	80	22.153759	3.0980072	0.1039167	2.4340385
729	0	21.511825	3.0686028	0.1032873	0.0220627
730	45	21.558228	3.0707575	0.1039167	1.414185
731	20	23.70214	3.1655653	0.1039167	0.586185
732	25	18.55322	2.9206434	0.0912	0.9147851
733	17	21.086543	3.0486351	0.0926179	0.5594048
734	5	21.086543	3.0486351	0.0926179	0.1803981
735	15	17.873259	2.8833057	0.0912	0.5786384
736	9	20.0244	2.9969515	0.0934737	0.3218877
737	12	13.987768	2.6381832	0.0912	0.585669
738	4	18.92627	2.9405509	0.1032873	0.1645712
739	7	21.086543	3.0486351	0.0926179	0.2435659
740	13	21.547451	3.0702575	0.0926179	0.4243983
741	17	18.358946	2.910117	0.0912	0.6363275

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
742	0	19.133114	2.9514206	0.1032873	0.0246093
743	13	19.133114	2.9514206	0.1032873	0.474118
744	34	21.20177	3.0540847	0.0926179	1.0907598
745	2	21.086543	3.0486351	0.0926179	0.0856464
746	4	20.919345	3.0406743	0.0934737	0.1499253
747	18	19.029692	2.9460005	0.1032873	0.6502689
748	10	21.432224	3.0648956	0.0926179	0.3332117
749	36	21.915546	3.0871963	0.1039167	1.1183991
750	20	21.25495	3.0565898	0.0934737	0.6493094
751	22	22.573563	3.1167794	0.1053249	0.6729627
752	32	19.029692	2.9460005	0.1032873	1.1367965
753	25	20.695609	3.0299216	0.0934737	0.8263962
754	19	18.92627	2.9405509	0.1032873	0.6884928
755	10	21.366818	3.0618392	0.0934737	0.3341659
756	13	20.583741	3.0245015	0.0934737	0.4429411
757	12	20.471873	3.0190519	0.0934737	0.4127304
758	29	21.20177	3.0540847	0.0926179	0.9336428
759	1	17.873259	2.8833057	0.0912	0.0630397
760	1	21.20177	3.0540847	0.0926179	0.0537878
761	1	20.695609	3.0299216	0.0934737	0.0550158
762	10	21.086543	3.0486351	0.0926179	0.3383176
763	4	20.583741	3.0245015	0.0934737	0.1522064
764	20	20.919345	3.0406743	0.0934737	0.6590409
765	17	21.086543	3.0486351	0.0926179	0.5594048
766	9	22.818928	3.1275904	0.1053249	0.2848572

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767	22	21.20177	3.0540847	0.0926179	0.7136791
768	5	17.776122	2.8778561	0.0912	0.2114146
769	5	20.695609	3.0299216	0.0934737	0.1835792
770	10	22.008359	3.0914223	0.0926179	0.3250356
771	24	20.695609	3.0299216	0.0934737	0.7942554
772	24	21.316997	3.0595047	0.0926179	0.7725997
773	39	20.248136	3.0080628	0.0934737	1.3026602
774	50	20.807477	3.0353124	0.0934737	1.6217341
775	15	21.20177	3.0540847	0.0926179	0.4937153
776	6	20.583741	3.0245015	0.0934737	0.2168141
777	37	17.873259	2.8833057	0.0912	1.3888648
778	47	20.695609	3.0299216	0.0934737	1.5334949
779	5	5.6339622	1.728813	0.0912	0.5687592
780	10	17.873259	2.8833057	0.0912	0.394496
781	15	19.029692	2.9460005	0.1032873	0.5460129
782	36	20.807477	3.0353124	0.0934737	1.1740214
783	39	21.20177	3.0540847	0.0926179	1.2478768
784	19	18.55322	2.9206434	0.0912	0.7013139
785	11	20.360005	3.0135724	0.0934737	0.3822101
786	23	19.029692	2.9460005	0.1032873	0.8240287
787	41	19.029692	2.9460005	0.1032873	1.4495642
788	22	21.031213	3.0460077	0.0934737	0.7190879
789	12	19.029692	2.9460005	0.1032873	0.441757
790	48	22.008359	3.0914223	0.0926179	1.4781055
791	17	23.716049	3.166152	0.0934737	0.5010018

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Parameter Code=HYCNFSEX Parameter=Severe or BG confirmed hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
792	12	18.456083	2.915394	0.0912	0.4544677
793	2	21.20177	3.0540847	0.0926179	0.0852112
794	41	21.316997	3.0595047	0.0926179	1.3040964
795	118	21.432224	3.0648956	0.0926179	3.6927927
796	4	17.873259	2.8833057	0.0912	0.1735251
797	1	20.583741	3.0245015	0.0934737	0.0552949
798	0	17.873259	2.8833057	0.0912	0.0262112
799	22	23.309658	3.1488678	0.1053249	0.6529711
800	6	20.063914	2.9989229	0.1032873	0.2220468
801	0	20.270759	3.0091794	0.1032873	0.0233219
802	70	18.92627	2.9405509	0.1032873	2.4698265
803	0	21.915546	3.0871963	0.1039167	0.0216818
804	0	22.573563	3.1167794	0.1053249	0.0210885
805	3	23.186975	3.1435907	0.1053249	0.1072442
806	24	22.868396	3.1297559	0.1039167	0.7233537
807	39	22.818928	3.1275904	0.1053249	1.1647967
808	11	23.800387	3.1697018	0.1053249	0.3301772
809	57	22.153759	3.0980072	0.1039167	1.7404231
810	9	22.391971	3.1087025	0.1039167	0.2899542
811	3	23.43234	3.1541171	0.1053249	0.1061875
812	10	18.650358	2.9258653	0.0912	0.379268
813	6	18.261808	2.9048119	0.0912	0.2423176
814	0	22.261763	3.1028706	0.0934737	0.0213655
815	42	17.193298	2.8445197	0.0912	1.6302747
816	18	17.970397	2.8887258	0.0912	0.6856826

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Hypoglycaemic episodes - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=HYCNFSEX Parameter=Severe or BG confirmed hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
817	1	21.915546	3.0871963	0.1039167	0.0521462
818	0	17.581848	2.866867	0.0912	0.0266119
819	11	21.086543	3.0486351	0.0926179	0.3699015
820	6	22.123586	3.0966443	0.0926179	0.2026652
821	17	22.008359	3.0914223	0.0926179	0.5374432
822	5	21.926159	3.0876804	0.0934737	0.1739248
823	2	20.360005	3.0135724	0.0934737	0.0884963
824	0	17.970397	2.8887258	0.0912	0.0260803
825	23	17.970397	2.8887258	0.0912	0.8689055
826	14	20.856089	3.0376459	0.0926179	0.4694486
827	1	19.029692	2.9460005	0.1032873	0.0594853
828	7	19.62173	2.9766376	0.0912	0.2604774
829	29	20.471873	3.0190519	0.0934737	0.9646951
830	21	21.366818	3.0618392	0.0934737	0.6773254
831	19	22.238813	3.1018391	0.0926179	0.5923173
832	20	21.20177	3.0540847	0.0926179	0.6508323
833	23	20.583741	3.0245015	0.0934737	0.7659796
834	2	20.583741	3.0245015	0.0934737	0.0875987
835	11	18.456083	2.915394	0.0912	0.4187158
836	5	23.43234	3.1541171	0.1053249	0.163405
837	27	23.43234	3.1541171	0.1053249	0.7927978
838	3	19.029692	2.9460005	0.1032873	0.1289893
839	9	18.822847	2.9350714	0.1032873	0.3409397
840	2	22.573563	3.1167794	0.1053249	0.0803498
841	0	22.391971	3.1087025	0.1039167	0.0212489

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Parameter Code=HYCNFSEX Parameter=Severe or BG confirmed hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
842	0	23.555022	3.1593391	0.1053249	0.0202613
843	0	22.450881	3.1113298	0.1053249	0.0211966
844	44	19.029692	2.9460005	0.1032873	1.5538201
845	23	24.168434	3.1850474	0.1053249	0.6588845
846	30	19.133114	2.9514206	0.1032873	1.0619372
847	17	22.573563	3.1167794	0.1053249	0.5248095
848	4	21.915546	3.0871963	0.1039167	0.1435393
849	2	22.153759	3.0980072	0.1039167	0.0817776
850	108	19.029692	2.9460005	0.1032873	3.7779464
851	4	19.236536	2.9568114	0.1032873	0.1621063
852	40	21.915546	3.0871963	0.1039167	1.2402566
853	52	21.915546	3.0871963	0.1039167	1.605829
854	0	21.20177	3.0540847	0.0926179	0.0223644
855	9	21.20177	3.0540847	0.0926179	0.3051749
856	0	20.583741	3.0245015	0.0934737	0.022991
857	16	20.583741	3.0245015	0.0934737	0.5398526
858	5	19.524593	2.9716749	0.0912	0.193816
859	10	19.233181	2.956637	0.0912	0.3685957
860	39	21.915546	3.0871963	0.1039167	1.2097922
861	14	19.236536	2.9568114	0.1032873	0.5061559
862	3	22.450881	3.1113298	0.1053249	0.1105445
863	33	20.248136	3.0080628	0.0934737	1.1058427
864	8	21.915546	3.0871963	0.1039167	0.2653968
865	1	20.919345	3.0406743	0.0934737	0.0544662
866	8	20.919345	3.0406743	0.0934737	0.2772042

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Parameter Code=HYCNFSEX Parameter=Severe or BG confirmed hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
867	4	21.086543	3.0486351	0.0926179	0.1488142
868	2	18.844632	2.9362281	0.0912	0.0950954
869	30	20.919345	3.0406743	0.0934737	0.9772381
870	20	20.971316	3.0431556	0.0926179	0.6575149
871	31	19.029692	2.9460005	0.1032873	1.1020445
872	15	18.067534	2.8941166	0.0912	0.5728881
873	39	21.432224	3.0648956	0.0926179	1.2353214
874	26	21.316997	3.0595047	0.0926179	0.8351287
875	9	18.164671	2.8994786	0.0912	0.3523623
876	20	18.067534	2.8941166	0.0912	0.7552006
877	19	21.432224	3.0648956	0.0926179	0.6131768
878	39	20.248136	3.0080628	0.0934737	1.3026602
879	0	17.776122	2.8778561	0.0912	0.0263434
880	29	20.583741	3.0245015	0.0934737	0.9598027
881	3	17.776122	2.8778561	0.0912	0.1373861
882	3	5.5368249	1.7114212	0.0912	0.3746124
883	41	17.678985	2.8723766	0.0912	1.5517535
884	40	21.20177	3.0540847	0.0926179	1.2793002
885	1	21.086543	3.0486351	0.0926179	0.0540625
886	51	20.919345	3.0406743	0.0934737	1.6454522
887	4	21.20177	3.0540847	0.0926179	0.148058
888	12	17.873259	2.8833057	0.0912	0.4681529
889	45	21.20177	3.0540847	0.0926179	1.4364171
890	54	21.25495	3.0565898	0.0934737	1.7152049
891	17	20.471873	3.0190519	0.0934737	0.575073

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
892	27	20.971316	3.0431556	0.0926179	0.8797371
893	9	20.695609	3.0299216	0.0934737	0.3121426
894	3	20.471873	3.0190519	0.0934737	0.1205137
895	56	22.123586	3.0966443	0.0926179	1.712453
896	10	21.20177	3.0540847	0.0926179	0.3365983
897	30	21.79644	3.0817467	0.1039167	0.9404023
898	21	18.067534	2.8941166	0.0912	0.7916631
899	1	19.912532	2.9913493	0.0934737	0.0570302
900	87	20.583741	3.0245015	0.0934737	2.8334261
901	15	17.776122	2.8778561	0.0912	0.5815569
902	3	17.776122	2.8778561	0.0912	0.1373861
903	25	18.067534	2.8941166	0.0912	0.9375131
904	44	20.471873	3.0190519	0.0934737	1.4517229
905	0	22.573563	3.1167794	0.1053249	0.0210885
906	9	23.677705	3.1645339	0.1053249	0.2751289
907	0	20.583741	3.0245015	0.0934737	0.022991
908	5	19.029692	2.9460005	0.1032873	0.1984932
909	3	21.915546	3.0871963	0.1039167	0.1130749
910	9	22.450881	3.1113298	0.1053249	0.2892401
911	14	20.248136	3.0080628	0.0934737	0.4825871
912	0	23.309658	3.1488678	0.1053249	0.020462
913	0	22.034653	3.0926163	0.1039167	0.021572
914	0	22.153759	3.0980072	0.1039167	0.0214632
915	20	19.339958	2.9621733	0.1032873	0.7090456
916	87	22.450881	3.1113298	0.1053249	2.612284

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Parameter Code=HYCNFSEX Parameter=Severe or BG confirmed hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
917	2	22.450881	3.1113298	0.1053249	0.0807618
918	0	17.970397	2.8887258	0.0912	0.0260803
919	16	18.067534	2.8941166	0.0912	0.6093506
920	4	18.92627	2.9405509	0.1032873	0.1645712
921	11	21.316997	3.0595047	0.0926179	0.366161
922	0	19.650225	2.9780888	0.1032873	0.0240069
923	2	17.970397	2.8887258	0.0912	0.0993695
924	1	20.807477	3.0353124	0.0934737	0.0547396
925	36	19.029692	2.9460005	0.1032873	1.2758044
926	12	20.583741	3.0245015	0.0934737	0.4106372
927	1	21.316997	3.0595047	0.0926179	0.0535158
928	15	21.915546	3.0871963	0.1039167	0.4786474
929	23	17.970397	2.8887258	0.0912	0.8689055
930	7	18.92627	2.9405509	0.1032873	0.2693555
931	47	21.677334	3.0762672	0.1039167	1.4684645
932	52	20.695609	3.0299216	0.0934737	1.6941991
933	7	14.353842	2.6640176	0.1053249	0.3470983
934	40	19.236536	2.9568114	0.1032873	1.400685
935	37	19.029692	2.9460005	0.1032873	1.3105563
936	9	21.20177	3.0540847	0.0926179	0.3051749
937	43	19.029692	2.9460005	0.1032873	1.5190682
938	46	23.344821	3.1503752	0.1039167	1.3410779
939	6	20.695609	3.0299216	0.0934737	0.2157201
940	55	17.873259	2.8833057	0.0912	2.0517774
941	5	22.205516	3.1003407	0.1053249	0.1718726

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942	14	18.650358	2.9258653	0.0912	0.5208955
943	23	20.360005	3.0135724	0.0934737	0.7738285
944	5	17.873259	2.8833057	0.0912	0.2103536
945	2	17.678985	2.8723766	0.0912	0.1008807
946	47	19.029692	2.9460005	0.1032873	1.6580761
947	1	23.380445	3.1519	0.0934737	0.0490722
948	13	21.366818	3.0618392	0.0934737	0.4277549
949	36	20.695609	3.0299216	0.0934737	1.1799455
950	27	23.555022	3.1593391	0.1053249	0.7889109
951	9	17.970397	2.8887258	0.0912	0.3558815
952	37	21.822092	3.0829229	0.1032873	1.1534728
953	48	21.20177	3.0540847	0.0926179	1.5306873
954	20	21.893132	3.086173	0.0926179	0.6315745
955	55	20.471873	3.0190519	0.0934737	1.8088765
956	11	17.873259	2.8833057	0.0912	0.4313245
957	9	19.029692	2.9460005	0.1032873	0.3375011
958	27	17.581848	2.866867	0.0912	1.03618
959	16	20.583741	3.0245015	0.0934737	0.5398526
960	4	20.583741	3.0245015	0.0934737	0.1522064
961	4	17.873259	2.8833057	0.0912	0.1735251
962	0	19.029692	2.9460005	0.1032873	0.0247334
963	8	17.873259	2.8833057	0.0912	0.320839
964	1	22.008359	3.0914223	0.0926179	0.0519401
965	15	19.133114	2.9514206	0.1032873	0.5432732
966	32	21.20177	3.0540847	0.0926179	1.027913

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
967	22	17.970397	2.8887258	0.0912	0.8322609
968	2	4.7597267	1.5601902	0.0912	0.3068501
969	15	17.290436	2.8501535	0.0912	0.5966018
970	11	21.662678	3.0755909	0.0926179	0.3606898
971	52	22.573563	3.1167794	0.1053249	1.5618821
972	8	20.583741	3.0245015	0.0934737	0.2814218
973	56	22.272865	3.1033691	0.1039167	1.7016865
974	25	22.573563	3.1167794	0.1053249	0.7618546
975	0	21.79644	3.0817467	0.1039167	0.0217928
976	4	19.029692	2.9460005	0.1032873	0.1637413
977	8	21.547451	3.0702575	0.0926179	0.2696407
978	8	22.450881	3.1113298	0.1053249	0.2594575
979	13	18.55322	2.9206434	0.0912	0.4878426
980	26	23.186975	3.1435907	0.1053249	0.7717941
981	10	18.822847	2.9350714	0.1032873	0.3760458
982	0	20.374181	3.0142685	0.1032873	0.0232115
983	19	22.469267	3.1121485	0.0926179	0.5866154
984	25	17.776122	2.8778561	0.0912	0.9516992
985	62	21.086543	3.0486351	0.0926179	1.9806801
986	48	22.034653	3.0926163	0.1039167	1.4764521
987	22	20.583741	3.0245015	0.0934737	0.7336757
988	45	20.971316	3.0431556	0.0926179	1.4511659
989	51	20.971316	3.0431556	0.0926179	1.6416422
990	32	18.067534	2.8941166	0.0912	1.1927505
991	22	21.20177	3.0540847	0.0926179	0.7136791

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Parameter Code=HYCNFSEX Parameter=Severe or BG confirmed hypoglycaemic episodes Study Identifier=NN1218-4131

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
992	52	20.279954	3.0096329	0.0926179	1.7265694
993	20	20.583741	3.0245015	0.0934737	0.669068
994	42	21.432224	3.0648956	0.0926179	1.3286431
995	24	20.583741	3.0245015	0.0934737	0.7982835
996	17	20.695609	3.0299216	0.0934737	0.5692694
997	28	13.020652	2.5665367	0.0926179	1.4109284
998	60	18.616003	2.9240216	0.1032873	2.1532857
999	2	22.123586	3.0966443	0.0926179	0.0818822
1000	26	17.970397	2.8887258	0.0912	0.9788392
1001	18	19.960492	2.9937549	0.1032873	0.6220352
1002	55	21.79644	3.0817467	0.1039167	1.7059101
1003	11	18.090641	2.8953947	0.0926179	0.426534
1004	2	7.830771	2.058061	0.0934737	0.2071016
1005	55	21.316997	3.0595047	0.0926179	1.7417996
1006	17	17.873259	2.8833057	0.0912	0.6522953
1007	72	17.970397	2.8887258	0.0912	2.6644895
1008	48	21.20177	3.0540847	0.0926179	1.5306873
1009	20	21.777905	3.0808959	0.0926179	0.6347047
1010	22	20.360005	3.0135724	0.0934737	0.7411936
1011	34	20.01028	2.9962461	0.0912	1.1512508
1012	18	17.776122	2.8778561	0.0912	0.6925996
1013	51	18.067534	2.8941166	0.0912	1.8855379
1014	10	20.807477	3.0353124	0.0934737	0.3425549
1015	0	17.970397	2.8887258	0.0912	0.0260803
1016	14	21.143082	3.0513127	0.0934737	0.4634915

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
1017	15	20.471873	3.0190519	0.0934737	0.5101359
1018	47	21.20177	3.0540847	0.0926179	1.4992639
1019	8	19.029692	2.9460005	0.1032873	0.3027491
1020	24	18.164671	2.8994786	0.0912	0.8965955
1021	16	20.807477	3.0353124	0.0934737	0.5344318
1022	33	17.873259	2.8833057	0.0912	1.2415509
1023	31	21.20177	3.0540847	0.0926179	0.9964896
1024	37	21.20177	3.0540847	0.0926179	1.18503
1025	49	21.20177	3.0540847	0.0926179	1.5621107

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Hypoglycaemic episodes - treatment emergent - statistical analysis - on-treatment - full analysis set

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The GENMOD Procedure

Model Information

Data Set	WORK.ENDPOINT	
Distribution	Negative Binomial	
Link Function	Log	
Dependent Variable	AVAL	Analysis Value
Offset Variable	log_offset	

Number of Observations Read	1025
Number of Observations Used	1025

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Parameter Information

Parameter	Effect	TRTPN	REGION1	BOLAD1
Prm1	Intercept			
Prm2	TRTPN	2		
Prm3	TRTPN	3		
Prm4	TRTPN	4		
Prm5	REGION1		ASIA (EXCLUDING JAPAN)	
Prm6	REGION1		EUROPE	

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Parameter Information

Parameter	Effect	TRTPN	REGION1	BOLAD1
Prm7	REGION1		JAPAN	
Prm8	REGION1		NORTH AMERICA	
Prm9	BOLAD1			BOLUS INSULIN ALGORITHM (SLIDING SCALE)
Prm10	BOLAD1			CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Criteria For Assessing Goodness Of Fit

Criterion	DF	Value	Value/DF
Deviance	1018	297.7444	0.2925
Scaled Deviance	1018	297.7444	0.2925
Pearson Chi-Square	1018	971.6419	0.9545
Scaled Pearson X2	1018	971.6419	0.9545
Log Likelihood		-300.5639	
Full Log Likelihood		-338.7413	
AIC (smaller is better)		693.4826	
AICC (smaller is better)		693.6244	
BIC (smaller is better)		732.9422	

Algorithm converged.

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Analysis Of Maximum Likelihood Parameter Estimates

Parameter		DF	Estimate	Standard Error	Wald 95% Confidence Limits		Wald Chi-Square
Intercept		1	2.6426	0.3272	2.0013	3.2839	65.22
TRTPN	2	1	0.0144	0.2858	-0.5457	0.5745	0.00
TRTPN	3	1	-0.3032	0.3081	-0.9070	0.3006	0.97
TRTPN	4	0	0.0000	0.0000	0.0000	0.0000	.
REGION1	ASIA (EXCLUDING JAPAN)	1	1.2260	0.3702	0.5004	1.9517	10.97
REGION1	EUROPE	1	-0.1885	0.3335	-0.8422	0.4652	0.32
REGION1	JAPAN	1	-0.5543	0.3976	-1.3336	0.2250	1.94
REGION1	NORTH AMERICA	0	0.0000	0.0000	0.0000	0.0000	.
BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	1	0.6039	0.3060	0.0041	1.2037	3.89
BOLAD1	CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY	0	0.0000	0.0000	0.0000	0.0000	.
Dispersion		1	4.4289	1.1472	2.6657	7.3582	

Analysis Of Maximum Likelihood Parameter Estimates

Parameter		Pr > ChiSq
Intercept		<.0001
TRTPN	2	0.9598
TRTPN	3	0.3250
TRTPN	4	.
REGION1	ASIA (EXCLUDING JAPAN)	0.0009
REGION1	EUROPE	0.5719
REGION1	JAPAN	0.1633
REGION1	NORTH AMERICA	.
BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.0485
BOLAD1	CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY	.
Dispersion		

NOTE: The negative binomial dispersion parameter was estimated by maximum likelihood.

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Coefficients for TRTPN Least Squares Means Using WORK.ENDPOINT Margins

Parameter	Geographic Region Grouping Method 1
Intercept	
Planned Treatment (N) 2	
Planned Treatment (N) 3	
Planned Treatment (N) 4	
Geographic Region Grouping Method 1 ASIA (EXCLUDING JAPAN)	ASIA (EXCLUDING JAPAN)
Geographic Region Grouping Method 1 EUROPE	EUROPE
Geographic Region Grouping Method 1 JAPAN	JAPAN
Geographic Region Grouping Method 1 NORTH AMERICA	NORTH AMERICA
Bolus Adjustment Method at Timepoint 1 BOLUS INSULIN ALGORITHM (SLIDING SCALE)	
Bolus Adjustment Method at Timepoint 1 CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY	

Coefficients for TRTPN Least Squares Means Using WORK.ENDPOINT Margins

Bolus Adjustment Method at Timepoint 1	Planned Treatment (N)	Row1	Row2	Row3
	1	1	1	1
	2	1		
	3		1	
	4			1
		0.1307	0.1307	0.1307
		0.3366	0.3366	0.3366
		0.239	0.239	0.239
BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.2937	0.2937	0.2937
CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0.5824	0.5824	0.5824
		0.4176	0.4176	0.4176

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TRTPN Least Squares Means

Planned Treatment (N)	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
2	WORK.ENDPOINT	2.9730	0.2090	14.22	<.0001	0.05	2.5634	3.3827
3	WORK.ENDPOINT	2.6554	0.2358	11.26	<.0001	0.05	2.1933	3.1175
4	WORK.ENDPOINT	2.9586	0.2097	14.11	<.0001	0.05	2.5476	3.3696

Differences of TRTPN Least Squares Means

Planned Treatment (N)	Planned Treatment (N)	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
2	4	WORK.ENDPOINT	0.01439	0.2858	0.05	0.9598	0.05	-0.5457	0.5745
3	4	WORK.ENDPOINT	-0.3032	0.3081	-0.98	0.3250	0.05	-0.9070	0.3006

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) / NovoRapid (meal)	WORK.ENDPOINT	0.01439	0.2858	0.05	0.9598	0.05	-0.5457	0.5745

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Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
TRTPN	Faster aspart (post) / NovoRapid (meal)	WORK.ENDPOINT	-0.3032	0.3081	-0.98	0.3250	0.05	-0.9070	0.3006

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
1	0	0.0412485	-3.188141	0.4178096	0.0294897
2	0	0.0412485	-3.188141	0.4178096	0.0294897
3	1	0.0412485	-3.188141	0.4178096	0.1600957
4	0	0.0412485	-3.188141	0.4178096	0.0294897
5	0	0.0412485	-3.188141	0.4178096	0.0294897
6	0	0.0758609	-2.578854	0.3554345	0.042503
7	0	0.0300242	-3.505751	0.4348915	0.0233901
8	0	0.0308401	-3.47894	0.4348915	0.0238732
9	0	0.0428177	-3.150804	0.4178096	0.030255
10	0	0.0125302	-4.379617	0.3465628	0.0112472
11	0	0.0408001	-3.19907	0.4178096	0.0292674
12	0	0.0308401	-3.47894	0.4348915	0.0238732
13	0	0.0300242	-3.505751	0.4348915	0.0233901
14	0	0.040217	-3.213464	0.417166	0.0289757
15	0	0.0412485	-3.188141	0.4178096	0.0294897
16	0	0.04088	-3.197115	0.417166	0.0293071

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
17	0	0.0754508	-2.584274	0.3554345	0.0423884
18	1	0.0573075	-2.859324	0.3608634	0.197906
19	0	0.0743725	-2.598668	0.3465628	0.0420834
20	0	0.040217	-3.213464	0.417166	0.0289757
21	0	0.0754508	-2.584274	0.3554345	0.0423884
22	0	0.0072921	-4.920964	0.417166	0.006843
23	0	0.0300242	-3.505751	0.4348915	0.0233901
24	1	0.0549197	-2.901884	0.3608634	0.1929002
25	0	0.0311664	-3.468413	0.4348915	0.0240646
26	0	0.0300242	-3.505751	0.4348915	0.0233901
27	0	0.0334509	-3.397677	0.4348915	0.0253753
28	0	0.0549197	-2.901884	0.3608634	0.0355323
29	0	0.0414726	-3.182721	0.4178096	0.0296003
30	0	0.0767977	-2.56658	0.3465628	0.0427619
31	0	0.0549197	-2.901884	0.3608634	0.0355323
32	0	0.0412485	-3.188141	0.4178096	0.0294897
33	0	0.0300242	-3.505751	0.4348915	0.0233901
34	0	0.0739683	-2.604118	0.3465628	0.0419676
35	0	0.0321455	-3.437483	0.4348915	0.0246325
36	0	0.040659	-3.202535	0.417166	0.029197
37	0	0.040659	-3.202535	0.417166	0.029197
38	0	0.0300242	-3.505751	0.4348915	0.0233901
39	0	0.0300242	-3.505751	0.4348915	0.0233901
40	1	0.0295347	-3.52219	0.4348915	0.1253909
41	0	0.0300242	-3.505751	0.4348915	0.0233901

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Observation Statistics

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42	0	0.0555166	-2.891073	0.3608634	0.0357663
43	1	0.0549197	-2.901884	0.3608634	0.1929002
44	0	0.0743725	-2.598668	0.3465628	0.0420834
45	0	0.0754508	-2.584274	0.3554345	0.0423884
46	0	0.0787313	-2.541715	0.3554345	0.0432835
47	0	0.0754508	-2.584274	0.3554345	0.0423884
48	0	0.0558151	-2.885711	0.3608634	0.0358824
49	0	0.0739683	-2.604118	0.3465628	0.0419676
50	0	0.0762709	-2.573464	0.3554345	0.0426168
51	0	0.0762709	-2.573464	0.3554345	0.0426168
52	0	0.0549197	-2.901884	0.3608634	0.0355323
53	0	0.0555166	-2.891073	0.3608634	0.0357663
54	0	0.0751809	-2.587857	0.3465628	0.0423126
55	0	0.0543227	-2.912813	0.3608634	0.0352961
56	0	0.0762709	-2.573464	0.3554345	0.0426168
57	0	0.0611877	-2.79381	0.3608634	0.0378772
58	0	0.077091	-2.562768	0.3554345	0.0428421
59	0	0.0747767	-2.593248	0.3465628	0.0421983
60	0	0.0549197	-2.901884	0.3608634	0.0355323
61	0	0.0755851	-2.582496	0.3465628	0.042426
62	0	0.077091	-2.562768	0.3554345	0.0428421
63	0	0.0543227	-2.912813	0.3608634	0.0352961
64	0	0.0743725	-2.598668	0.3465628	0.0420834
65	0	0.056412	-2.875073	0.3608634	0.0361129
66	0	0.0558151	-2.885711	0.3608634	0.0358824

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
67	0	0.0549197	-2.901884	0.3608634	0.0355323
68	0	0.0543227	-2.912813	0.3608634	0.0352961
69	0	0.0742206	-2.600713	0.3554345	0.0420399
70	0	0.0754508	-2.584274	0.3554345	0.0423884
71	0	0.0791413	-2.53652	0.3554345	0.043392
72	0	0.0743725	-2.598668	0.3465628	0.0420834
73	0	0.0549197	-2.901884	0.3608634	0.0355323
74	1	0.0743725	-2.598668	0.3465628	0.2284649
75	0	0.0758609	-2.578854	0.3554345	0.042503
76	0	0.0743725	-2.598668	0.3465628	0.0420834
77	0	0.0549197	-2.901884	0.3608634	0.0355323
78	0	0.0743725	-2.598668	0.3465628	0.0420834
79	0	0.0754508	-2.584274	0.3554345	0.0423884
80	0	0.0758609	-2.578854	0.3554345	0.042503
81	0	0.0743725	-2.598668	0.3465628	0.0420834
82	0	0.0754508	-2.584274	0.3554345	0.0423884
83	0	0.0743725	-2.598668	0.3465628	0.0420834
84	0	0.07316	-2.615107	0.3465628	0.0417337
85	0	0.0754508	-2.584274	0.3554345	0.0423884
86	0	0.0546212	-2.907334	0.3608634	0.0354145
87	0	0.0754508	-2.584274	0.3554345	0.0423884
88	0	0.0549197	-2.901884	0.3608634	0.0355323
89	0	0.0755851	-2.582496	0.3465628	0.042426
90	0	0.0540242	-2.918323	0.3608634	0.0351771
91	0	0.0739683	-2.604118	0.3465628	0.0419676

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
92	0	0.0743725	-2.598668	0.3465628	0.0420834
93	0	0.07316	-2.615107	0.3465628	0.0417337
94	0	0.0739683	-2.604118	0.3465628	0.0419676
95	0	0.0754508	-2.584274	0.3554345	0.0423884
96	0	0.07316	-2.615107	0.3465628	0.0417337
97	0	0.0549197	-2.901884	0.3608634	0.0355323
98	0	0.040659	-3.202535	0.417166	0.029197
99	0	0.0754508	-2.584274	0.3554345	0.0423884
100	0	0.0295347	-3.52219	0.4348915	0.0230971
101	0	0.0743725	-2.598668	0.3465628	0.0420834
102	0	0.0410243	-3.193591	0.4178096	0.0293787
103	0	0.0305137	-3.489578	0.4348915	0.0236808
104	0	0.0743725	-2.598668	0.3465628	0.0420834
105	0	0.040217	-3.213464	0.417166	0.0289757
106	0	0.0399961	-3.218974	0.417166	0.0288644
107	0	0.0743725	-2.598668	0.3465628	0.0420834
108	0	0.0552181	-2.896464	0.3608634	0.0356496
109	0	0.0543227	-2.912813	0.3608634	0.0352961
110	0	0.0412485	-3.188141	0.4178096	0.0294897
111	0	0.040217	-3.213464	0.417166	0.0289757
112	0	0.040659	-3.202535	0.417166	0.029197
113	0	0.040659	-3.202535	0.417166	0.029197
114	0	0.040659	-3.202535	0.417166	0.029197
115	0	0.0412485	-3.188141	0.4178096	0.0294897
116	0	0.0300242	-3.505751	0.4348915	0.0233901

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Observation Statistics

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117	0	0.04088	-3.197115	0.417166	0.0293071
118	0	0.0412485	-3.188141	0.4178096	0.0294897
119	0	0.040659	-3.202535	0.417166	0.029197
120	0	0.0412485	-3.188141	0.4178096	0.0294897
121	0	0.040659	-3.202535	0.417166	0.029197
122	0	0.0412485	-3.188141	0.4178096	0.0294897
123	0	0.0295347	-3.52219	0.4348915	0.0230971
124	1	0.040659	-3.202535	0.417166	0.1585068
125	0	0.0412485	-3.188141	0.4178096	0.0294897
126	0	0.029861	-3.511201	0.4348915	0.0232927
127	0	0.0300242	-3.505751	0.4348915	0.0233901
128	0	0.0305137	-3.489578	0.4348915	0.0236808
129	0	0.0549197	-2.901884	0.3608634	0.0355323
130	0	0.0428177	-3.150804	0.4178096	0.030255
131	0	0.0795514	-2.531352	0.3554345	0.0434998
132	0	0.0300242	-3.505751	0.4348915	0.0233901
133	0	0.0355722	-3.336192	0.4348915	0.0265482
134	0	0.0763935	-2.571857	0.3465628	0.0426507
135	0	0.04088	-3.197115	0.417166	0.0293071
136	0	0.0455204	-3.089595	0.417166	0.0315271
137	0	0.0194178	-3.941563	0.4348915	0.0164643
138	0	0.0816481	-2.505336	0.3465628	0.0440394
139	0	0.0416968	-3.17733	0.4178096	0.0297104
140	0	0.040217	-3.213464	0.417166	0.0289757
141	0	0.0311664	-3.468413	0.4348915	0.0240646

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Observation Statistics

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142	0	0.0296979	-3.51668	0.4348915	0.023195
143	0	0.0743725	-2.598668	0.3465628	0.0420834
144	0	0.0754508	-2.584274	0.3554345	0.0423884
145	0	0.0754508	-2.584274	0.3554345	0.0423884
146	0	0.0763935	-2.571857	0.3465628	0.0426507
147	0	0.0590983	-2.828553	0.3608634	0.0371224
148	0	0.0716343	-2.636181	0.3608634	0.0412837
149	1	0.0747767	-2.593248	0.3465628	0.2290892
150	0	0.0742206	-2.600713	0.3554345	0.0420399
151	0	0.0549197	-2.901884	0.3608634	0.0355323
152	0	0.0743725	-2.598668	0.3465628	0.0420834
153	0	0.07316	-2.615107	0.3465628	0.0417337
154	0	0.0546212	-2.907334	0.3608634	0.0354145
155	0	0.0735642	-2.609597	0.3465628	0.0418511
156	1	0.0537177	-2.924013	0.3554345	0.1903047
157	0	0.0453684	-3.092939	0.3608634	0.031457
158	0	0.0549197	-2.901884	0.3608634	0.0355323
159	0	0.0762709	-2.573464	0.3554345	0.0426168
160	1	0.076681	-2.568102	0.3554345	0.2319745
161	0	0.0754508	-2.584274	0.3554345	0.0423884
162	0	0.0549197	-2.901884	0.3608634	0.0355323
163	0	0.0549197	-2.901884	0.3608634	0.0355323
164	0	0.0549197	-2.901884	0.3608634	0.0355323
165	0	0.0505248	-2.98529	0.3465628	0.033737
166	0	0.0543227	-2.912813	0.3608634	0.0352961

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
167	0	0.0743725	-2.598668	0.3465628	0.0420834
168	1	0.0751809	-2.587857	0.3465628	0.2297093
169	0	0.0735642	-2.609597	0.3465628	0.0418511
170	0	0.0750407	-2.589724	0.3554345	0.042273
171	0	0.0546212	-2.907334	0.3608634	0.0354145
172	0	0.076681	-2.568102	0.3554345	0.0427298
173	0	0.0758609	-2.578854	0.3554345	0.042503
174	0	0.07316	-2.615107	0.3465628	0.0417337
175	1	0.0751809	-2.587857	0.3465628	0.2297093
176	0	0.0739683	-2.604118	0.3465628	0.0419676
177	0	0.057009	-2.864546	0.3608634	0.0363411
178	0	0.076681	-2.568102	0.3554345	0.0427298
179	0	0.0549197	-2.901884	0.3608634	0.0355323
180	0	0.0739683	-2.604118	0.3465628	0.0419676
181	0	0.0742206	-2.600713	0.3554345	0.0420399
182	0	0.0735642	-2.609597	0.3465628	0.0418511
183	0	0.0549197	-2.901884	0.3608634	0.0355323
184	0	0.0549197	-2.901884	0.3608634	0.0355323
185	0	0.0558151	-2.885711	0.3608634	0.0358824
186	0	0.0739683	-2.604118	0.3465628	0.0419676
187	0	0.0754508	-2.584274	0.3554345	0.0423884
188	0	0.0758609	-2.578854	0.3554345	0.042503
189	0	0.0298476	-3.511649	0.3608634	0.0232847
190	0	0.0742206	-2.600713	0.3554345	0.0420399
191	0	0.0391122	-3.241321	0.417166	0.0284152

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
192	0	0.0735642	-2.609597	0.3465628	0.0418511
193	0	0.0754508	-2.584274	0.3554345	0.0423884
194	0	0.0743725	-2.598668	0.3465628	0.0420834
195	0	0.0561136	-2.880378	0.3608634	0.0359979
196	0	0.0413219	-3.186362	0.417166	0.029526
197	0	0.0743725	-2.598668	0.3465628	0.0420834
198	0	0.07316	-2.615107	0.3465628	0.0417337
199	0	0.0754508	-2.584274	0.3554345	0.0423884
200	0	0.0747767	-2.593248	0.3465628	0.0421983
201	0	0.0762709	-2.573464	0.3554345	0.0426168
202	0	0.0234435	-3.753161	0.3465628	0.0192407
203	0	0.0286537	-3.552471	0.3608634	0.0225636
204	0	0.0754508	-2.584274	0.3554345	0.0423884
205	0	0.0552181	-2.896464	0.3608634	0.0356496
206	0	0.0783212	-2.546937	0.3554345	0.0431743
207	1	0.0754508	-2.584274	0.3554345	0.230121
208	0	0.0552181	-2.896464	0.3608634	0.0356496
209	0	0.0742206	-2.600713	0.3554345	0.0420399
210	0	0.0743725	-2.598668	0.3465628	0.0420834
211	0	0.0311664	-3.468413	0.4348915	0.0240646
212	0	0.0543227	-2.912813	0.3608634	0.0352961
213	0	0.0549197	-2.901884	0.3608634	0.0355323
214	0	0.0300242	-3.505751	0.4348915	0.0233901
215	0	0.0020893	-6.17091	0.3608634	0.0020512
216	0	0.0412485	-3.188141	0.4178096	0.0294897

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217	0	0.040217	-3.213464	0.417166	0.0289757
218	0	0.0414726	-3.182721	0.4178096	0.0296003
219	0	0.04088	-3.197115	0.417166	0.0293071
220	0	0.040217	-3.213464	0.417166	0.0289757
221	0	0.0739683	-2.604118	0.3465628	0.0419676
222	0	0.0754508	-2.584274	0.3554345	0.0423884
223	0	0.0549197	-2.901884	0.3608634	0.0355323
224	0	0.057009	-2.864546	0.3608634	0.0363411
225	0	0.0754508	-2.584274	0.3554345	0.0423884
226	0	0.0754508	-2.584274	0.3554345	0.0423884
227	0	0.0549197	-2.901884	0.3608634	0.0355323
228	0	0.0743725	-2.598668	0.3465628	0.0420834
229	0	0.0772019	-2.561331	0.3465628	0.0428723
230	0	0.0549197	-2.901884	0.3608634	0.0355323
231	0	0.0552181	-2.896464	0.3608634	0.0356496
232	0	0.0759893	-2.577162	0.3465628	0.0425387
233	0	0.0549197	-2.901884	0.3608634	0.0355323
234	0	0.076681	-2.568102	0.3554345	0.0427298
235	0	0.0549197	-2.901884	0.3608634	0.0355323
236	0	0.0552181	-2.896464	0.3608634	0.0356496
237	0	0.0549197	-2.901884	0.3608634	0.0355323
238	0	0.0743725	-2.598668	0.3465628	0.0420834
239	0	0.0549197	-2.901884	0.3608634	0.0355323
240	0	0.0754508	-2.584274	0.3554345	0.0423884
241	0	0.0754508	-2.584274	0.3554345	0.0423884

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Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
242	0	0.0754508	-2.584274	0.3554345	0.0423884
243	1	0.0743725	-2.598668	0.3465628	0.2284649
244	0	0.0715432	-2.637454	0.3465628	0.0412565
245	0	0.057009	-2.864546	0.3608634	0.0363411
246	0	0.441162	-0.818343	0.2714186	0.0505617
247	2	0.441162	-0.818343	0.2714186	0.498424
248	0	0.3257717	-1.121559	0.3126085	0.0545931
249	0	0.4867168	-0.720073	0.2714186	0.0488778
250	0	0.3257717	-1.121559	0.3126085	0.0545931
251	0	0.441162	-0.818343	0.2714186	0.0505617
252	0	0.4645847	-0.766611	0.2761746	0.0496945
253	0	0.3328536	-1.100052	0.3126085	0.0543746
254	0	0.3275422	-1.116139	0.3126085	0.0545391
255	2	0.447558	-0.803949	0.2761746	0.4960897
256	0	0.3293127	-1.110748	0.3126085	0.0544847
257	0	0.447558	-0.803949	0.2761746	0.0503249
258	1	0.3257717	-1.121559	0.3126085	0.2963787
259	0	0.3363946	-1.08947	0.3126085	0.054263
260	0	0.3275422	-1.116139	0.3126085	0.0545391
261	0	0.441162	-0.818343	0.2714186	0.0505617
262	0	0.3257717	-1.121559	0.3126085	0.0545931
263	1	0.447558	-0.803949	0.2761746	0.2732073
264	4	0.4435597	-0.812923	0.2714186	0.9446253
265	1	0.4435597	-0.812923	0.2714186	0.2740111
266	0	0.441162	-0.818343	0.2714186	0.0505617

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267	0	0.441162	-0.818343	0.2714186	0.0505617
268	0	0.4555478	-0.786255	0.2714186	0.050029
269	0	0.4572875	-0.782443	0.2761746	0.0499646
270	0	0.3257717	-1.121559	0.3126085	0.0545931
271	0	0.447558	-0.803949	0.2761746	0.0503249
272	1	0.3293127	-1.110748	0.3126085	0.2957901
273	0	0.3204602	-1.137997	0.3126085	0.0547524
274	0	0.4548552	-0.787776	0.2761746	0.0500547
275	3	0.4819216	-0.729974	0.2714186	0.7008188
276	1	0.3275422	-1.116139	0.3126085	0.2960855
277	0	0.3293127	-1.110748	0.3126085	0.0544847
278	0	0.3257717	-1.121559	0.3126085	0.0545931
279	0	0.4548552	-0.787776	0.2761746	0.0500547
280	0	0.4499904	-0.798529	0.2761746	0.0502348
281	0	0.3275422	-1.116139	0.3126085	0.0545391
282	3	0.4499904	-0.798529	0.2761746	0.7176851
283	0	0.4402609	-0.820388	0.2761746	0.0505951
284	2	0.447558	-0.803949	0.2761746	0.4960897
285	0	0.3222307	-1.132488	0.3126085	0.0546998
286	0	0.4435597	-0.812923	0.2714186	0.050473
287	0	0.4435597	-0.812923	0.2714186	0.050473
288	0	0.4459573	-0.807532	0.2714186	0.0503842
289	4	0.4435597	-0.812923	0.2714186	0.9446253
290	0	0.441162	-0.818343	0.2714186	0.0505617
291	0	0.4483549	-0.80217	0.2714186	0.0502954

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Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
292	0	0.3257717	-1.121559	0.3126085	0.0545931
293	1	0.447558	-0.803949	0.2761746	0.2732073
294	0	0.441162	-0.818343	0.2714186	0.0505617
295	0	0.3275422	-1.116139	0.3126085	0.0545391
296	0	0.4339692	-0.834782	0.2714186	0.0508278
297	0	0.4387644	-0.823793	0.2714186	0.0506504
298	0	0.3257717	-1.121559	0.3126085	0.0545931
299	0	0.3137771	-1.159072	0.2761746	0.0549469
300	6	0.447558	-0.803949	0.2761746	1.3876193
301	0	0.441162	-0.818343	0.2714186	0.0505617
302	0	0.3257717	-1.121559	0.3126085	0.0545931
303	0	0.3293127	-1.110748	0.3126085	0.0544847
304	0	0.4459573	-0.807532	0.2714186	0.0503842
305	0	0.4670171	-0.761389	0.2761746	0.0496045
306	0	0.447558	-0.803949	0.2761746	0.0503249
307	0	0.4363668	-0.829272	0.2714186	0.0507391
308	0	0.447558	-0.803949	0.2761746	0.0503249
309	1	0.4499904	-0.798529	0.2761746	0.2727183
310	2	0.4499904	-0.798529	0.2761746	0.4952017
311	0	0.3293127	-1.110748	0.3126085	0.0544847
312	0	0.4459573	-0.807532	0.2714186	0.0503842
313	3	0.441162	-0.818343	0.2714186	0.7223552
314	5	0.3363946	-1.08947	0.3126085	1.2558808
315	1	0.4426933	-0.814878	0.2761746	0.2741852
316	0	0.4459573	-0.807532	0.2714186	0.0503842

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Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
317	0	0.3275422	-1.116139	0.3126085	0.0545391
318	0	0.4451256	-0.809399	0.2761746	0.050415
319	0	0.3240012	-1.127008	0.3126085	0.0546467
320	0	0.4524228	-0.793138	0.2761746	0.0501448
321	0	0.4483549	-0.80217	0.2714186	0.0502954
322	0	0.3328536	-1.100052	0.3126085	0.0543746
323	0	0.4670171	-0.761389	0.2761746	0.0496045
324	0	0.4483549	-0.80217	0.2714186	0.0502954
325	0	0.447558	-0.803949	0.2761746	0.0503249
326	1	0.4524228	-0.793138	0.2761746	0.2722292
327	0	0.4483549	-0.80217	0.2714186	0.0502954
328	0	0.441162	-0.818343	0.2714186	0.0505617
329	1	0.4435597	-0.812923	0.2714186	0.2740111
330	0	0.3275422	-1.116139	0.3126085	0.0545391
331	2	0.441162	-0.818343	0.2714186	0.498424
332	0	0.4524228	-0.793138	0.2761746	0.0501448
333	0	0.3310832	-1.105386	0.3126085	0.0544299
334	2	0.4645847	-0.766611	0.2761746	0.489875
335	0	0.447558	-0.803949	0.2761746	0.0503249
336	0	0.0551453	-2.897785	0.2714186	0.035621
337	0	0.441162	-0.818343	0.2714186	0.0505617
338	1	0.4499904	-0.798529	0.2761746	0.2727183
339	0	0.4579454	-0.781005	0.2714186	0.0499402
340	0	0.3310832	-1.105386	0.3126085	0.0544299
341	0	0.4572875	-0.782443	0.2761746	0.0499646

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Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
342	0	0.441162	-0.818343	0.2714186	0.0505617
343	0	0.447558	-0.803949	0.2761746	0.0503249
344	0	0.4483549	-0.80217	0.2714186	0.0502954
345	1	0.447558	-0.803949	0.2761746	0.2732073
346	0	0.3257717	-1.121559	0.3126085	0.0545931
347	0	0.4483549	-0.80217	0.2714186	0.0502954
348	0	0.4524228	-0.793138	0.2761746	0.0501448
349	0	0.0787443	-2.541549	0.3125298	0.043287
350	0	0.1081821	-2.22394	0.3043713	0.0494477
351	0	0.1069998	-2.234929	0.3043713	0.0492554
352	0	0.1087732	-2.21849	0.3043713	0.0495424
353	0	0.1087732	-2.21849	0.3043713	0.0495424
354	0	0.1081821	-2.22394	0.3043713	0.0494477
355	1	0.1072188	-2.232884	0.2949394	0.2675961
356	0	0.1072188	-2.232884	0.2949394	0.0492913
357	0	0.0594656	-2.822357	0.3407624	0.037257
358	0	0.0432842	-3.139966	0.3630827	0.0304787
359	0	0.0592529	-2.82594	0.3408179	0.0371792
360	0	0.0594656	-2.822357	0.3407624	0.037257
361	0	0.0449309	-3.102629	0.3630827	0.0312545
362	0	0.0594656	-2.822357	0.3407624	0.037257
363	0	0.0579787	-2.84768	0.3408179	0.0367071
364	0	0.0604352	-2.806184	0.3407624	0.0376084
365	0	0.0594656	-2.822357	0.3407624	0.037257
366	0	0.0588193	-2.833286	0.3407624	0.0370196

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367	0	0.0584961	-2.838796	0.3407624	0.0369
368	0	0.0586158	-2.836751	0.3408179	0.0369444
369	0	0.0584961	-2.838796	0.3407624	0.0369
370	0	0.0605272	-2.804663	0.3408179	0.0376414
371	0	0.0584961	-2.838796	0.3407624	0.0369
372	0	0.0435195	-3.134546	0.3630827	0.0305908
373	0	0.0456367	-3.087044	0.3630827	0.0315805
374	0	0.0435195	-3.134546	0.3630827	0.0305908
375	0	0.0594656	-2.822357	0.3407624	0.037257
376	0	0.0432842	-3.139966	0.3630827	0.0304787
377	0	0.0432842	-3.139966	0.3630827	0.0304787
378	0	0.0432842	-3.139966	0.3630827	0.0304787
379	0	0.0586158	-2.836751	0.3408179	0.0369444
380	0	0.0437547	-3.129156	0.3630827	0.0307025
381	0	0.0432842	-3.139966	0.3630827	0.0304787
382	0	0.0432842	-3.139966	0.3630827	0.0304787
383	0	0.0586158	-2.836751	0.3408179	0.0369444
384	0	0.1087732	-2.21849	0.3043713	0.0495424
385	0	0.0586158	-2.836751	0.3408179	0.0369444
386	0	0.043049	-3.145416	0.3630827	0.0303661
387	0	0.0594656	-2.822357	0.3407624	0.037257
388	0	0.0432842	-3.139966	0.3630827	0.0304787
389	1	0.0432842	-3.139966	0.3630827	0.1654646
390	0	0.0437547	-3.129156	0.3630827	0.0307025
391	0	0.0586158	-2.836751	0.3408179	0.0369444

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
392	0	0.0791746	-2.5361	0.3125298	0.0434008
393	0	0.0817564	-2.504011	0.3125298	0.0440668
394	0	0.1081821	-2.22394	0.3043713	0.0494477
395	0	0.1146848	-2.165568	0.3043713	0.0504368
396	0	0.0796049	-2.530679	0.3125298	0.0435138
397	0	0.0588193	-2.833286	0.3407624	0.0370196
398	0	0.1093644	-2.21307	0.3043713	0.0496361
399	0	0.1087732	-2.21849	0.3043713	0.0495424
400	0	0.1123202	-2.186402	0.3043713	0.0500902
401	0	0.1099555	-2.207679	0.3043713	0.0497288
402	0	0.0791746	-2.5361	0.3125298	0.0434008
403	0	0.1078015	-2.227464	0.2949394	0.0493862
404	0	0.0804655	-2.519927	0.3125298	0.0437374
405	0	0.1093644	-2.21307	0.3043713	0.0496361
406	0	0.0800352	-2.525289	0.3125298	0.043626
407	0	0.1093644	-2.21307	0.3043713	0.0496361
408	0	0.1087732	-2.21849	0.3043713	0.0495424
409	0	0.0428138	-3.150896	0.3630827	0.0302531
410	0	0.0584961	-2.838796	0.3407624	0.0369
411	0	0.043049	-3.145416	0.3630827	0.0303661
412	0	0.0597888	-2.816937	0.3407624	0.0373748
413	0	0.0444605	-3.113155	0.3630827	0.031035
414	0	0.0592529	-2.82594	0.3408179	0.0371792
415	0	0.0428138	-3.150896	0.3630827	0.0302531
416	0	0.0582972	-2.842201	0.3408179	0.036826

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The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
417	0	0.0586158	-2.836751	0.3408179	0.0369444
418	0	0.0432842	-3.139966	0.3630827	0.0304787
419	0	0.0428138	-3.150896	0.3630827	0.0302531
420	0	0.1072188	-2.232884	0.2949394	0.0492913
421	1	0.0791746	-2.5361	0.3125298	0.2356172
422	0	0.1078015	-2.227464	0.2949394	0.0493862
423	0	0.1078015	-2.227464	0.2949394	0.0493862
424	0	0.1093644	-2.21307	0.3043713	0.0496361
425	0	0.1075909	-2.229419	0.3043713	0.0493521
426	0	0.0800352	-2.525289	0.3125298	0.043626
427	0	0.1093644	-2.21307	0.3043713	0.0496361
428	0	0.1093644	-2.21307	0.3043713	0.0496361
429	0	0.0813261	-2.509288	0.3125298	0.0439578
430	0	0.1142113	-2.169705	0.2949394	0.0503685
431	0	0.0813261	-2.509288	0.3125298	0.0439578
432	0	0.1072188	-2.232884	0.2949394	0.0492913
433	0	0.1087732	-2.21849	0.3043713	0.0495424
434	0	0.1083842	-2.222073	0.2949394	0.0494802
435	0	0.1072188	-2.232884	0.2949394	0.0492913
436	0	0.1066361	-2.238334	0.2949394	0.0491955
437	0	0.0594656	-2.822357	0.3407624	0.037257
438	0	0.1095496	-2.211378	0.2949394	0.0496652
439	0	0.0597888	-2.816937	0.3407624	0.0373748
440	0	0.0589344	-2.831331	0.3408179	0.0370621
441	0	0.1105467	-2.202317	0.3043713	0.0498205

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
442	0	0.0594656	-2.822357	0.3407624	0.037257
443	0	0.1072188	-2.232884	0.2949394	0.0492913
444	0	0.1089669	-2.216711	0.2949394	0.0495732
445	0	0.0594656	-2.822357	0.3407624	0.037257
446	0	0.0597888	-2.816937	0.3407624	0.0373748
447	0	0.0791746	-2.5361	0.3125298	0.0434008
448	0	0.0425785	-3.156405	0.3630827	0.0301396
449	0	0.0586158	-2.836751	0.3408179	0.0369444
450	0	0.1087732	-2.21849	0.3043713	0.0495424
451	0	0.1072188	-2.232884	0.2949394	0.0492913
452	0	0.1136286	-2.17482	0.2949394	0.0502837
453	0	0.0435195	-3.134546	0.3630827	0.0305908
454	0	0.0620511	-2.779797	0.3407624	0.0381816
455	1	0.0484595	-3.027026	0.3630827	0.1783228
456	1	0.1130459	-2.179962	0.2949394	0.2725187
457	0	0.0588193	-2.833286	0.3407624	0.0370196
458	0	0.04399	-3.123794	0.3630827	0.0308138
459	0	0.0449309	-3.102629	0.3630827	0.0312545
460	0	0.1066361	-2.238334	0.2949394	0.0491955
461	0	0.122952	-2.095962	0.2949394	0.0515393
462	0	0.0604352	-2.806184	0.3407624	0.0376084
463	1	0.0586158	-2.836751	0.3408179	0.2005661
464	0	0.1087732	-2.21849	0.3043713	0.0495424
465	1	0.0582972	-2.842201	0.3408179	0.1999237
466	0	0.0877806	-2.432915	0.3125298	0.0455133

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
467	0	0.110715	-2.200796	0.2949394	0.0498465
468	0	0.0800352	-2.525289	0.3125298	0.043626
469	0	0.0791746	-2.5361	0.3125298	0.0434008
470	0	0.0432842	-3.139966	0.3630827	0.0304787
471	0	0.1182318	-2.135108	0.3043713	0.05093
472	0	0.0817564	-2.504011	0.3125298	0.0440668
473	1	0.0617279	-2.785019	0.3407624	0.2066671
474	0	0.0808958	-2.514593	0.3125298	0.043848
475	0	0.0787443	-2.541549	0.3125298	0.043287
476	0	0.1099555	-2.207679	0.3043713	0.0497288
477	1	0.1095496	-2.211378	0.2949394	0.2696258
478	0	0.0800352	-2.525289	0.3125298	0.043626
479	0	0.1075909	-2.229419	0.3043713	0.0493521
480	0	0.0804655	-2.519927	0.3125298	0.0437374
481	0	0.1089669	-2.216711	0.2949394	0.0495732
482	0	0.0796049	-2.530679	0.3125298	0.0435138
483	0	0.078314	-2.547029	0.3125298	0.0431724
484	0	0.0787443	-2.541549	0.3125298	0.043287
485	0	0.1060533	-2.243813	0.2949394	0.0490986
486	0	0.1069998	-2.234929	0.3043713	0.0492554
487	0	0.0787443	-2.541549	0.3125298	0.043287
488	0	0.1087732	-2.21849	0.3043713	0.0495424
489	0	0.1093644	-2.21307	0.3043713	0.0496361
490	0	0.0804655	-2.519927	0.3125298	0.0437374
491	0	0.0796049	-2.530679	0.3125298	0.0435138

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
492	0	0.1066361	-2.238334	0.2949394	0.0491955
493	2	0.1083842	-2.222073	0.2949394	0.4877624
494	0	0.1052263	-2.251642	0.3043713	0.0489595
495	0	0.1087732	-2.21849	0.3043713	0.0495424
496	0	0.1089669	-2.216711	0.2949394	0.0495732
497	0	0.0791746	-2.5361	0.3125298	0.0434008
498	0	0.0791746	-2.5361	0.3125298	0.0434008
499	0	0.1089669	-2.216711	0.2949394	0.0495732
500	0	0.1072188	-2.232884	0.2949394	0.0492913
501	0	0.1060533	-2.243813	0.2949394	0.0490986
502	0	0.0800352	-2.525289	0.3125298	0.043626
503	0	0.1087732	-2.21849	0.3043713	0.0495424
504	0	0.078314	-2.547029	0.3125298	0.0431724
505	0	0.1089669	-2.216711	0.2949394	0.0495732
506	0	0.1089669	-2.216711	0.2949394	0.0495732
507	1	0.078314	-2.547029	0.3125298	0.2343771
508	0	0.0129089	-4.349838	0.3125298	0.0115504
509	0	0.0778837	-2.552538	0.3125298	0.0430569
510	0	0.0791746	-2.5361	0.3125298	0.0434008
511	0	0.1072188	-2.232884	0.2949394	0.0492913
512	0	0.0791746	-2.5361	0.3125298	0.0434008
513	0	0.1072188	-2.232884	0.2949394	0.0492913
514	0	0.0796049	-2.530679	0.3125298	0.0435138
515	0	0.1087732	-2.21849	0.3043713	0.0495424
516	0	0.1087732	-2.21849	0.3043713	0.0495424

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
517	0	0.0791746	-2.5361	0.3125298	0.0434008
518	0	0.0796049	-2.530679	0.3125298	0.0435138
519	0	0.1083842	-2.222073	0.2949394	0.0494802
520	2	0.0804655	-2.519927	0.3125298	0.4311514
521	0	0.1087732	-2.21849	0.3043713	0.0495424
522	0	0.1072188	-2.232884	0.2949394	0.0492913
523	0	0.1072188	-2.232884	0.2949394	0.0492913
524	0	0.0791746	-2.5361	0.3125298	0.0434008
525	0	0.1093644	-2.21307	0.3043713	0.0496361
526	0	0.1093644	-2.21307	0.3043713	0.0496361
527	0	0.0800352	-2.525289	0.3125298	0.043626
528	0	0.1093644	-2.21307	0.3043713	0.0496361
529	0	0.1087732	-2.21849	0.3043713	0.0495424
530	0	0.1111379	-2.196984	0.3043713	0.0499114
531	0	0.1078015	-2.227464	0.2949394	0.0493862
532	0	0.111729	-2.191679	0.3043713	0.0500012
533	0	0.0791746	-2.5361	0.3125298	0.0434008
534	0	0.078314	-2.547029	0.3125298	0.0431724
535	0	0.1087732	-2.21849	0.3043713	0.0495424
536	0	0.1072188	-2.232884	0.2949394	0.0492913
537	0	0.1078015	-2.227464	0.2949394	0.0493862
538	0	0.1078015	-2.227464	0.2949394	0.0493862
539	0	0.1093644	-2.21307	0.3043713	0.0496361
540	2	0.1089669	-2.216711	0.2949394	0.4886791
541	0	0.1081821	-2.22394	0.3043713	0.0494477

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
542	0	0.1083842	-2.222073	0.2949394	0.0494802
543	0	0.1048879	-2.254863	0.2949394	0.048902
544	0	0.1111379	-2.196984	0.3043713	0.0499114
545	0	0.111729	-2.191679	0.3043713	0.0500012
546	0	0.1087732	-2.21849	0.3043713	0.0495424
547	0	0.1099555	-2.207679	0.3043713	0.0497288
548	0	0.0796049	-2.530679	0.3125298	0.0435138
549	0	0.1081821	-2.22394	0.3043713	0.0494477
550	0	0.1072188	-2.232884	0.2949394	0.0492913
551	0	0.1072188	-2.232884	0.2949394	0.0492913
552	0	0.1087732	-2.21849	0.3043713	0.0495424
553	0	0.1093644	-2.21307	0.3043713	0.0496361
554	0	0.1083842	-2.222073	0.2949394	0.0494802
555	0	0.1087732	-2.21849	0.3043713	0.0495424
556	0	0.111729	-2.191679	0.3043713	0.0500012
557	0	0.1078015	-2.227464	0.2949394	0.0493862
558	1	0.1093644	-2.21307	0.3043713	0.2694675
559	0	0.1087732	-2.21849	0.3043713	0.0495424
560	0	0.1089669	-2.216711	0.2949394	0.0495732
561	0	0.0791746	-2.5361	0.3125298	0.0434008
562	0	0.1078015	-2.227464	0.2949394	0.0493862
563	0	0.0586158	-2.836751	0.3408179	0.0369444
564	0	0.0800352	-2.525289	0.3125298	0.043626
565	0	0.1089669	-2.216711	0.2949394	0.0495732
566	0	0.1087732	-2.21849	0.3043713	0.0495424

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
567	0	0.0592529	-2.82594	0.3408179	0.0371792
568	1	0.0791746	-2.5361	0.3125298	0.2356172
569	1	0.1054706	-2.249323	0.2949394	0.2660187
570	1	0.0796049	-2.530679	0.3125298	0.2362307
571	2	0.1093644	-2.21307	0.3043713	0.489299
572	0	0.0817564	-2.504011	0.3125298	0.0440668
573	0	0.1111379	-2.196984	0.3043713	0.0499114
574	0	0.0804655	-2.519927	0.3125298	0.0437374
575	0	0.0791746	-2.5361	0.3125298	0.0434008
576	0	0.1111379	-2.196984	0.3043713	0.0499114
577	0	0.1078015	-2.227464	0.2949394	0.0493862
578	0	0.1066361	-2.238334	0.2949394	0.0491955
579	0	0.0791746	-2.5361	0.3125298	0.0434008
580	0	0.0791746	-2.5361	0.3125298	0.0434008
581	0	0.1078015	-2.227464	0.2949394	0.0493862
582	0	0.1072188	-2.232884	0.2949394	0.0492913
583	0	0.1087732	-2.21849	0.3043713	0.0495424
584	0	0.0428138	-3.150896	0.3630827	0.0302531
585	0	0.0589344	-2.831331	0.3408179	0.0370621
586	0	0.0605272	-2.804663	0.3408179	0.0376414
587	0	0.0586158	-2.836751	0.3408179	0.0369444
588	0	0.0594656	-2.822357	0.3407624	0.037257
589	0	0.060112	-2.811546	0.3407624	0.0374919
590	0	0.0432842	-3.139966	0.3630827	0.0304787
591	0	0.0586158	-2.836751	0.3408179	0.0369444

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
592	0	0.0586158	-2.836751	0.3408179	0.0369444
593	0	0.0432842	-3.139966	0.3630827	0.0304787
594	0	0.0597888	-2.816937	0.3407624	0.0373748
595	0	0.0432842	-3.139966	0.3630827	0.0304787
596	0	0.0639902	-2.749026	0.3407624	0.0388496
597	0	0.0594656	-2.822357	0.3407624	0.037257
598	0	0.0594656	-2.822357	0.3407624	0.037257
599	0	0.0584961	-2.838796	0.3407624	0.0369
600	0	0.0582972	-2.842201	0.3408179	0.036826
601	0	0.0437547	-3.129156	0.3630827	0.0307025
602	0	0.0588193	-2.833286	0.3407624	0.0370196
603	0	0.0796049	-2.530679	0.3125298	0.0435138
604	0	0.0584961	-2.838796	0.3407624	0.0369
605	0	0.0586158	-2.836751	0.3408179	0.0369444
606	0	0.0586158	-2.836751	0.3408179	0.0369444
607	0	0.043049	-3.145416	0.3630827	0.0303661
608	0	0.0804655	-2.519927	0.3125298	0.0437374
609	0	0.0594656	-2.822357	0.3407624	0.037257
610	0	0.0437547	-3.129156	0.3630827	0.0307025
611	0	0.0602086	-2.80994	0.3408179	0.0375268
612	0	0.0432842	-3.139966	0.3630827	0.0304787
613	0	0.0589344	-2.831331	0.3408179	0.0370621
614	0	0.0597888	-2.816937	0.3407624	0.0373748
615	0	0.0591424	-2.827807	0.3407624	0.0371386
616	0	0.0594656	-2.822357	0.3407624	0.037257

Hypoglycaemic episodes - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=SEV_HYPO Parameter=Severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
617	0	0.0425785	-3.156405	0.3630827	0.0301396
618	0	0.0589344	-2.831331	0.3408179	0.0370621
619	0	0.0432842	-3.139966	0.3630827	0.0304787
620	0	0.0607583	-2.800851	0.3407624	0.0377243
621	0	0.0446957	-3.107878	0.3630827	0.0311449
622	0	0.0591424	-2.827807	0.3407624	0.0371386
623	0	0.0432842	-3.139966	0.3630827	0.0304787
624	0	0.0586158	-2.836751	0.3408179	0.0369444
625	0	0.0579787	-2.84768	0.3408179	0.0367071
626	0	0.0594656	-2.822357	0.3407624	0.037257
627	0	0.0261117	-3.645372	0.3630827	0.0209789
628	0	0.0608458	-2.799413	0.3408179	0.0377555
629	1	0.0604352	-2.806184	0.3407624	0.2041709
630	0	0.0589344	-2.831331	0.3408179	0.0370621
631	0	0.0428138	-3.150896	0.3630827	0.0302531
632	0	0.0597888	-2.816937	0.3407624	0.0373748
633	0	0.0582972	-2.842201	0.3408179	0.036826
634	0	0.04399	-3.123794	0.3630827	0.0308138
635	0	0.0586158	-2.836751	0.3408179	0.0369444
636	0	0.0604352	-2.806184	0.3407624	0.0376084
637	0	0.0591424	-2.827807	0.3407624	0.0371386
638	0	0.06435	-2.743419	0.3408179	0.0389712
639	0	0.043049	-3.145416	0.3630827	0.0303661
640	0	0.0588193	-2.833286	0.3407624	0.0370196
641	0	0.0432842	-3.139966	0.3630827	0.0304787

Hypoglycaemic episodes - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=SEV_HYPO Parameter=Severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
642	0	0.1078015	-2.227464	0.2949394	0.0493862
643	0	0.0597888	-2.816937	0.3407624	0.0373748
644	0	0.1066361	-2.238334	0.2949394	0.0491955
645	0	0.0594656	-2.822357	0.3407624	0.037257
646	0	0.0791746	-2.5361	0.3125298	0.0434008
647	0	0.0594656	-2.822357	0.3407624	0.037257
648	0	0.0791746	-2.5361	0.3125298	0.0434008
649	0	0.110715	-2.200796	0.2949394	0.0498465
650	0	0.0800352	-2.525289	0.3125298	0.043626
651	0	0.0586158	-2.836751	0.3408179	0.0369444
652	0	0.0432842	-3.139966	0.3630827	0.0304787
653	0	0.0432842	-3.139966	0.3630827	0.0304787
654	0	0.0804655	-2.519927	0.3125298	0.0437374
655	0	0.1060533	-2.243813	0.2949394	0.0490986
656	0	0.0800352	-2.525289	0.3125298	0.043626
657	0	0.1083842	-2.222073	0.2949394	0.0494802
658	1	0.1066361	-2.238334	0.2949394	0.2670756
659	0	0.0882109	-2.428025	0.3125298	0.0456112
660	0	0.1087732	-2.21849	0.3043713	0.0495424
661	1	0.060112	-2.811546	0.3407624	0.2035384
662	0	0.0632536	-2.760603	0.3125298	0.0385984
663	0	0.1480085	-1.910485	0.2949394	0.0540037
664	0	0.1095496	-2.211378	0.2949394	0.0496652
665	0	0.1136286	-2.17482	0.2949394	0.0502837
666	0	0.111729	-2.191679	0.3043713	0.0500012

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Hypoglycaemic episodes - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=SEV_HYPO Parameter=Severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
667	0	0.1099555	-2.207679	0.3043713	0.0497288
668	0	0.0640982	-2.747339	0.2949394	0.0388862
669	0	0.0973127	-2.329826	0.2949394	0.0475225
670	0	0.0610815	-2.795546	0.3407624	0.0378395
671	0	0.0428138	-3.150896	0.3630827	0.0302531
672	0	0.0607583	-2.800851	0.3407624	0.0377243
673	0	0.0594656	-2.822357	0.3407624	0.037257
674	0	0.0432842	-3.139966	0.3630827	0.0304787
675	0	0.0432842	-3.139966	0.3630827	0.0304787
676	0	0.0586158	-2.836751	0.3408179	0.0369444
677	1	0.0579787	-2.84768	0.3408179	0.1992779
678	1	0.0639902	-2.749026	0.3407624	0.2109093
679	0	0.043049	-3.145416	0.3630827	0.0303661
680	0	0.0586158	-2.836751	0.3408179	0.0369444
681	0	0.0435195	-3.134546	0.3630827	0.0305908
682	0	0.0432842	-3.139966	0.3630827	0.0304787
683	0	0.0605272	-2.804663	0.3408179	0.0376414
684	0	0.0573415	-2.85873	0.3408179	0.0364673
685	0	0.0594656	-2.822357	0.3407624	0.037257
686	0	0.04399	-3.123794	0.3630827	0.0308138
687	0	0.0620511	-2.779797	0.3407624	0.0381816
688	0	0.0576601	-2.85319	0.3408179	0.0365875
689	0	0.0586158	-2.836751	0.3408179	0.0369444
690	0	0.0586158	-2.836751	0.3408179	0.0369444
691	0	0.0579787	-2.84768	0.3408179	0.0367071

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Hypoglycaemic episodes - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=SEV_HYPO Parameter=Severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
692	0	0.0435195	-3.134546	0.3630827	0.0305908
693	0	0.0594656	-2.822357	0.3407624	0.037257
694	0	0.441162	-0.818343	0.2714186	0.0505617
695	0	0.4507525	-0.796837	0.2714186	0.0502066
696	0	0.447558	-0.803949	0.2761746	0.0503249
697	1	0.4315716	-0.840322	0.2714186	0.276418
698	0	0.4426933	-0.814878	0.2761746	0.0505051
699	0	0.4339692	-0.834782	0.2714186	0.0508278
700	0	0.4645847	-0.766611	0.2761746	0.0496945
701	0	0.3257717	-1.121559	0.3126085	0.0545931
702	0	0.441162	-0.818343	0.2714186	0.0505617
703	0	0.4243787	-0.857129	0.2714186	0.0511817
704	0	0.3257717	-1.121559	0.3126085	0.0545931
705	0	0.4387644	-0.823793	0.2714186	0.0506504
706	0	0.4363668	-0.829272	0.2714186	0.0507391
707	0	0.3222307	-1.132488	0.3126085	0.0546998
708	0	0.4524228	-0.793138	0.2761746	0.0501448
709	0	0.441162	-0.818343	0.2714186	0.0505617
710	0	0.3257717	-1.121559	0.3126085	0.0545931
711	0	0.4402609	-0.820388	0.2761746	0.0505951
712	0	0.4402609	-0.820388	0.2761746	0.0505951
713	0	0.441162	-0.818343	0.2714186	0.0505617
714	0	0.4339692	-0.834782	0.2714186	0.0508278
715	0	0.4147882	-0.879987	0.2714186	0.0515341
716	0	0.447558	-0.803949	0.2761746	0.0503249

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Hypoglycaemic episodes - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=SEV_HYPO Parameter=Severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
717	0	0.3240012	-1.127008	0.3126085	0.0546467
718	0	0.4387644	-0.823793	0.2714186	0.0506504
719	0	0.3257717	-1.121559	0.3126085	0.0545931
720	3	0.441162	-0.818343	0.2714186	0.7223552
721	0	0.441162	-0.818343	0.2714186	0.0505617
722	0	0.3240012	-1.127008	0.3126085	0.0546467
723	0	0.3240012	-1.127008	0.3126085	0.0546467
724	0	0.3257717	-1.121559	0.3126085	0.0545931
725	0	0.0745334	-2.596508	0.3094857	0.0421292
726	0	0.0981972	-2.320777	0.3427234	0.047693
727	0	0.1406176	-1.961711	0.3325449	0.0533977
728	0	0.0966385	-2.336778	0.3427234	0.0473908
729	0	0.1484694	-1.907377	0.3325449	0.0540385
730	0	0.0940407	-2.364027	0.3427234	0.0468691
731	0	0.1033929	-2.269219	0.3427234	0.0486438
732	0	0.0745334	-2.596508	0.3094857	0.0421292
733	0	0.070391	-2.65369	0.3272066	0.0409085
734	0	0.070391	-2.65369	0.3272066	0.0409085
735	0	0.0718018	-2.633846	0.3094857	0.0413337
736	0	0.0508434	-2.979005	0.3366477	0.0338716
737	0	0.0561927	-2.878968	0.3094857	0.0360284
738	0	0.1306245	-2.035429	0.3325449	0.0524234
739	0	0.070391	-2.65369	0.3272066	0.0409085
740	0	0.0719296	-2.632067	0.3272066	0.0413717
741	0	0.0737529	-2.607035	0.3094857	0.0419056

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Hypoglycaemic episodes - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=SEV_HYPO Parameter=Severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
742	0	0.1320521	-2.024559	0.3325449	0.0525743
743	0	0.1320521	-2.024559	0.3325449	0.0525743
744	0	0.0707757	-2.64824	0.3272066	0.0410254
745	0	0.070391	-2.65369	0.3272066	0.0409085
746	0	0.0531157	-2.935283	0.3366477	0.0348112
747	0	0.1313383	-2.029979	0.3325449	0.0524994
748	0	0.071545	-2.637429	0.3272066	0.041257
749	0	0.0955994	-2.347588	0.3427234	0.0471849
750	0	0.0539678	-2.919367	0.3366477	0.0351545
751	0	0.1294613	-2.044373	0.3408495	0.0522974
752	0	0.1313383	-2.029979	0.3325449	0.0524994
753	0	0.0525476	-2.946035	0.3366477	0.0345796
754	0	0.1306245	-2.035429	0.3325449	0.0524234
755	0	0.0542519	-2.914118	0.3366477	0.0352679
756	0	0.0522636	-2.951455	0.3366477	0.034463
757	1	0.0519795	-2.956905	0.3366477	0.1864588
758	0	0.0707757	-2.64824	0.3272066	0.0410254
759	0	0.0718018	-2.633846	0.3094857	0.0413337
760	0	0.0707757	-2.64824	0.3272066	0.0410254
761	0	0.0525476	-2.946035	0.3366477	0.0345796
762	0	0.070391	-2.65369	0.3272066	0.0409085
763	0	0.0522636	-2.951455	0.3366477	0.034463
764	0	0.0531157	-2.935283	0.3366477	0.0348112
765	0	0.070391	-2.65369	0.3272066	0.0409085
766	0	0.1308685	-2.033562	0.3408495	0.0524495

Hypoglycaemic episodes - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=SEV_HYPO Parameter=Severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
767	0	0.0707757	-2.64824	0.3272066	0.0410254
768	0	0.0714116	-2.639296	0.3094857	0.0412171
769	0	0.0525476	-2.946035	0.3366477	0.0345796
770	1	0.0734682	-2.610902	0.3272066	0.227053
771	0	0.0525476	-2.946035	0.3366477	0.0345796
772	0	0.0711603	-2.64282	0.3272066	0.0411416
773	0	0.0514115	-2.967894	0.3366477	0.0341098
774	0	0.0528317	-2.940645	0.3366477	0.0346956
775	0	0.0707757	-2.64824	0.3272066	0.0410254
776	0	0.0522636	-2.951455	0.3366477	0.034463
777	0	0.0718018	-2.633846	0.3094857	0.0413337
778	0	0.0525476	-2.946035	0.3366477	0.0345796
779	0	0.0226332	-3.788339	0.3094857	0.018697
780	1	0.0718018	-2.633846	0.3094857	0.224395
781	0	0.1313383	-2.029979	0.3325449	0.0524994
782	0	0.0528317	-2.940645	0.3366477	0.0346956
783	0	0.0707757	-2.64824	0.3272066	0.0410254
784	0	0.0745334	-2.596508	0.3094857	0.0421292
785	0	0.0516955	-2.962385	0.3366477	0.0342281
786	0	0.1313383	-2.029979	0.3325449	0.0524994
787	0	0.1313383	-2.029979	0.3325449	0.0524994
788	0	0.0533997	-2.929949	0.3366477	0.0349262
789	0	0.1313383	-2.029979	0.3325449	0.0524994
790	0	0.0734682	-2.610902	0.3272066	0.0418233
791	0	0.0602167	-2.809805	0.3366477	0.0375297

Hypoglycaemic episodes - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=SEV_HYPO Parameter=Severe hypoglycaemic episodes Study Identifier=NN1218-4131

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
792	1	0.0741431	-2.601758	0.3094857	0.2281088
793	0	0.0707757	-2.64824	0.3272066	0.0410254
794	0	0.0711603	-2.64282	0.3272066	0.0411416
795	0	0.071545	-2.637429	0.3272066	0.041257
796	2	0.0718018	-2.633846	0.3094857	0.4074564
797	0	0.0522636	-2.951455	0.3366477	0.034463
798	0	0.0718018	-2.633846	0.3094857	0.0413337
799	0	0.1336829	-2.012285	0.3408495	0.0527418
800	0	0.1384762	-1.977057	0.3325449	0.0532046
801	0	0.1399038	-1.9668	0.3325449	0.0533342
802	0	0.1306245	-2.035429	0.3325449	0.0524234
803	0	0.0955994	-2.347588	0.3427234	0.0471849
804	0	0.1294613	-2.044373	0.3408495	0.0522974
805	0	0.1329793	-2.017562	0.3408495	0.0526702
806	0	0.0997559	-2.305029	0.3427234	0.0479872
807	0	0.1308685	-2.033562	0.3408495	0.0524495
808	0	0.1364973	-1.991451	0.3408495	0.0530187
809	0	0.0966385	-2.336778	0.3427234	0.0473908
810	0	0.0976777	-2.326082	0.3427234	0.0475932
811	0	0.1343865	-2.007035	0.3408495	0.0528125
812	0	0.0749236	-2.591286	0.3094857	0.0422399
813	0	0.0733627	-2.61234	0.3094857	0.0417927
814	0	0.0565242	-2.873086	0.3366477	0.0361559
815	0	0.0690702	-2.672632	0.3094857	0.0405013
816	0	0.072192	-2.628426	0.3094857	0.0414495

Hypoglycaemic episodes - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=SEV_HYPO Parameter=Severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
817	0	0.0955994	-2.347588	0.3427234	0.0471849
818	0	0.0706311	-2.650285	0.3094857	0.0409816
819	0	0.070391	-2.65369	0.3272066	0.0409085
820	0	0.0738529	-2.60568	0.3272066	0.0419344
821	0	0.0734682	-2.610902	0.3272066	0.0418233
822	0	0.0556721	-2.888277	0.3366477	0.0358268
823	0	0.0516955	-2.962385	0.3366477	0.0342281
824	0	0.072192	-2.628426	0.3094857	0.0414495
825	0	0.072192	-2.628426	0.3094857	0.0414495
826	0	0.0696217	-2.664679	0.3272066	0.0406724
827	0	0.1313383	-2.029979	0.3325449	0.0524994
828	0	0.0788259	-2.540514	0.3094857	0.0433086
829	0	0.0519795	-2.956905	0.3366477	0.0343458
830	0	0.0542519	-2.914118	0.3366477	0.0352679
831	0	0.0742375	-2.600485	0.3272066	0.0420448
832	0	0.0707757	-2.64824	0.3272066	0.0410254
833	0	0.0522636	-2.951455	0.3366477	0.034463
834	0	0.0522636	-2.951455	0.3366477	0.034463
835	0	0.0741431	-2.601758	0.3094857	0.0420178
836	0	0.1343865	-2.007035	0.3408495	0.0528125
837	0	0.1343865	-2.007035	0.3408495	0.0528125
838	0	0.1313383	-2.029979	0.3325449	0.0524994
839	0	0.1299107	-2.040908	0.3325449	0.0523464
840	1	0.1294613	-2.044373	0.3408495	0.2839156
841	0	0.0976777	-2.326082	0.3427234	0.0475932

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Hypoglycaemic episodes - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=SEV_HYPO Parameter=Severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
842	0	0.1350901	-2.001813	0.3408495	0.0528821
843	0	0.1287578	-2.049823	0.3408495	0.0522198
844	0	0.1313383	-2.029979	0.3325449	0.0524994
845	0	0.1386081	-1.976105	0.3408495	0.0532167
846	0	0.1320521	-2.024559	0.3325449	0.0525743
847	0	0.1294613	-2.044373	0.3408495	0.0522974
848	0	0.0955994	-2.347588	0.3427234	0.0471849
849	0	0.0966385	-2.336778	0.3427234	0.0473908
850	1	0.1313383	-2.029979	0.3325449	0.2850122
851	1	0.1327659	-2.019168	0.3325449	0.2858205
852	4	0.0955994	-2.347588	0.3427234	0.8830876
853	0	0.0955994	-2.347588	0.3427234	0.0471849
854	0	0.0707757	-2.64824	0.3272066	0.0410254
855	0	0.0707757	-2.64824	0.3272066	0.0410254
856	0	0.0522636	-2.951455	0.3366477	0.034463
857	0	0.0522636	-2.951455	0.3366477	0.034463
858	0	0.0784356	-2.545477	0.3094857	0.0432049
859	0	0.077265	-2.560515	0.3094857	0.0428895
860	0	0.0955994	-2.347588	0.3427234	0.0471849
861	0	0.1327659	-2.019168	0.3325449	0.0526483
862	0	0.1287578	-2.049823	0.3408495	0.0522198
863	0	0.0514115	-2.967894	0.3366477	0.0341098
864	0	0.0955994	-2.347588	0.3427234	0.0471849
865	0	0.0531157	-2.935283	0.3366477	0.0348112
866	0	0.0531157	-2.935283	0.3366477	0.0348112

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Hypoglycaemic episodes - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=SEV_HYPO Parameter=Severe hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
867	0	0.070391	-2.65369	0.3272066	0.0409085
868	0	0.0757041	-2.580924	0.3094857	0.0424593
869	0	0.0531157	-2.935283	0.3366477	0.0348112
870	0	0.0700064	-2.659169	0.3272066	0.0407908
871	0	0.1313383	-2.029979	0.3325449	0.0524994
872	0	0.0725822	-2.623035	0.3094857	0.0415647
873	0	0.071545	-2.637429	0.3272066	0.041257
874	0	0.0711603	-2.64282	0.3272066	0.0411416
875	0	0.0729725	-2.617673	0.3094857	0.041679
876	0	0.0725822	-2.623035	0.3094857	0.0415647
877	0	0.071545	-2.637429	0.3272066	0.041257
878	0	0.0514115	-2.967894	0.3366477	0.0341098
879	0	0.0714116	-2.639296	0.3094857	0.0412171
880	0	0.0522636	-2.951455	0.3366477	0.034463
881	0	0.0714116	-2.639296	0.3094857	0.0412171
882	0	0.0222429	-3.80573	0.3094857	0.0184325
883	2	0.0710213	-2.644775	0.3094857	0.4051498
884	1	0.0707757	-2.64824	0.3272066	0.2227215
885	0	0.070391	-2.65369	0.3272066	0.0409085
886	0	0.0531157	-2.935283	0.3366477	0.0348112
887	0	0.0707757	-2.64824	0.3272066	0.0410254
888	0	0.0718018	-2.633846	0.3094857	0.0413337
889	0	0.0707757	-2.64824	0.3272066	0.0410254
890	0	0.0539678	-2.919367	0.3366477	0.0351545
891	0	0.0519795	-2.956905	0.3366477	0.0343458

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
892	0	0.0700064	-2.659169	0.3272066	0.0407908
893	0	0.0525476	-2.946035	0.3366477	0.0345796
894	0	0.0519795	-2.956905	0.3366477	0.0343458
895	0	0.0738529	-2.60568	0.3272066	0.0419344
896	0	0.0707757	-2.64824	0.3272066	0.0410254
897	3	0.0950799	-2.353038	0.3427234	0.6726212
898	0	0.0725822	-2.623035	0.3094857	0.0415647
899	0	0.0505593	-2.984608	0.3366477	0.0337516
900	0	0.0522636	-2.951455	0.3366477	0.034463
901	0	0.0714116	-2.639296	0.3094857	0.0412171
902	0	0.0714116	-2.639296	0.3094857	0.0412171
903	1	0.0725822	-2.623035	0.3094857	0.225649
904	0	0.0519795	-2.956905	0.3366477	0.0343458
905	0	0.1294613	-2.044373	0.3408495	0.0522974
906	0	0.1357937	-1.996619	0.3408495	0.0529509
907	0	0.0522636	-2.951455	0.3366477	0.034463
908	0	0.1313383	-2.029979	0.3325449	0.0524994
909	0	0.0955994	-2.347588	0.3427234	0.0471849
910	1	0.1287578	-2.049823	0.3408495	0.2834944
911	0	0.0514115	-2.967894	0.3366477	0.0341098
912	0	0.1336829	-2.012285	0.3408495	0.0527418
913	0	0.096119	-2.342168	0.3427234	0.0472883
914	0	0.0966385	-2.336778	0.3427234	0.0473908
915	0	0.1334797	-2.013806	0.3325449	0.0527212
916	0	0.1287578	-2.049823	0.3408495	0.0522198

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
917	0	0.1287578	-2.049823	0.3408495	0.0522198
918	0	0.072192	-2.628426	0.3094857	0.0414495
919	0	0.0725822	-2.623035	0.3094857	0.0415647
920	0	0.1306245	-2.035429	0.3325449	0.0524234
921	0	0.0711603	-2.64282	0.3272066	0.0411416
922	0	0.1356211	-1.997891	0.3325449	0.0529341
923	0	0.072192	-2.628426	0.3094857	0.0414495
924	0	0.0528317	-2.940645	0.3366477	0.0346956
925	0	0.1313383	-2.029979	0.3325449	0.0524994
926	0	0.0522636	-2.951455	0.3366477	0.034463
927	0	0.0711603	-2.64282	0.3272066	0.0411416
928	0	0.0955994	-2.347588	0.3427234	0.0471849
929	0	0.072192	-2.628426	0.3094857	0.0414495
930	0	0.1306245	-2.035429	0.3325449	0.0524234
931	1	0.0945603	-2.358518	0.3427234	0.2550226
932	0	0.0525476	-2.946035	0.3366477	0.0345796
933	0	0.0823205	-2.497135	0.3408495	0.0442085
934	0	0.1327659	-2.019168	0.3325449	0.0526483
935	0	0.1313383	-2.029979	0.3325449	0.0524994
936	0	0.0707757	-2.64824	0.3272066	0.0410254
937	0	0.1313383	-2.029979	0.3325449	0.0524994
938	0	0.1018342	-2.28441	0.3427234	0.0483674
939	0	0.0525476	-2.946035	0.3366477	0.0345796
940	0	0.0718018	-2.633846	0.3094857	0.0413337
941	0	0.1273506	-2.060812	0.3408495	0.0520615

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Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
942	0	0.0749236	-2.591286	0.3094857	0.0422399
943	0	0.0516955	-2.962385	0.3366477	0.0342281
944	0	0.0718018	-2.633846	0.3094857	0.0413337
945	0	0.0710213	-2.644775	0.3094857	0.0410997
946	0	0.1313383	-2.029979	0.3325449	0.0524994
947	0	0.0593646	-2.824057	0.3366477	0.0372201
948	0	0.0542519	-2.914118	0.3366477	0.0352679
949	0	0.0525476	-2.946035	0.3366477	0.0345796
950	0	0.1350901	-2.001813	0.3408495	0.0528821
951	0	0.072192	-2.628426	0.3094857	0.0414495
952	1	0.1506107	-1.893057	0.3325449	0.2942224
953	0	0.0707757	-2.64824	0.3272066	0.0410254
954	0	0.0730836	-2.616152	0.3272066	0.0417115
955	0	0.0519795	-2.956905	0.3366477	0.0343458
956	0	0.0718018	-2.633846	0.3094857	0.0413337
957	0	0.1313383	-2.029979	0.3325449	0.0524994
958	0	0.0706311	-2.650285	0.3094857	0.0409816
959	0	0.0522636	-2.951455	0.3366477	0.034463
960	0	0.0522636	-2.951455	0.3366477	0.034463
961	0	0.0718018	-2.633846	0.3094857	0.0413337
962	0	0.1313383	-2.029979	0.3325449	0.0524994
963	0	0.0718018	-2.633846	0.3094857	0.0413337
964	0	0.0734682	-2.610902	0.3272066	0.0418233
965	0	0.1320521	-2.024559	0.3325449	0.0525743
966	0	0.0707757	-2.64824	0.3272066	0.0410254

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Parameter Code=SEV_HYPO Parameter=Severe hypoglycaemic episodes Study Identifier=NN1218-4131

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
967	0	0.072192	-2.628426	0.3094857	0.0414495
968	0	0.0191211	-3.956961	0.3094857	0.016252
969	0	0.0694604	-2.666998	0.3094857	0.0406225
970	0	0.0723143	-2.626734	0.3272066	0.0414857
971	0	0.1294613	-2.044373	0.3408495	0.0522974
972	0	0.0522636	-2.951455	0.3366477	0.034463
973	0	0.0971581	-2.331416	0.3427234	0.0474925
974	0	0.1294613	-2.044373	0.3408495	0.0522974
975	0	0.0950799	-2.353038	0.3427234	0.0470806
976	0	0.1313383	-2.029979	0.3325449	0.0524994
977	0	0.0719296	-2.632067	0.3272066	0.0413717
978	0	0.1287578	-2.049823	0.3408495	0.0522198
979	0	0.0745334	-2.596508	0.3094857	0.0421292
980	0	0.1329793	-2.017562	0.3408495	0.0526702
981	0	0.1299107	-2.040908	0.3325449	0.0523464
982	0	0.1406176	-1.961711	0.3325449	0.0533977
983	0	0.0750068	-2.590176	0.3272066	0.0422635
984	1	0.0714116	-2.639296	0.3094857	0.2237619
985	0	0.070391	-2.65369	0.3272066	0.0409085
986	0	0.096119	-2.342168	0.3427234	0.0472883
987	0	0.0522636	-2.951455	0.3366477	0.034463
988	0	0.0700064	-2.659169	0.3272066	0.0407908
989	0	0.0700064	-2.659169	0.3272066	0.0407908
990	0	0.0725822	-2.623035	0.3094857	0.0415647
991	0	0.0707757	-2.64824	0.3272066	0.0410254

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Parameter Code=SEV_HYPO Parameter=Severe hypoglycaemic episodes Study Identifier=NN1218-4131

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
992	0	0.0676985	-2.692692	0.3272066	0.0400689
993	0	0.0522636	-2.951455	0.3366477	0.034463
994	1	0.071545	-2.637429	0.3272066	0.2239789
995	0	0.0522636	-2.951455	0.3366477	0.034463
996	0	0.0525476	-2.946035	0.3366477	0.0345796
997	0	0.0434655	-3.135788	0.3272066	0.0305651
998	0	0.1284831	-2.051958	0.3325449	0.0521892
999	0	0.0738529	-2.60568	0.3272066	0.0419344
1000	0	0.072192	-2.628426	0.3094857	0.0414495
1001	0	0.1377624	-1.982225	0.3325449	0.0531384
1002	0	0.0950799	-2.353038	0.3427234	0.0470806
1003	0	0.0603901	-2.80693	0.3272066	0.0375922
1004	0	0.0198829	-3.917896	0.3366477	0.0167948
1005	0	0.0711603	-2.64282	0.3272066	0.0411416
1006	0	0.0718018	-2.633846	0.3094857	0.0413337
1007	0	0.072192	-2.628426	0.3094857	0.0414495
1008	0	0.0707757	-2.64824	0.3272066	0.0410254
1009	0	0.0726989	-2.621429	0.3272066	0.0415989
1010	0	0.0516955	-2.962385	0.3366477	0.0342281
1011	0	0.0803868	-2.520906	0.3094857	0.0437171
1012	0	0.0714116	-2.639296	0.3094857	0.0412171
1013	0	0.0725822	-2.623035	0.3094857	0.0415647
1014	0	0.0528317	-2.940645	0.3366477	0.0346956
1015	0	0.072192	-2.628426	0.3094857	0.0414495
1016	0	0.0536838	-2.924644	0.3366477	0.0350406

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Parameter Code=SEV_HYPO Parameter=Severe hypoglycaemic episodes Study Identifier=NN1218-4131

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
1017	0	0.0519795	-2.956905	0.3366477	0.0343458
1018	0	0.0707757	-2.64824	0.3272066	0.0410254
1019	0	0.1313383	-2.029979	0.3325449	0.0524994
1020	0	0.0729725	-2.617673	0.3094857	0.041679
1021	0	0.0528317	-2.940645	0.3366477	0.0346956
1022	0	0.0718018	-2.633846	0.3094857	0.0413337
1023	0	0.0707757	-2.64824	0.3272066	0.0410254
1024	0	0.0707757	-2.64824	0.3272066	0.0410254
1025	0	0.0707757	-2.64824	0.3272066	0.0410254

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31: Daytime hypoglycaemic episodes - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=HYDSEBGC Parameter=Daytime severe or BG confirmed hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Model Information			
Data Set	WORK.ENDPOINT		
Distribution	Negative Binomial		
Link Function	Log		
Dependent Variable	AVAL	Analysis Value	
Offset Variable	log_offset		
Number of Observations Read	1025		
Number of Observations Used	1025		

Class Level Information		
Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Parameter Information				
Parameter	Effect	TRTPN	REGION1	BOLAD1
Prm1	Intercept			
Prm2	TRTPN	2		
Prm3	TRTPN	3		
Prm4	TRTPN	4		
Prm5	REGION1		ASIA (EXCLUDING JAPAN)	
Prm6	REGION1		EUROPE	

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Parameter Code=HYDSEBGC Parameter=Daytime severe or BG confirmed hypoglycaemic episodes Study Identifier=NN1218-4131

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Parameter Information

Parameter	Effect	TRTPN	REGION1	BOLAD1
Prm7	REGION1		JAPAN	
Prm8	REGION1		NORTH AMERICA	
Prm9	BOLAD1			BOLUS INSULIN ALGORITHM (SLIDING SCALE)
Prm10	BOLAD1			CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Criteria For Assessing Goodness Of Fit

Criterion	DF	Value	Value/DF
Deviance	1018	1207.6884	1.1863
Scaled Deviance	1018	1207.6884	1.1863
Pearson Chi-Square	1018	803.2095	0.7890
Scaled Pearson X2	1018	803.2095	0.7890
Log Likelihood		39858.1238	
Full Log Likelihood		-3916.6781	
AIC (smaller is better)		7849.3562	
AICC (smaller is better)		7849.4979	
BIC (smaller is better)		7888.8158	

Algorithm converged.

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Parameter Code=HYDSEBGC Parameter=Daytime severe or BG confirmed hypoglycaemic episodes Study Identifier=NN1218-4131

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Analysis Of Maximum Likelihood Parameter Estimates

Parameter		DF	Estimate	Standard Error	Wald 95% Confidence Limits	Wald Chi-Square
Intercept		1	8.2123	0.0936	8.0288 8.3958	7694.32
TRTPN	2	1	-0.1732	0.0937	-0.3568 0.0105	3.41
TRTPN	3	1	-0.0232	0.0940	-0.2074 0.1610	0.06
TRTPN	4	0	0.0000	0.0000	0.0000 0.0000	.
REGION1	ASIA (EXCLUDING JAPAN)	1	-0.1218	0.1395	-0.3953 0.1517	0.76
REGION1	EUROPE	1	-0.0999	0.0980	-0.2919 0.0921	1.04
REGION1	JAPAN	1	-0.0883	0.1104	-0.3047 0.1281	0.64
REGION1	NORTH AMERICA	0	0.0000	0.0000	0.0000 0.0000	.
BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	1	0.0901	0.0861	-0.0785 0.2588	1.10
BOLAD1	CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY	0	0.0000	0.0000	0.0000 0.0000	.
Dispersion		1	1.4386	0.0653	1.3161 1.5725	

Analysis Of Maximum Likelihood Parameter Estimates

Parameter	Pr > ChiSq
Intercept	<.0001
TRTPN 2	0.0646
TRTPN 3	0.8050
TRTPN 4	.
REGION1 ASIA (EXCLUDING JAPAN)	0.3829
REGION1 EUROPE	0.3079
REGION1 JAPAN	0.4239
REGION1 NORTH AMERICA	.
BOLAD1 BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.2950
BOLAD1 CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY	.
Dispersion	

NOTE: The negative binomial dispersion parameter was estimated by maximum likelihood.

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Coefficients for TRTPN Least Squares Means Using WORK.ENDPOINT Margins

Parameter	Geographic Region Grouping Method 1
Intercept	
Planned Treatment (N) 2	
Planned Treatment (N) 3	
Planned Treatment (N) 4	
Geographic Region Grouping Method 1 ASIA (EXCLUDING JAPAN)	ASIA (EXCLUDING JAPAN)
Geographic Region Grouping Method 1 EUROPE	EUROPE
Geographic Region Grouping Method 1 JAPAN	JAPAN
Geographic Region Grouping Method 1 NORTH AMERICA	NORTH AMERICA
Bolus Adjustment Method at Timepoint 1 BOLUS INSULIN ALGORITHM (SLIDING SCALE)	
Bolus Adjustment Method at Timepoint 1 CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY	

Coefficients for TRTPN Least Squares Means Using WORK.ENDPOINT Margins

Bolus Adjustment Method at Timepoint 1	Planned Treatment (N)	Row1	Row2	Row3
	1	1	1	1
	2	1		
	3		1	
	4			1
		0.1307	0.1307	0.1307
		0.3366	0.3366	0.3366
		0.239	0.239	0.239
		0.2937	0.2937	0.2937
BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.5824	0.5824	0.5824
CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0.4176	0.4176	0.4176

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The GENMOD Procedure

TRTPN Least Squares Means

Planned Treatment (N)	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
2	WORK.ENDPOINT	8.0210	0.06639	120.82	<.0001	0.05	7.8909	8.1511
3	WORK.ENDPOINT	8.1709	0.06645	122.96	<.0001	0.05	8.0407	8.3012
4	WORK.ENDPOINT	8.1941	0.06622	123.75	<.0001	0.05	8.0644	8.3239

Differences of TRTPN Least Squares Means

Planned Treatment (N)	Planned Treatment (N)	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
2	4	WORK.ENDPOINT	-0.1732	0.09371	-1.85	0.0646	0.05	-0.3568	0.01051
3	4	WORK.ENDPOINT	-0.02320	0.09397	-0.25	0.8050	0.05	-0.2074	0.1610

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) / NovoRapid (meal)	WORK.ENDPOINT	-0.1732	0.09371	-1.85	0.0646	0.05	-0.3568	0.01051

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Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
TRTPN	Faster aspart (post) / NovoRapid (meal)	WORK.ENDPOINT	-0.02320	0.09397	-0.25	0.8050	0.05	-0.2074	0.1610

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
1	25	14.296591	2.6600211	0.1143089	1.1361412
2	9	14.296591	2.6600211	0.1143089	0.4286812
3	4	14.296591	2.6600211	0.1143089	0.2076
4	11	14.296591	2.6600211	0.1143089	0.5171137
5	17	14.296591	2.6600211	0.1143089	0.7824112
6	67	15.729947	2.7555664	0.098896	2.7436075
7	16	16.60955	2.8099778	0.1139766	0.6436831
8	18	17.060896	2.8367891	0.1139766	0.7032187
9	17	14.840483	2.6973588	0.1143089	0.7563046
10	5	3.1341376	1.142354	0.0986824	0.8461452
11	10	14.141194	2.6490921	0.1143089	0.4776073
12	33	17.060896	2.8367891	0.1139766	1.2674455
13	3	16.60955	2.8099778	0.1139766	0.1424655
14	48	16.814614	2.8222484	0.1131287	1.8563712
15	25	14.296591	2.6600211	0.1143089	1.1361412
16	24	17.091778	2.8385975	0.1131287	0.9273622

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
17	42	15.64492	2.7501463	0.098896	1.7389895
18	1	18.966278	2.9426626	0.0968956	0.0578098
19	6	18.602623	2.9233026	0.0986824	0.2324718
20	10	16.814614	2.8222484	0.1131287	0.4077224
21	12	15.64492	2.7501463	0.098896	0.517077
22	0	3.0488036	1.1147493	0.1131287	0.1050947
23	1	16.60955	2.8099778	0.1139766	0.0653551
24	38	18.176017	2.900103	0.0968956	1.3728095
25	1	17.241435	2.8473155	0.1139766	0.0631457
26	3	16.60955	2.8099778	0.1139766	0.1424655
27	7	18.505205	2.918052	0.1139766	0.2684992
28	21	18.176017	2.900103	0.0968956	0.7696903
29	11	14.37429	2.6654412	0.1143089	0.5145764
30	41	19.20923	2.9553909	0.0986824	1.4052405
31	24	18.176017	2.900103	0.0968956	0.8761231
32	7	14.296591	2.6600211	0.1143089	0.3402487
33	4	16.60955	2.8099778	0.1139766	0.1810207
34	0	18.501522	2.917853	0.0986824	0.0242583
35	3	17.783051	2.8782458	0.1139766	0.1337725
36	1	16.99939	2.8331775	0.1131287	0.0639742
37	4	16.99939	2.8331775	0.1131287	0.1771958
38	13	16.60955	2.8099778	0.1139766	0.5280175
39	2	16.60955	2.8099778	0.1139766	0.1039103
40	4	16.338742	2.7935391	0.1139766	0.1837763
41	14	16.60955	2.8099778	0.1139766	0.5665727

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
42	54	18.373582	2.9109139	0.0968956	1.9211075
43	52	18.176017	2.900103	0.0968956	1.8694959
44	33	18.602623	2.9233026	0.0986824	1.1699832
45	13	15.64492	2.7501463	0.098896	0.5578074
46	0	16.325134	2.7927059	0.098896	0.0272287
47	14	15.64492	2.7501463	0.098896	0.5985378
48	11	18.472365	2.9162758	0.0968956	0.4087408
49	67	18.501522	2.917853	0.0986824	2.3624675
50	15	15.814974	2.7609572	0.098896	0.6329733
51	32	15.814974	2.7609572	0.098896	1.3185721
52	20	18.176017	2.900103	0.0968956	0.7342127
53	0	18.373582	2.9109139	0.0968956	0.0244149
54	0	18.804826	2.9341135	0.0986824	0.0238949
55	6	17.978451	2.8891739	0.0968956	0.2399422
56	23	15.814974	2.7609572	0.098896	0.955608
57	55	20.250454	3.0081772	0.0968956	1.7869766
58	42	15.985027	2.7716525	0.098896	1.7050749
59	30	18.703724	2.9287227	0.0986824	1.060467
60	44	18.176017	2.900103	0.0968956	1.5856751
61	59	18.905927	2.9394755	0.0986824	2.041878
62	6	15.985027	2.7716525	0.098896	0.2673762
63	26	17.978451	2.8891739	0.0968956	0.9567111
64	3	18.602623	2.9233026	0.0986824	0.1283038
65	53	18.66993	2.9269142	0.0968956	1.8581971
66	51	18.472365	2.9162758	0.0968956	1.8067302

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
67	11	18.176017	2.900103	0.0968956	0.4149143
68	22	17.978451	2.8891739	0.0968956	0.8133573
69	11	15.38984	2.7337076	0.098896	0.4835596
70	14	15.64492	2.7501463	0.098896	0.5985378
71	31	16.410161	2.7979007	0.098896	1.2356525
72	0	18.602623	2.9233026	0.0986824	0.0241359
73	59	18.176017	2.900103	0.0968956	2.1178391
74	8	18.602623	2.9233026	0.0986824	0.3019171
75	19	15.729947	2.7555664	0.098896	0.7982208
76	26	18.602623	2.9233026	0.0986824	0.9269246
77	12	18.176017	2.900103	0.0968956	0.4503919
78	24	18.602623	2.9233026	0.0986824	0.8574794
79	9	15.64492	2.7501463	0.098896	0.3948857
80	40	15.729947	2.7555664	0.098896	1.6493275
81	2	18.602623	2.9233026	0.0986824	0.0935812
82	3	15.64492	2.7501463	0.098896	0.1505032
83	0	18.602623	2.9233026	0.0986824	0.0241359
84	2	18.299319	2.9068639	0.0986824	0.0950188
85	6	15.64492	2.7501463	0.098896	0.2726945
86	0	18.077234	2.8946534	0.0968956	0.0247855
87	39	15.64492	2.7501463	0.098896	1.6167982
88	3	18.176017	2.900103	0.0968956	0.1310935
89	25	18.905927	2.9394755	0.0986824	0.8789041
90	2	17.879669	2.8836642	0.0968956	0.0970821
91	10	18.501522	2.917853	0.0986824	0.3732447

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
92	41	18.602623	2.9233026	0.0986824	1.4477643
93	40	18.299319	2.9068639	0.0986824	1.4347486
94	4	18.501522	2.917853	0.0986824	0.1638528
95	1	15.64492	2.7501463	0.098896	0.0690424
96	9	18.299319	2.9068639	0.0986824	0.3418111
97	4	18.176017	2.900103	0.0968956	0.1665711
98	11	16.99939	2.8331775	0.1131287	0.4413795
99	8	15.64492	2.7501463	0.098896	0.3541553
100	11	16.338742	2.7935391	0.1139766	0.457771
101	21	18.602623	2.9233026	0.0986824	0.7533114
102	1	14.218892	2.6545715	0.1143089	0.0753226
103	16	16.880358	2.8261507	0.1139766	0.6341737
104	47	18.602623	2.9233026	0.0986824	1.6561002
105	22	16.814614	2.8222484	0.1131287	0.8651905
106	3	16.722226	2.8167387	0.1131287	0.1415822
107	66	18.602623	2.9233026	0.0986824	2.3158304
108	50	18.2748	2.905523	0.0968956	1.7895314
109	33	17.978451	2.8891739	0.0968956	1.2075802
110	9	14.296591	2.6600211	0.1143089	0.4286812
111	21	16.814614	2.8222484	0.1131287	0.8270681
112	35	16.99939	2.8331775	0.1131287	1.3471521
113	4	16.99939	2.8331775	0.1131287	0.1771958
114	3	16.99939	2.8331775	0.1131287	0.1394552
115	27	14.296591	2.6600211	0.1143089	1.2245737
116	40	16.60955	2.8099778	0.1139766	1.5690079

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Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
117	1	17.091778	2.8385975	0.1131287	0.0636554
118	3	14.296591	2.6600211	0.1143089	0.1633837
119	26	16.99939	2.8331775	0.1131287	1.0074874
120	13	14.296591	2.6600211	0.1143089	0.6055462
121	0	16.99939	2.8331775	0.1131287	0.0262337
122	4	14.296591	2.6600211	0.1143089	0.2076
123	39	16.338742	2.7935391	0.1139766	1.5537497
124	14	16.99939	2.8331775	0.1131287	0.554601
125	38	14.296591	2.6600211	0.1143089	1.7109524
126	28	16.519281	2.8045282	0.1139766	1.1119029
127	29	16.60955	2.8099778	0.1139766	1.1449007
128	0	16.880358	2.8261507	0.1139766	0.026404
129	14	18.176017	2.900103	0.0968956	0.5213471
130	70	14.840483	2.6973588	0.1143089	3.0215719
131	2	16.495188	2.8030687	0.098896	0.1045725
132	3	16.60955	2.8099778	0.1139766	0.1424655
133	0	19.678706	2.9795371	0.1139766	0.0229062
134	20	19.108129	2.9501139	0.0986824	0.7009137
135	1	17.091778	2.8385975	0.1131287	0.0636554
136	19	19.031926	2.9461179	0.1131287	0.6695277
137	21	10.742046	2.3741656	0.1139766	1.2384088
138	11	20.422445	3.0166345	0.0986824	0.3722852
139	24	14.451989	2.6708321	0.1143089	1.0812617
140	32	16.814614	2.8222484	0.1131287	1.2464138
141	9	17.241435	2.8473155	0.1139766	0.36116

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
142	13	16.429011	2.7990488	0.1139766	0.533349
143	21	18.602623	2.9233026	0.0986824	0.7533114
144	41	15.64492	2.7501463	0.098896	1.6982591
145	15	15.64492	2.7501463	0.098896	0.6392682
146	19	19.108129	2.9501139	0.0986824	0.6670451
147	41	19.558975	2.9734342	0.0968956	1.3818379
148	24	23.707848	3.1658061	0.0968956	0.683391
149	28	18.703724	2.9287227	0.0986824	0.9913702
150	5	15.38984	2.7337076	0.098896	0.2354766
151	30	18.176017	2.900103	0.0968956	1.0889887
152	16	18.602623	2.9233026	0.0986824	0.5796982
153	3	18.299319	2.9068639	0.0986824	0.1302748
154	0	18.077234	2.8946534	0.0968956	0.0247855
155	19	18.400421	2.9123735	0.0986824	0.6908341
156	2	11.138503	2.4104079	0.098896	0.1490113
157	4	15.01497	2.7090477	0.0968956	0.1985474
158	11	18.176017	2.900103	0.0968956	0.4149143
159	33	15.814974	2.7609572	0.098896	1.3589015
160	15	15.900001	2.7663191	0.098896	0.629872
161	16	15.64492	2.7501463	0.098896	0.6799986
162	3	18.176017	2.900103	0.0968956	0.1310935
163	13	18.176017	2.900103	0.0968956	0.4858695
164	10	18.176017	2.900103	0.0968956	0.3794367
165	31	12.637652	2.5366806	0.0986824	1.5662808
166	9	17.978451	2.8891739	0.0968956	0.3474575

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
167	28	18.602623	2.9233026	0.0986824	0.9963699
168	20	18.804826	2.9341135	0.0986824	0.711413
169	19	18.400421	2.9123735	0.0986824	0.6908341
170	15	15.559894	2.7446967	0.098896	0.6424628
171	9	18.077234	2.8946534	0.0968956	0.3456995
172	10	15.900001	2.7663191	0.098896	0.4292133
173	2	15.729947	2.7555664	0.098896	0.1092297
174	48	18.299319	2.9068639	0.0986824	1.716797
175	1	18.804826	2.9341135	0.0986824	0.0582708
176	6	18.501522	2.917853	0.0986824	0.2336501
177	21	18.867496	2.9374406	0.0968956	0.7434877
178	10	15.900001	2.7663191	0.098896	0.4292133
179	5	18.176017	2.900103	0.0968956	0.2020487
180	23	18.501522	2.917853	0.0986824	0.8269271
181	35	15.38984	2.7337076	0.098896	1.475892
182	1	18.400421	2.9123735	0.0986824	0.0594583
183	27	18.176017	2.900103	0.0968956	0.9825559
184	5	18.176017	2.900103	0.0968956	0.2020487
185	36	18.472365	2.9162758	0.0968956	1.2824842
186	8	18.501522	2.917853	0.0986824	0.3034474
187	0	15.64492	2.7501463	0.098896	0.028312
188	1	15.729947	2.7555664	0.098896	0.0687008
189	1	9.87827	2.2903374	0.0968956	0.1041121
190	18	15.38984	2.7337076	0.098896	0.7729899
191	36	16.352674	2.7943914	0.1131287	1.4351995

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The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
192	10	18.400421	2.9123735	0.0986824	0.3751462
193	13	15.64492	2.7501463	0.098896	0.5578074
194	13	18.602623	2.9233026	0.0986824	0.4755303
195	49	18.571148	2.9216092	0.0968956	1.728259
196	58	17.276554	2.8493503	0.1131287	2.1823964
197	0	18.602623	2.9233026	0.0986824	0.0241359
198	2	18.299319	2.9068639	0.0986824	0.0950188
199	5	15.64492	2.7501463	0.098896	0.231964
200	0	18.703724	2.9287227	0.0986824	0.0240148
201	14	15.814974	2.7609572	0.098896	0.592644
202	4	5.8638703	1.7688099	0.0986824	0.4448449
203	13	9.4831392	2.2495154	0.0968956	0.8714103
204	39	15.64492	2.7501463	0.098896	1.6167982
205	62	18.2748	2.905523	0.0968956	2.21313
206	4	16.240108	2.787484	0.098896	0.1848008
207	2	15.64492	2.7501463	0.098896	0.1097728
208	26	18.2748	2.905523	0.0968956	0.9423342
209	9	15.38984	2.7337076	0.098896	0.4008653
210	48	18.602623	2.9233026	0.0986824	1.6908228
211	5	17.241435	2.8473155	0.1139766	0.2121528
212	6	17.978451	2.8891739	0.0968956	0.2399422
213	5	18.176017	2.900103	0.0968956	0.2020487
214	7	16.60955	2.8099778	0.1139766	0.2966863
215	0	0.6914789	-0.368923	0.0968956	0.1737753
216	8	14.296591	2.6600211	0.1143089	0.384465

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The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
217	1	16.814614	2.8222484	0.1131287	0.0646214
218	0	14.37429	2.6654412	0.1143089	0.0305842
219	4	17.091778	2.8385975	0.1131287	0.1763128
220	12	16.814614	2.8222484	0.1131287	0.4839671
221	2	18.501522	2.917853	0.0986824	0.0940555
222	53	15.64492	2.7501463	0.098896	2.1870241
223	44	18.176017	2.900103	0.0968956	1.5856751
224	1	18.867496	2.9374406	0.0968956	0.058091
225	14	15.64492	2.7501463	0.098896	0.5985378
226	41	15.64492	2.7501463	0.098896	1.6982591
227	9	18.176017	2.900103	0.0968956	0.3439591
228	7	18.602623	2.9233026	0.0986824	0.2671944
229	19	19.310332	2.9606403	0.0986824	0.6605458
230	9	18.176017	2.900103	0.0968956	0.3439591
231	0	18.2748	2.905523	0.0968956	0.0245372
232	4	19.007028	2.9448088	0.0986824	0.1598027
233	10	18.176017	2.900103	0.0968956	0.3794367
234	1	15.900001	2.7663191	0.098896	0.0680276
235	17	18.176017	2.900103	0.0968956	0.6277799
236	12	18.2748	2.905523	0.0968956	0.4481358
237	0	18.176017	2.900103	0.0968956	0.0246607
238	8	18.602623	2.9233026	0.0986824	0.3019171
239	3	18.176017	2.900103	0.0968956	0.1310935
240	0	15.64492	2.7501463	0.098896	0.028312
241	0	15.64492	2.7501463	0.098896	0.028312

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The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
242	3	15.64492	2.7501463	0.098896	0.1505032
243	12	18.602623	2.9233026	0.0986824	0.4408076
244	2	17.894915	2.8845166	0.0986824	0.0970056
245	2	18.867496	2.9374406	0.0968956	0.0923608
246	20	17.990013	2.8898168	0.1168884	0.7412392
247	11	17.990013	2.8898168	0.1168884	0.4188851
248	3	17.577456	2.8666172	0.1230297	0.1352182
249	21	19.847678	2.988087	0.1168884	0.7092574
250	20	17.577456	2.8666172	0.1230297	0.7573137
251	2	17.990013	2.8898168	0.1168884	0.096531
252	14	15.705299	2.7539981	0.117654	0.5964318
253	5	17.959574	2.8881234	0.1230297	0.2043023
254	0	17.672985	2.8720372	0.1230297	0.0253095
255	11	15.129712	2.7166605	0.117654	0.4911435
256	5	17.768515	2.8774281	0.1230297	0.2063337
257	4	15.129712	2.7166605	0.117654	0.197174
258	1	17.577456	2.8666172	0.1230297	0.0620305
259	20	18.150634	2.8987055	0.1230297	0.7351637
260	0	17.672985	2.8720372	0.1230297	0.0253095
261	1	17.990013	2.8898168	0.1168884	0.0607138
262	0	17.577456	2.8666172	0.1230297	0.0254366
263	29	15.129712	2.7166605	0.117654	1.247065
264	32	18.087785	2.8952369	0.1168884	1.1651833
265	1	18.087785	2.8952369	0.1168884	0.0604099
266	42	17.990013	2.8898168	0.1168884	1.529216

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
267	6	17.990013	2.8898168	0.1168884	0.2397995
268	17	18.576644	2.9219051	0.1168884	0.6152181
269	1	15.458619	2.7381667	0.117654	0.0698029
270	10	17.577456	2.8666172	0.1230297	0.3913751
271	20	15.129712	2.7166605	0.117654	0.8691043
272	4	17.768515	2.8774281	0.1230297	0.1701037
273	5	17.290867	2.8501784	0.1230297	0.2115932
274	1	15.376392	2.7328333	0.117654	0.0701438
275	4	19.652134	2.9781859	0.1168884	0.1549156
276	4	17.672985	2.8720372	0.1230297	0.1709536
277	1	17.768515	2.8774281	0.1230297	0.0614137
278	1	17.577456	2.8666172	0.1230297	0.0620305
279	2	15.376392	2.7328333	0.117654	0.1115241
280	1	15.211938	2.7220805	0.117654	0.0708359
281	29	17.672985	2.8720372	0.1230297	1.0812291
282	45	15.211938	2.7220805	0.117654	1.909529
283	6	14.883032	2.7002218	0.117654	0.2854097
284	19	15.129712	2.7166605	0.117654	0.8271086
285	0	17.386396	2.8556881	0.1230297	0.0256946
286	0	18.087785	2.8952369	0.1168884	0.0247721
287	1	18.087785	2.8952369	0.1168884	0.0604099
288	1	18.185557	2.9006277	0.1168884	0.0601091
289	4	18.087785	2.8952369	0.1168884	0.1673235
290	0	17.990013	2.8898168	0.1168884	0.0248967
291	0	18.283329	2.9059896	0.1168884	0.0245266

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
292	0	17.577456	2.8666172	0.1230297	0.0254366
293	2	15.129712	2.7166605	0.117654	0.1131827
294	0	17.990013	2.8898168	0.1168884	0.0248967
295	0	17.672985	2.8720372	0.1230297	0.0253095
296	0	17.696698	2.8733781	0.1168884	0.0252782
297	9	17.892241	2.8843672	0.1168884	0.3490065
298	33	17.577456	2.8666172	0.1230297	1.2330338
299	1	10.607244	2.3615371	0.117654	0.0978392
300	58	15.129712	2.7166605	0.117654	2.4649387
301	18	17.990013	2.8898168	0.1168884	0.669605
302	19	17.577456	2.8666172	0.1230297	0.7207198
303	0	17.768515	2.8774281	0.1230297	0.0251837
304	26	18.185557	2.9006277	0.1168884	0.9466181
305	51	15.787525	2.7592201	0.117654	2.0881486
306	4	15.129712	2.7166605	0.117654	0.197174
307	28	17.79447	2.8788877	0.1168884	1.0382215
308	7	15.129712	2.7166605	0.117654	0.3231609
309	18	15.211938	2.7220805	0.117654	0.7812401
310	57	15.211938	2.7220805	0.117654	2.4109908
311	0	17.768515	2.8774281	0.1230297	0.0251837
312	3	18.185557	2.9006277	0.1168884	0.1310298
313	10	17.990013	2.8898168	0.1168884	0.383068
314	46	18.150634	2.8987055	0.1230297	1.6587762
315	1	14.965258	2.7057314	0.117654	0.0718999
316	40	18.185557	2.9006277	0.1168884	1.4430631

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
317	57	17.672985	2.8720372	0.1230297	2.1007377
318	8	15.047485	2.7112109	0.117654	0.3669758
319	15	17.481926	2.8611676	0.1230297	0.5772429
320	19	15.294165	2.7274714	0.117654	0.8189884
321	0	18.283329	2.9059896	0.1168884	0.0245266
322	0	17.959574	2.8881234	0.1230297	0.0249357
323	0	15.787525	2.7592201	0.117654	0.0280778
324	14	18.283329	2.9059896	0.1168884	0.5185113
325	14	15.129712	2.7166605	0.117654	0.6171304
326	12	15.294165	2.7274714	0.117654	0.527905
327	1	18.283329	2.9059896	0.1168884	0.0598112
328	3	17.990013	2.8898168	0.1168884	0.1323481
329	42	18.087785	2.8952369	0.1168884	1.5215619
330	29	17.672985	2.8720372	0.1230297	1.0812291
331	32	17.990013	2.8898168	0.1168884	1.1710447
332	1	15.294165	2.7274714	0.117654	0.0704882
333	1	17.864045	2.88279	0.1230297	0.0611099
334	4	15.705299	2.7539981	0.117654	0.1905608
335	1	15.129712	2.7166605	0.117654	0.0711871
336	3	2.2487517	0.8103752	0.1168884	0.666478
337	30	17.990013	2.8898168	0.1168884	1.0994105
338	5	15.211938	2.7220805	0.117654	0.2379898
339	0	18.674416	2.9271545	0.1168884	0.0240498
340	0	17.864045	2.88279	0.1230297	0.0250591
341	3	15.458619	2.7381667	0.117654	0.152161

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
342	47	17.990013	2.8898168	0.1168884	1.7083016
343	39	15.129712	2.7166605	0.117654	1.6670215
344	59	18.283329	2.9059896	0.1168884	2.1063194
345	62	15.129712	2.7166605	0.117654	2.6329212
346	3	17.577456	2.8666172	0.1230297	0.1352182
347	28	18.283329	2.9059896	0.1168884	1.012496
348	40	15.294165	2.7274714	0.117654	1.6922387
349	12	17.868861	2.8830596	0.0921908	0.4575543
350	0	15.380537	2.7331029	0.0957118	0.0287566
351	0	15.212444	2.7221138	0.0957118	0.0290465
352	6	15.464584	2.7385525	0.0957118	0.2756009
353	1	15.464584	2.7385525	0.0957118	0.0697782
354	0	15.380537	2.7331029	0.0957118	0.0287566
355	92	18.388194	2.9117088	0.0955038	3.2534186
356	0	18.388194	2.9117088	0.0955038	0.0243969
357	42	14.131797	2.6484273	0.0978843	1.9077682
358	56	16.418094	2.798384	0.0961017	2.209311
359	0	16.986087	2.8323946	0.0965161	0.0262526
360	3	14.131797	2.6484273	0.0978843	0.1651104
361	19	17.042696	2.8357217	0.0961017	0.741563
362	13	14.131797	2.6484273	0.0978843	0.6119457
363	6	16.620794	2.8106546	0.0965161	0.2579705
364	25	14.362206	2.6646002	0.0978843	1.1314299
365	1	14.131797	2.6484273	0.0978843	0.0757433
366	9	13.97819	2.6374983	0.0978843	0.4375212

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
367	20	13.901387	2.6319886	0.0978843	0.9385983
368	14	16.803441	2.8215837	0.0965161	0.5605547
369	27	13.901387	2.6319886	0.0978843	1.2560737
370	4	17.351379	2.853672	0.0965161	0.1738782
371	3	13.901387	2.6319886	0.0978843	0.1675865
372	2	16.507323	2.8038041	0.0961017	0.1045018
373	10	17.310382	2.8513064	0.0961017	0.3969474
374	25	16.507323	2.8038041	0.0961017	0.9963193
375	5	14.131797	2.6484273	0.0978843	0.2544775
376	23	16.418094	2.798384	0.0961017	0.9233576
377	14	16.418094	2.798384	0.0961017	0.5726431
378	0	16.418094	2.798384	0.0961017	0.0270871
379	7	16.803441	2.8215837	0.0965161	0.293535
380	0	16.596552	2.8091949	0.0961017	0.0268192
381	0	16.418094	2.798384	0.0961017	0.0270871
382	4	16.418094	2.798384	0.0961017	0.1829602
383	0	16.803441	2.8215837	0.0965161	0.0265153
384	0	15.464584	2.7385525	0.0957118	0.0286137
385	1	16.803441	2.8215837	0.0965161	0.064661
386	0	16.328865	2.7929344	0.0961017	0.027223
387	0	14.131797	2.6484273	0.0978843	0.0310598
388	12	16.418094	2.798384	0.0961017	0.4947065
389	2	16.418094	2.798384	0.0961017	0.1050237
390	1	16.596552	2.8091949	0.0961017	0.0654022
391	0	16.803441	2.8215837	0.0965161	0.0265153

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
392	0	17.966505	2.8885092	0.0921908	0.0249268
393	10	18.552369	2.9205975	0.0921908	0.3722956
394	0	15.380537	2.7331029	0.0957118	0.0287566
395	2	16.30505	2.7914749	0.0957118	0.1056923
396	15	18.064149	2.8939292	0.0921908	0.5600175
397	1	13.97819	2.6374983	0.0978843	0.0764968
398	13	15.54863	2.7439726	0.0957118	0.5609662
399	1	15.464584	2.7385525	0.0957118	0.0697782
400	2	15.968864	2.7706408	0.0957118	0.1077318
401	6	15.632677	2.7493634	0.0957118	0.2728898
402	0	17.966505	2.8885092	0.0921908	0.0249268
403	0	18.488129	2.9171289	0.0955038	0.0242746
404	56	18.259437	2.904682	0.0921908	2.0028911
405	0	15.54863	2.7439726	0.0957118	0.0284723
406	6	18.161793	2.8993201	0.0921908	0.2376986
407	5	15.54863	2.7439726	0.0957118	0.2332776
408	0	15.464584	2.7385525	0.0957118	0.0286137
409	0	16.239637	2.787455	0.0961017	0.0273603
410	2	13.901387	2.6319886	0.0978843	0.1222328
411	0	16.328865	2.7929344	0.0961017	0.027223
412	29	14.2086	2.6538474	0.0978843	1.3203791
413	0	16.864238	2.8251953	0.0961017	0.0264273
414	0	16.986087	2.8323946	0.0965161	0.0262526
415	1	16.239637	2.787455	0.0961017	0.0667217
416	7	16.712117	2.8161341	0.0965161	0.2950109

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The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
417	0	16.803441	2.8215837	0.0965161	0.0265153
418	3	16.418094	2.798384	0.0961017	0.1439919
419	5	16.239637	2.787455	0.0961017	0.2241671
420	114	18.388194	2.9117088	0.0955038	4.025576
421	11	17.966505	2.8885092	0.0921908	0.4193924
422	25	18.488129	2.9171289	0.0955038	0.8973269
423	41	18.488129	2.9171289	0.0955038	1.4560804
424	14	15.54863	2.7439726	0.0957118	0.6019272
425	4	15.296491	2.7276234	0.0957118	0.1952111
426	8	18.161793	2.8993201	0.0921908	0.3087053
427	0	15.54863	2.7439726	0.0957118	0.0284723
428	18	15.54863	2.7439726	0.0957118	0.7657715
429	22	18.454725	2.9153204	0.0921908	0.7938911
430	0	19.587424	2.9748877	0.0955038	0.0230057
431	0	18.454725	2.9153204	0.0921908	0.0243153
432	0	18.388194	2.9117088	0.0955038	0.0243969
433	0	15.464584	2.7385525	0.0957118	0.0286137
434	11	18.588065	2.9225197	0.0955038	0.4063801
435	0	18.388194	2.9117088	0.0955038	0.0243969
436	6	18.288258	2.9062592	0.0955038	0.2361753
437	9	14.131797	2.6484273	0.0978843	0.4332116
438	1	18.787937	2.933215	0.0955038	0.0583194
439	6	14.2086	2.6538474	0.0978843	0.2976948
440	5	16.894764	2.8270037	0.0965161	0.2161622
441	0	15.716724	2.7547254	0.0957118	0.0281936

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The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
442	46	14.131797	2.6484273	0.0978843	2.0865023
443	11	18.388194	2.9117088	0.0955038	0.4104756
444	2	18.688001	2.9278817	0.0955038	0.0931843
445	14	14.131797	2.6484273	0.0978843	0.6566293
446	32	14.2086	2.6538474	0.0978843	1.4537727
447	26	17.966505	2.8885092	0.0921908	0.9572999
448	12	16.150408	2.7819453	0.0961017	0.5022296
449	4	16.803441	2.8215837	0.0965161	0.179098
450	16	15.464584	2.7385525	0.0957118	0.6872463
451	30	18.388194	2.9117088	0.0955038	1.0773387
452	12	19.487488	2.9697726	0.0955038	0.4221718
453	16	16.507323	2.8038041	0.0961017	0.6473472
454	26	14.746223	2.690987	0.0978843	1.1476094
455	40	18.381127	2.9113244	0.0961017	1.4288284
456	6	19.387552	2.9646312	0.0955038	0.2237119
457	61	13.97819	2.6374983	0.0978843	2.7841799
458	0	16.68578	2.8145569	0.0961017	0.0266873
459	0	17.042696	2.8357217	0.0961017	0.0261722
460	7	18.288258	2.9062592	0.0955038	0.2714511
461	33	21.086461	3.0486312	0.0955038	1.0409822
462	11	14.362206	2.6646002	0.0978843	0.5149694
463	46	16.803441	2.8215837	0.0965161	1.7812162
464	6	15.464584	2.7385525	0.0957118	0.2756009
465	17	16.712117	2.8161341	0.0965161	0.6783856
466	0	19.919386	2.9916934	0.0921908	0.0226481

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Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
467	1	18.987809	2.9437971	0.0955038	0.0577489
468	12	18.161793	2.8993201	0.0921908	0.4507186
469	0	17.966505	2.8885092	0.0921908	0.0249268
470	11	16.418094	2.798384	0.0961017	0.4557382
471	5	16.80933	2.8219341	0.0957118	0.2171736
472	11	18.552369	2.9205975	0.0921908	0.4071055
473	19	14.669419	2.685765	0.0978843	0.8507147
474	2	18.357081	2.9100154	0.0921908	0.0947416
475	3	17.868861	2.8830596	0.0921908	0.1331782
476	24	15.632677	2.7493634	0.0957118	1.0065627
477	5	18.787937	2.933215	0.0955038	0.1959378
478	0	18.161793	2.8993201	0.0921908	0.0246786
479	0	15.296491	2.7276234	0.0957118	0.0289008
480	4	18.259437	2.904682	0.0921908	0.1658659
481	23	18.688001	2.9278817	0.0955038	0.8192675
482	35	18.064149	2.8939292	0.0921908	1.273638
483	23	17.771217	2.8775801	0.0921908	0.8583531
484	0	17.868861	2.8830596	0.0921908	0.0250529
485	1	18.188322	2.9007797	0.0955038	0.0601006
486	1	15.212444	2.7221138	0.0957118	0.0708338
487	16	17.868861	2.8830596	0.0921908	0.6017214
488	3	15.464584	2.7385525	0.0957118	0.1521073
489	35	15.54863	2.7439726	0.0957118	1.4621097
490	0	18.259437	2.904682	0.0921908	0.0245563
491	1	18.064149	2.8939292	0.0921908	0.0604831

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Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
492	1	18.288258	2.9062592	0.0955038	0.0597962
493	11	18.588065	2.9225197	0.0955038	0.4063801
494	25	14.960304	2.7054003	0.0957118	1.090217
495	20	15.464584	2.7385525	0.0957118	0.8519044
496	55	18.688001	2.9278817	0.0955038	1.9256799
497	40	17.966505	2.8885092	0.0921908	1.4593469
498	1	17.966505	2.8885092	0.0921908	0.0607873
499	1	18.688001	2.9278817	0.0955038	0.0586089
500	0	18.388194	2.9117088	0.0955038	0.0243969
501	44	18.188322	2.9007797	0.0955038	1.5846813
502	22	18.161793	2.8993201	0.0921908	0.805752
503	0	15.464584	2.7385525	0.0957118	0.0286137
504	0	17.771217	2.8775801	0.0921908	0.0251802
505	0	18.688001	2.9278817	0.0955038	0.0240336
506	0	18.688001	2.9278817	0.0955038	0.0240336
507	1	17.771217	2.8775801	0.0921908	0.0614051
508	0	2.9293214	1.0747708	0.0921908	0.1077433
509	17	17.673573	2.8720704	0.0921908	0.6442771
510	22	17.966505	2.8885092	0.0921908	0.8138579
511	23	18.388194	2.9117088	0.0955038	0.8316523
512	12	17.966505	2.8885092	0.0921908	0.4552529
513	56	18.388194	2.9117088	0.0955038	1.9898883
514	53	18.064149	2.8939292	0.0921908	1.9158965
515	56	15.464584	2.7385525	0.0957118	2.3338276
516	1	15.464584	2.7385525	0.0957118	0.0697782

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
517	34	17.966505	2.8885092	0.0921908	1.2441839
518	5	18.064149	2.8939292	0.0921908	0.2032072
519	58	18.588065	2.9225197	0.0955038	2.0395303
520	4	18.259437	2.904682	0.0921908	0.1658659
521	5	15.464584	2.7385525	0.0957118	0.2344364
522	10	18.388194	2.9117088	0.0955038	0.3753775
523	0	18.388194	2.9117088	0.0955038	0.0243969
524	6	17.966505	2.8885092	0.0921908	0.2400899
525	12	15.54863	2.7439726	0.0957118	0.5200051
526	0	15.54863	2.7439726	0.0957118	0.0284723
527	20	18.161793	2.8993201	0.0921908	0.7347453
528	1	15.54863	2.7439726	0.0957118	0.0694334
529	8	15.464584	2.7385525	0.0957118	0.35793
530	17	15.80077	2.7600587	0.0957118	0.7142194
531	0	18.488129	2.9171289	0.0955038	0.0242746
532	7	15.884817	2.7653638	0.0957118	0.3090885
533	41	17.966505	2.8885092	0.0921908	1.4952074
534	83	17.771217	2.8775801	0.0921908	3.0318478
535	26	15.464584	2.7385525	0.0957118	1.0988916
536	31	18.388194	2.9117088	0.0955038	1.1124368
537	8	18.488129	2.9171289	0.0955038	0.3036513
538	0	18.488129	2.9171289	0.0955038	0.0242746
539	0	15.54863	2.7439726	0.0957118	0.0284723
540	3	18.688001	2.9278817	0.0955038	0.1277597
541	0	15.380537	2.7331029	0.0957118	0.0287566

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
542	2	18.588065	2.9225197	0.0955038	0.0936492
543	0	17.98845	2.8897299	0.0955038	0.0248987
544	3	15.80077	2.7600587	0.0957118	0.1491439
545	0	15.884817	2.7653638	0.0957118	0.0279202
546	11	15.464584	2.7385525	0.0957118	0.4814236
547	24	15.632677	2.7493634	0.0957118	1.0065627
548	112	18.064149	2.8939292	0.0921908	4.0210771
549	40	15.380537	2.7331029	0.0957118	1.6835576
550	49	18.388194	2.9117088	0.0955038	1.7442019
551	45	18.388194	2.9117088	0.0955038	1.6038097
552	23	15.464584	2.7385525	0.0957118	0.975398
553	14	15.54863	2.7439726	0.0957118	0.6019272
554	9	18.588065	2.9225197	0.0955038	0.3368844
555	34	15.464584	2.7385525	0.0957118	1.4282079
556	1	15.884817	2.7653638	0.0957118	0.0680871
557	10	18.488129	2.9171289	0.0955038	0.3734955
558	2	15.54863	2.7439726	0.0957118	0.1103944
559	60	15.464584	2.7385525	0.0957118	2.4984858
560	50	18.688001	2.9278817	0.0955038	1.752803
561	75	17.966505	2.8885092	0.0921908	2.7144644
562	32	18.488129	2.9171289	0.0955038	1.1417815
563	82	16.803441	2.8215837	0.0965161	3.1544604
564	56	18.161793	2.8993201	0.0921908	2.0128655
565	1	18.688001	2.9278817	0.0955038	0.0586089
566	2	15.464584	2.7385525	0.0957118	0.1109428

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
567	33	16.986087	2.8323946	0.0965161	1.2725887
568	4	17.966505	2.8885092	0.0921908	0.1683689
569	18	18.088386	2.8952701	0.0955038	0.6662329
570	31	18.064149	2.8939292	0.0921908	1.1309139
571	9	15.54863	2.7439726	0.0957118	0.3971219
572	19	18.552369	2.9205975	0.0921908	0.6855848
573	34	15.80077	2.7600587	0.0957118	1.4003826
574	38	18.259437	2.904682	0.0921908	1.3669977
575	50	17.966505	2.8885092	0.0921908	1.8179519
576	18	15.80077	2.7600587	0.0957118	0.7545819
577	12	18.488129	2.9171289	0.0955038	0.4433397
578	93	18.288258	2.9062592	0.0955038	3.3051708
579	62	17.966505	2.8885092	0.0921908	2.2482779
580	50	17.966505	2.8885092	0.0921908	1.8179519
581	26	18.488129	2.9171289	0.0955038	0.932249
582	11	18.388194	2.9117088	0.0955038	0.4104756
583	43	15.464584	2.7385525	0.0957118	1.7986887
584	0	16.239637	2.787455	0.0961017	0.0273603
585	29	16.894764	2.8270037	0.0965161	1.1271008
586	8	17.351379	2.853672	0.0965161	0.3220139
587	28	16.803441	2.8215837	0.0965161	1.0945941
588	3	14.131797	2.6484273	0.0978843	0.1651104
589	2	14.285403	2.6592383	0.0978843	0.1192521
590	10	16.418094	2.798384	0.0961017	0.4167699
591	39	16.803441	2.8215837	0.0965161	1.5141965

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Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
592	89	16.803441	2.8215837	0.0965161	3.4214801
593	19	16.418094	2.798384	0.0961017	0.7674845
594	34	14.2086	2.6538474	0.0978843	1.5427017
595	9	16.418094	2.798384	0.0961017	0.3778016
596	9	15.207042	2.7217586	0.0978843	0.4052628
597	27	14.131797	2.6484273	0.0978843	1.2375152
598	17	14.131797	2.6484273	0.0978843	0.7906799
599	2	13.901387	2.6319886	0.0978843	0.1222328
600	2	16.712117	2.8161341	0.0965161	0.1033236
601	18	16.596552	2.8091949	0.0961017	0.7213126
602	34	13.97819	2.6374983	0.0978843	1.5657225
603	3	18.064149	2.8939292	0.0921908	0.1318452
604	8	13.901387	2.6319886	0.0978843	0.3943547
605	11	16.803441	2.8215837	0.0965161	0.4461177
606	28	16.803441	2.8215837	0.0965161	1.0945941
607	16	16.328865	2.7929344	0.0961017	0.6538444
608	1	18.259437	2.904682	0.0921908	0.0598837
609	0	14.131797	2.6484273	0.0978843	0.0310598
610	34	16.596552	2.8091949	0.0961017	1.3386401
611	12	17.260056	2.8483949	0.0965161	0.4724446
612	125	16.418094	2.798384	0.0961017	4.8981227
613	22	16.894764	2.8270037	0.0965161	0.8614104
614	6	14.2086	2.6538474	0.0978843	0.2976948
615	29	14.054994	2.6429777	0.0978843	1.3334497
616	33	14.131797	2.6484273	0.0978843	1.5056164

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
617	36	16.150408	2.7819453	0.0961017	1.4516908
618	7	16.894764	2.8270037	0.0965161	0.2920737
619	12	16.418094	2.798384	0.0961017	0.4947065
620	11	14.43901	2.6699336	0.0978843	0.5124818
621	107	16.953467	2.8304723	0.0961017	4.0746125
622	22	14.054994	2.6429777	0.0978843	1.0191168
623	5	16.418094	2.798384	0.0961017	0.2219285
624	10	16.803441	2.8215837	0.0965161	0.407972
625	0	16.620794	2.8106546	0.0965161	0.0267833
626	14	14.131797	2.6484273	0.0978843	0.6566293
627	2	9.9043937	2.2929785	0.0961017	0.1651521
628	0	17.442702	2.8589213	0.0965161	0.0256181
629	24	14.362206	2.6646002	0.0978843	1.087397
630	4	16.894764	2.8270037	0.0965161	0.1782064
631	26	16.239637	2.787455	0.0961017	1.0507557
632	0	14.2086	2.6538474	0.0978843	0.0309076
633	13	16.712117	2.8161341	0.0965161	0.5250357
634	96	16.68578	2.8145569	0.0961017	3.7124292
635	28	16.803441	2.8215837	0.0965161	1.0945941
636	20	14.362206	2.6646002	0.0978843	0.9112654
637	25	14.054994	2.6429777	0.0978843	1.1538309
638	27	18.447255	2.9149156	0.0965161	0.9691584
639	12	16.328865	2.7929344	0.0961017	0.4971891
640	54	13.97819	2.6374983	0.0978843	2.4682836
641	13	16.418094	2.798384	0.0961017	0.5336748

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The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
642	1	18.488129	2.9171289	0.0955038	0.0591966
643	6	14.2086	2.6538474	0.0978843	0.2976948
644	26	18.288258	2.9062592	0.0955038	0.9416915
645	10	14.131797	2.6484273	0.0978843	0.4778951
646	6	17.966505	2.8885092	0.0921908	0.2400899
647	8	14.131797	2.6484273	0.0978843	0.3885281
648	11	17.966505	2.8885092	0.0921908	0.4193924
649	47	18.987809	2.9437971	0.0955038	1.6248784
650	30	18.161793	2.8993201	0.0921908	1.0897787
651	9	16.803441	2.8215837	0.0965161	0.3698263
652	4	16.418094	2.798384	0.0961017	0.1829602
653	39	16.418094	2.798384	0.0961017	1.5468502
654	29	18.259437	2.904682	0.0921908	1.0490511
655	30	18.188322	2.9007797	0.0955038	1.0883062
656	2	18.161793	2.8993201	0.0921908	0.0956853
657	15	18.588065	2.9225197	0.0955038	0.5453716
658	5	18.288258	2.9062592	0.0955038	0.2008995
659	30	20.01703	2.9965834	0.0921908	0.9955659
660	8	15.464584	2.7385525	0.0957118	0.35793
661	14	14.285403	2.6592383	0.0978843	0.6502241
662	2	14.353675	2.664006	0.0921908	0.1187373
663	1	25.383702	3.2341073	0.0955038	0.0439772
664	3	18.787937	2.933215	0.0955038	0.1271286
665	33	19.487488	2.9697726	0.0955038	1.1205203
666	13	15.884817	2.7653638	0.0957118	0.5500898

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The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
667	24	15.632677	2.7493634	0.0957118	1.0065627
668	1	10.992942	2.3972534	0.0955038	0.0948152
669	21	16.689284	2.8147669	0.0955038	0.8327825
670	6	14.515813	2.6752386	0.0978843	0.2919705
671	0	16.239637	2.787455	0.0961017	0.0273603
672	12	14.43901	2.6699336	0.0978843	0.556302
673	22	14.131797	2.6484273	0.0978843	1.0140975
674	4	16.418094	2.798384	0.0961017	0.1829602
675	33	16.418094	2.798384	0.0961017	1.3130405
676	18	16.803441	2.8215837	0.0965161	0.7131374
677	16	16.620794	2.8106546	0.0965161	0.6432826
678	6	15.207042	2.7217586	0.0978843	0.2798605
679	9	16.328865	2.7929344	0.0961017	0.3796976
680	36	16.803441	2.8215837	0.0965161	1.3997595
681	39	16.507323	2.8038041	0.0961017	1.5391646
682	28	16.418094	2.798384	0.0961017	1.1181991
683	1	17.351379	2.853672	0.0965161	0.0627764
684	19	16.438148	2.7996048	0.0965161	0.7666242
685	1	14.131797	2.6484273	0.0978843	0.0757433
686	1	16.68578	2.8145569	0.0961017	0.0650804
687	0	14.746223	2.690987	0.0978843	0.0298823
688	1	16.529471	2.8051449	0.0965161	0.0656462
689	7	16.803441	2.8215837	0.0965161	0.293535
690	39	16.803441	2.8215837	0.0965161	1.5141965
691	0	16.620794	2.8106546	0.0965161	0.0267833

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The GENMOD Procedure

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692	10	16.507323	2.8038041	0.0961017	0.4146992
693	3	14.131797	2.6484273	0.0978843	0.1651104
694	32	17.990013	2.8898168	0.1168884	1.1710447
695	18	18.381101	2.911323	0.1168884	0.6563967
696	28	15.129712	2.7166605	0.117654	1.2050694
697	34	17.598926	2.8678379	0.1168884	1.2681964
698	21	14.965258	2.7057314	0.117654	0.9202234
699	70	17.696698	2.8733781	0.1168884	2.5708926
700	48	15.705299	2.7539981	0.117654	1.9763934
701	41	17.577456	2.8666172	0.1230297	1.5257846
702	4	17.990013	2.8898168	0.1168884	0.1681652
703	20	17.305611	2.8510308	0.1168884	0.7682914
704	65	17.577456	2.8666172	0.1230297	2.4040371
705	13	17.892241	2.8843672	0.1168884	0.4929993
706	41	17.79447	2.8788877	0.1168884	1.5085762
707	1	17.386396	2.8556881	0.1230297	0.0626597
708	26	15.294165	2.7274714	0.117654	1.1100719
709	3	17.990013	2.8898168	0.1168884	0.1323481
710	0	17.577456	2.8666172	0.1230297	0.0254366
711	29	14.883032	2.7002218	0.117654	1.2658907
712	38	14.883032	2.7002218	0.117654	1.6495572
713	32	17.990013	2.8898168	0.1168884	1.1710447
714	24	17.696698	2.8733781	0.1168884	0.8980603
715	31	16.914523	2.8281726	0.1168884	1.201718
716	22	15.129712	2.7166605	0.117654	0.9530956

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Observation Statistics

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717	44	17.481926	2.8611676	0.1230297	1.6438202
718	4	17.892241	2.8843672	0.1168884	0.1690154
719	0	17.577456	2.8666172	0.1230297	0.0254366
720	3	17.990013	2.8898168	0.1168884	0.1323481
721	47	17.990013	2.8898168	0.1168884	1.7083016
722	50	17.481926	2.8611676	0.1230297	1.8644914
723	4	17.481926	2.8611676	0.1230297	0.1726791
724	21	17.577456	2.8666172	0.1230297	0.7939075
725	23	16.210141	2.785637	0.0926675	0.9342291
726	50	20.393015	3.0151925	0.1050608	1.6159306
727	27	18.296184	2.9066925	0.1046762	0.9765751
728	79	20.069317	2.9991921	0.1050608	2.5785498
729	0	19.317798	2.9610268	0.1046762	0.0233045
730	45	19.529819	2.9719425	0.1050608	1.5165093
731	14	21.472011	3.0667503	0.1050608	0.4463526
732	20	16.210141	2.785637	0.0926675	0.8159479
733	17	18.467383	2.9160061	0.0936221	0.618594
734	5	18.467383	2.9160061	0.0936221	0.1990922
735	11	15.616052	2.7482994	0.0926675	0.4771521
736	8	17.649476	2.8707061	0.0947825	0.3169874
737	11	12.221258	2.5031769	0.0926675	0.595512
738	4	16.995947	2.8329749	0.1046762	0.1772288
739	5	18.467383	2.9160061	0.0936221	0.1990922
740	13	18.871041	2.9376285	0.0936221	0.4692471
741	14	16.040401	2.7751106	0.0926675	0.5850072

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
742	0	17.181695	2.8438446	0.1046762	0.025977
743	13	17.181695	2.8438446	0.1046762	0.511803
744	33	18.568297	2.9214557	0.0936221	1.1719899
745	2	18.467383	2.9160061	0.0936221	0.0942168
746	2	18.43828	2.9144289	0.0947825	0.0943547
747	18	17.088821	2.8384245	0.1046762	0.7021594
748	10	18.770127	2.9322666	0.0936221	0.3682851
749	36	19.853518	2.9883812	0.1050608	1.1993091
750	16	18.734081	2.9303444	0.0947825	0.5759215
751	17	20.319496	3.0115808	0.1065887	0.5659457
752	24	17.088821	2.8384245	0.1046762	0.9275101
753	19	18.241079	2.9036761	0.0947825	0.6964259
754	18	16.995947	2.8329749	0.1046762	0.7056948
755	9	18.832681	2.9355937	0.0947825	0.3328202
756	8	18.142478	2.8982561	0.0947825	0.3090097
757	10	18.043878	2.8928064	0.0947825	0.3820093
758	24	18.568297	2.9214557	0.0936221	0.8589501
759	1	15.616052	2.7482994	0.0926675	0.0691591
760	1	18.568297	2.9214557	0.0936221	0.0589595
761	1	18.241079	2.9036761	0.0947825	0.0599395
762	6	18.467383	2.9160061	0.0936221	0.2340507
763	4	18.142478	2.8982561	0.0947825	0.1668563
764	20	18.43828	2.9144289	0.0947825	0.7245284
765	17	18.467383	2.9160061	0.0936221	0.618594
766	8	20.54036	3.0223917	0.1065887	0.2753026

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Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
767	21	18.568297	2.9214557	0.0936221	0.7546035
768	4	15.531182	2.7428498	0.0926675	0.1925141
769	3	18.241079	2.9036761	0.0947825	0.1306602
770	5	19.2747	2.9587934	0.0936221	0.1913343
771	17	18.241079	2.9036761	0.0947825	0.6257052
772	24	18.669212	2.9268757	0.0936221	0.8546405
773	34	17.846677	2.8818173	0.0947825	1.2519114
774	32	18.339679	2.909067	0.0947825	1.1503488
775	14	18.568297	2.9214557	0.0936221	0.5111281
776	6	18.142478	2.8982561	0.0947825	0.237933
777	29	15.616052	2.7482994	0.0926675	1.2115394
778	46	18.241079	2.9036761	0.0947825	1.6511553
779	5	4.9224512	1.5938066	0.0926675	0.6175032
780	10	15.616052	2.7482994	0.0926675	0.4363528
781	15	17.088821	2.8384245	0.1046762	0.589484
782	28	18.339679	2.909067	0.0947825	1.0096123
783	32	18.568297	2.9214557	0.0936221	1.1372077
784	16	16.210141	2.785637	0.0926675	0.6582395
785	8	17.945277	2.887327	0.0947825	0.3121522
786	21	17.088821	2.8384245	0.1046762	0.8148348
787	39	17.088821	2.8384245	0.1046762	1.490887
788	21	18.53688	2.9197623	0.0947825	0.75579
789	11	17.088821	2.8384245	0.1046762	0.4392502
790	36	19.2747	2.9587934	0.0936221	1.2328183
791	14	20.90329	3.0399066	0.0947825	0.4577152

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Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
792	12	16.125271	2.7803877	0.0926675	0.5029478
793	2	18.568297	2.9214557	0.0936221	0.0937417
794	38	18.669212	2.9268757	0.0936221	1.3391481
795	114	18.770127	2.9322666	0.0936221	3.9495162
796	3	15.616052	2.7482994	0.0926675	0.1507577
797	1	18.142478	2.8982561	0.0947825	0.0602413
798	0	15.616052	2.7482994	0.0926675	0.0283598
799	20	20.982088	3.0436691	0.1065887	0.6423345
800	4	18.017562	2.8913469	0.1046762	0.1679272
801	0	18.20331	2.9016034	0.1046762	0.0246264
802	67	16.995947	2.8329749	0.1046762	2.5553258
803	0	19.853518	2.9883812	0.1050608	0.0227182
804	0	20.319496	3.0115808	0.1065887	0.0222317
805	3	20.871656	3.0383921	0.1065887	0.1152564
806	23	20.716714	3.0309408	0.1050608	0.7442577
807	29	20.54036	3.0223917	0.1065887	0.9402002
808	11	21.423817	3.0645032	0.1065887	0.3559787
809	57	20.069317	2.9991921	0.1050608	1.8667358
810	4	20.285116	3.0098874	0.1050608	0.150402
811	3	21.092521	3.0489185	0.1065887	0.1141265
812	8	16.295011	2.790859	0.0926675	0.3411833
813	5	15.955532	2.7698056	0.0926675	0.2278255
814	0	19.621485	2.9766251	0.0947825	0.0229685
815	38	15.021963	2.7095133	0.0926675	1.6356509
816	15	15.700922	2.7537194	0.0926675	0.6371814

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Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
817	0	19.853518	2.9883812	0.1050608	0.0227182
818	0	15.361443	2.7318606	0.0926675	0.0287892
819	11	18.467383	2.9160061	0.0936221	0.4088431
820	6	19.375615	2.9640153	0.0936221	0.2238402
821	16	19.2747	2.9587934	0.0936221	0.5608931
822	4	19.325683	2.961435	0.0947825	0.1573508
823	2	17.945277	2.887327	0.0947825	0.0967536
824	0	15.700922	2.7537194	0.0926675	0.0282195
825	21	15.700922	2.7537194	0.0926675	0.8807662
826	9	18.265553	2.905017	0.0936221	0.3423967
827	1	17.088821	2.8384245	0.1046762	0.0636656
828	6	17.143709	2.8416313	0.0926675	0.2507155
829	24	18.043878	2.8928064	0.0947825	0.8820632
830	14	18.832681	2.9355937	0.0947825	0.5044636
831	15	19.476529	2.9692101	0.0936221	0.5222093
832	19	18.568297	2.9214557	0.0936221	0.6850391
833	23	18.142478	2.8982561	0.0947825	0.8420849
834	1	18.142478	2.8982561	0.0947825	0.0602413
835	7	16.125271	2.7803877	0.0926675	0.3048605
836	5	21.092521	3.0489185	0.1065887	0.1758982
837	23	21.092521	3.0489185	0.1065887	0.7318436
838	3	17.088821	2.8384245	0.1046762	0.1387825
839	4	16.903073	2.8274955	0.1046762	0.1781257
840	2	20.319496	3.0115808	0.1065887	0.086198
841	0	20.285116	3.0098874	0.1050608	0.0222669

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The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
842	0	21.202953	3.0541404	0.1065887	0.0213642
843	0	20.209064	3.0061312	0.1065887	0.0223451
844	37	17.088821	2.8384245	0.1046762	1.4157701
845	22	21.755113	3.0798488	0.1065887	0.6809315
846	25	17.181695	2.8438446	0.1046762	0.9602577
847	16	20.319496	3.0115808	0.1065887	0.5339625
848	3	19.853518	2.9883812	0.1050608	0.1207674
849	2	20.069317	2.9991921	0.1050608	0.0872006
850	98	17.088821	2.8384245	0.1046762	3.7068361
851	3	17.274569	2.8492354	0.1046762	0.1374057
852	34	19.853518	2.9883812	0.1050608	1.133943
853	46	19.853518	2.9883812	0.1050608	1.52614
854	0	18.568297	2.9214557	0.0936221	0.0241773
855	5	18.568297	2.9214557	0.0936221	0.1980883
856	0	18.142478	2.8982561	0.0947825	0.0247029
857	16	18.142478	2.8982561	0.0947825	0.5933164
858	5	17.05884	2.8366685	0.0926675	0.2142459
859	9	16.80423	2.8216306	0.0926675	0.3698103
860	39	19.853518	2.9883812	0.1050608	1.2973584
861	14	17.274569	2.8492354	0.1046762	0.5464501
862	3	20.209064	3.0061312	0.1065887	0.1187841
863	33	17.846677	2.8818173	0.0947825	1.2158282
864	8	19.853518	2.9883812	0.1050608	0.2841829
865	1	18.43828	2.9144289	0.0947825	0.0593451
866	7	18.43828	2.9144289	0.0947825	0.269403

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The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
867	2	18.467383	2.9160061	0.0936221	0.0942168
868	1	16.464751	2.8012218	0.0926675	0.0658834
869	26	18.43828	2.9144289	0.0947825	0.9345863
870	15	18.366468	2.9105266	0.0936221	0.5514719
871	31	17.088821	2.8384245	0.1046762	1.1904193
872	15	15.785792	2.7591103	0.0926675	0.6340447
873	36	18.770127	2.9322666	0.0936221	1.2635928
874	26	18.669212	2.9268757	0.0936221	0.9238559
875	9	15.870662	2.7644722	0.0926675	0.3897404
876	19	15.785792	2.7591103	0.0926675	0.7956352
877	16	18.770127	2.9322666	0.0936221	0.5748946
878	35	17.846677	2.8818173	0.0947825	1.2879947
879	0	15.531182	2.7428498	0.0926675	0.0285015
880	29	18.142478	2.8982561	0.0947825	1.0553149
881	3	15.531182	2.7428498	0.0926675	0.151511
882	3	4.8375814	1.5764149	0.0926675	0.4059139
883	39	15.446313	2.7373703	0.0926675	1.635797
884	33	18.568297	2.9214557	0.0936221	1.1719899
885	1	18.467383	2.9160061	0.0936221	0.0592583
886	48	18.43828	2.9144289	0.0947825	1.7047986
887	4	18.568297	2.9214557	0.0936221	0.1633061
888	10	15.616052	2.7482994	0.0926675	0.4363528
889	41	18.568297	2.9214557	0.0936221	1.4502475
890	54	18.734081	2.9303444	0.0947825	1.8867859
891	16	18.043878	2.8928064	0.0947825	0.5963181

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Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
892	20	18.366468	2.9105266	0.0936221	0.7271547
893	4	18.241079	2.9036761	0.0947825	0.1660206
894	2	18.043878	2.8928064	0.0947825	0.0962642
895	53	19.375615	2.9640153	0.0936221	1.79521
896	9	18.568297	2.9214557	0.0936221	0.3372171
897	29	19.745618	2.9829316	0.1050608	0.9754703
898	20	15.785792	2.7591103	0.0926675	0.8360328
899	1	17.550876	2.8651038	0.0947825	0.0621172
900	79	18.142478	2.8982561	0.0947825	2.8322322
901	14	15.531182	2.7428498	0.0926675	0.6025455
902	2	15.531182	2.7428498	0.0926675	0.1105078
903	16	15.785792	2.7591103	0.0926675	0.6744423
904	37	18.043878	2.8928064	0.0947825	1.346399
905	0	20.319496	3.0115808	0.1065887	0.0222317
906	9	21.313385	3.0593353	0.1065887	0.2965347
907	0	18.142478	2.8982561	0.0947825	0.0247029
908	5	17.088821	2.8384245	0.1046762	0.2138994
909	3	19.853518	2.9883812	0.1050608	0.1207674
910	8	20.209064	3.0061312	0.1065887	0.2795157
911	14	17.846677	2.8818173	0.0947825	0.5302469
912	0	20.982088	3.0436691	0.1065887	0.0215747
913	0	19.961417	2.9938013	0.1050608	0.0226037
914	0	20.069317	2.9991921	0.1050608	0.0224903
915	17	17.367443	2.8545974	0.1046762	0.6547597
916	75	20.209064	3.0061312	0.1065887	2.4333196

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The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
917	2	20.209064	3.0061312	0.1065887	0.0866378
918	0	15.700922	2.7537194	0.0926675	0.0282195
919	16	15.785792	2.7591103	0.0926675	0.6744423
920	4	16.995947	2.8329749	0.1046762	0.1772288
921	10	18.669212	2.9268757	0.0936221	0.3701329
922	0	17.646065	2.8705128	0.1046762	0.0253452
923	2	15.700922	2.7537194	0.0926675	0.1094145
924	1	18.339679	2.909067	0.0947825	0.0596408
925	32	17.088821	2.8384245	0.1046762	1.2279778
926	11	18.142478	2.8982561	0.0947825	0.4156247
927	1	18.669212	2.9268757	0.0936221	0.0586637
928	13	19.853518	2.9883812	0.1050608	0.4475983
929	19	15.700922	2.7537194	0.0926675	0.7995713
930	5	16.995947	2.8329749	0.1046762	0.2149764
931	44	19.637718	2.9774521	0.1050608	1.4757289
932	52	18.241079	2.9036761	0.0947825	1.8633174
933	7	12.920549	2.558819	0.1065887	0.3727945
934	32	17.274569	2.8492354	0.1046762	1.2157955
935	37	17.088821	2.8384245	0.1046762	1.4157701
936	6	18.568297	2.9214557	0.0936221	0.2328705
937	19	17.088821	2.8384245	0.1046762	0.7397178
938	46	21.148312	3.0515601	0.1050608	1.4386557
939	6	18.241079	2.9036761	0.0947825	0.2367413
940	39	15.616052	2.7482994	0.0926675	1.6195323
941	5	19.9882	2.9951421	0.1065887	0.1849637

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
942	9	16.295011	2.790859	0.0926675	0.3804219
943	15	17.945277	2.887327	0.0947825	0.5634505
944	2	15.616052	2.7482994	0.0926675	0.1099584
945	1	15.446313	2.7373703	0.0926675	0.0698537
946	46	17.088821	2.8384245	0.1046762	1.7537962
947	1	20.607489	3.0256545	0.0947825	0.0535067
948	12	18.832681	2.9355937	0.0947825	0.4358062
949	32	18.241079	2.9036761	0.0947825	1.1561104
950	26	21.202953	3.0541404	0.1065887	0.8204796
951	8	15.700922	2.7537194	0.0926675	0.3529992
952	36	19.59642	2.9753469	0.1046762	1.2139659
953	47	18.568297	2.9214557	0.0936221	1.6589407
954	19	19.173785	2.953544	0.0936221	0.6649208
955	50	18.043878	2.8928064	0.0947825	1.8107348
956	11	15.616052	2.7482994	0.0926675	0.4771521
957	9	17.088821	2.8384245	0.1046762	0.3641332
958	26	15.361443	2.7318606	0.0926675	1.1056311
959	12	18.142478	2.8982561	0.0947825	0.4511631
960	4	18.142478	2.8982561	0.0947825	0.1668563
961	4	15.616052	2.7482994	0.0926675	0.191557
962	0	17.088821	2.8384245	0.1046762	0.0261071
963	8	15.616052	2.7482994	0.0926675	0.3547542
964	1	19.2747	2.9587934	0.0936221	0.0569492
965	14	17.181695	2.8438446	0.1046762	0.5491742
966	31	18.568297	2.9214557	0.0936221	1.1024255

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
967	21	15.700922	2.7537194	0.0926675	0.8807662
968	2	4.1586226	1.4251839	0.0926675	0.3306933
969	10	15.106833	2.7151472	0.0926675	0.4497682
970	9	18.971956	2.9429619	0.0936221	0.3305497
971	43	20.319496	3.0115808	0.1065887	1.3975083
972	4	18.142478	2.8982561	0.0947825	0.1668563
973	50	20.177216	3.0045541	0.1050608	1.6320624
974	21	20.319496	3.0115808	0.1065887	0.6938784
975	0	19.745618	2.9829316	0.1050608	0.0228339
976	4	17.088821	2.8384245	0.1046762	0.1763409
977	8	18.871041	2.9376285	0.0936221	0.2979279
978	7	20.209064	3.0061312	0.1065887	0.2473694
979	13	16.210141	2.785637	0.0926675	0.5399582
980	22	20.871656	3.0383921	0.1065887	0.7078973
981	9	16.903073	2.8274955	0.1046762	0.3678187
982	0	18.296184	2.9066925	0.1046762	0.0245106
983	19	19.678359	2.9795195	0.0936221	0.6490355
984	22	15.531182	2.7428498	0.0926675	0.9305707
985	62	18.467383	2.9160061	0.0936221	2.1917256
986	46	19.961417	2.9938013	0.1050608	1.5184458
987	21	18.142478	2.8982561	0.0947825	0.7710082
988	44	18.366468	2.9105266	0.0936221	1.5704319
989	34	18.366468	2.9105266	0.0936221	1.2190664
990	31	15.785792	2.7591103	0.0926675	1.2804064
991	15	18.568297	2.9214557	0.0936221	0.5459103

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The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
992	43	17.76098	2.8770039	0.0936221	1.5836949
993	18	18.142478	2.8982561	0.0947825	0.6643931
994	41	18.770127	2.9322666	0.0936221	1.4357674
995	13	18.142478	2.8982561	0.0947825	0.4867014
996	14	18.241079	2.9036761	0.0947825	0.5196241
997	27	11.403357	2.4339077	0.0936221	1.4997759
998	57	16.717325	2.8164456	0.1046762	2.2112505
999	2	19.375615	2.9640153	0.0936221	0.0901066
1000	18	15.700922	2.7537194	0.0926675	0.7589738
1001	14	17.924687	2.886179	0.1046762	0.5281115
1002	49	19.745618	2.9829316	0.1050608	1.632461
1003	11	15.843602	2.7627657	0.0936221	0.4708753
1004	2	6.9020298	1.9318155	0.0947825	0.2240288
1005	46	18.669212	2.9268757	0.0936221	1.6160096
1006	10	15.616052	2.7482994	0.0926675	0.4363528
1007	70	15.700922	2.7537194	0.0926675	2.8700417
1008	46	18.568297	2.9214557	0.0936221	1.6241585
1009	19	19.072871	2.9482669	0.0936221	0.6681915
1010	20	17.945277	2.887327	0.0947825	0.7429493
1011	29	17.483189	2.8612398	0.0926675	1.0920694
1012	16	15.531182	2.7428498	0.0926675	0.6845518
1013	48	15.785792	2.7591103	0.0926675	1.9671658
1014	10	18.339679	2.909067	0.0947825	0.376298
1015	0	15.700922	2.7537194	0.0926675	0.0282195
1016	9	18.63548	2.9250673	0.0947825	0.3360888

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
1017	15	18.043878	2.8928064	0.0947825	0.5606
1018	40	18.568297	2.9214557	0.0936221	1.4154653
1019	8	17.088821	2.8384245	0.1046762	0.3265748
1020	16	15.870662	2.7644722	0.0926675	0.6711384
1021	10	18.339679	2.909067	0.0947825	0.376298
1022	26	15.616052	2.7482994	0.0926675	1.0891415
1023	27	18.568297	2.9214557	0.0936221	0.9632967
1024	31	18.568297	2.9214557	0.0936221	1.1024255
1025	49	18.568297	2.9214557	0.0936221	1.7285051

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Parameter Code=HYNOCSX Parameter=Nocturnal severe or BG confirmed hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Model Information			
Data Set	WORK.ENDPOINT		
Distribution	Negative Binomial		
Link Function	Log		
Dependent Variable	AVAL	Analysis Value	
Offset Variable	log_offset		
Number of Observations Read	1025		
Number of Observations Used	1025		

Class Level Information		
Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Parameter Information				
Parameter	Effect	TRTPN	REGION1	BOLAD1
Prm1	Intercept			
Prm2	TRTPN	2		
Prm3	TRTPN	3		
Prm4	TRTPN	4		
Prm5	REGION1		ASIA (EXCLUDING JAPAN)	
Prm6	REGION1		EUROPE	

Nocturnal hypoglycaemic episodes - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=HYNOCSEX Parameter=Nocturnal severe or BG confirmed hypoglycaemic episodes Study Identifier=NN1218-4131

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Parameter Information

Parameter	Effect	TRTPN	REGION1	BOLAD1
Prm7	REGION1		JAPAN	
Prm8	REGION1		NORTH AMERICA	
Prm9	BOLAD1			BOLUS INSULIN ALGORITHM (SLIDING SCALE)
Prm10	BOLAD1			CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Criteria For Assessing Goodness Of Fit

Criterion	DF	Value	Value/DF
Deviance	1018	945.8934	0.9292
Scaled Deviance	1018	945.8934	0.9292
Pearson Chi-Square	1018	1022.9162	1.0048
Scaled Pearson X2	1018	1022.9162	1.0048
Log Likelihood		131.9599	
Full Log Likelihood		-1766.2834	
AIC (smaller is better)		3548.5668	
AICC (smaller is better)		3548.7086	
BIC (smaller is better)		3588.0264	

Algorithm converged.

Nocturnal hypoglycaemic episodes - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=HYNOCSEX Parameter=Nocturnal severe or BG confirmed hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Analysis Of Maximum Likelihood Parameter Estimates

Parameter		DF	Estimate	Standard Error	Wald 95% Confidence Limits	Wald Chi-Square
Intercept		1	6.2885	0.1327	6.0285 6.5485	2247.00
TRTPN	2	1	-0.1744	0.1323	-0.4337 0.0850	1.74
TRTPN	3	1	-0.1089	0.1320	-0.3676 0.1499	0.68
TRTPN	4	0	0.0000	0.0000	0.0000 0.0000	.
REGION1	ASIA (EXCLUDING JAPAN)	1	-0.5490	0.2014	-0.9438 -0.1543	7.43
REGION1	EUROPE	1	-0.2851	0.1356	-0.5509 -0.0193	4.42
REGION1	JAPAN	1	-0.2956	0.1591	-0.6073 0.0162	3.45
REGION1	NORTH AMERICA	0	0.0000	0.0000	0.0000 0.0000	.
BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	1	-0.1948	0.1238	-0.4375 0.0478	2.48
BOLAD1	CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY	0	0.0000	0.0000	0.0000 0.0000	.
Dispersion		1	2.3852	0.1692	2.0757 2.7409	

Analysis Of Maximum Likelihood Parameter Estimates

Parameter		Pr > ChiSq
Intercept		<.0001
TRTPN	2	0.1876
TRTPN	3	0.4096
TRTPN	4	.
REGION1	ASIA (EXCLUDING JAPAN)	0.0064
REGION1	EUROPE	0.0355
REGION1	JAPAN	0.0631
REGION1	NORTH AMERICA	.
BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.1156
BOLAD1	CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY	.
Dispersion		

NOTE: The negative binomial dispersion parameter was estimated by maximum likelihood.

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Coefficients for TRTPN Least Squares Means Using WORK.ENDPOINT Margins

Parameter	Geographic Region Grouping Method 1
Intercept	
Planned Treatment (N) 2	
Planned Treatment (N) 3	
Planned Treatment (N) 4	
Geographic Region Grouping Method 1 ASIA (EXCLUDING JAPAN)	ASIA (EXCLUDING JAPAN)
Geographic Region Grouping Method 1 EUROPE	EUROPE
Geographic Region Grouping Method 1 JAPAN	JAPAN
Geographic Region Grouping Method 1 NORTH AMERICA	NORTH AMERICA
Bolus Adjustment Method at Timepoint 1 BOLUS INSULIN ALGORITHM (SLIDING SCALE)	
Bolus Adjustment Method at Timepoint 1 CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY	

Coefficients for TRTPN Least Squares Means Using WORK.ENDPOINT Margins

	Planned Treatment (N)	Row1	Row2	Row3
Bolus Adjustment Method at Timepoint 1				
	1	1	1	1
	2	1		
	3		1	
	4			1
		0.1307	0.1307	0.1307
		0.3366	0.3366	0.3366
		0.239	0.239	0.239
		0.2937	0.2937	0.2937
BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.5824	0.5824	0.5824
CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0.4176	0.4176	0.4176

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The GENMOD Procedure

TRTPN Least Squares Means

Planned Treatment (N)	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
2	WORK.ENDPOINT	5.7622	0.09414	61.21	<.0001	0.05	5.5777	5.9467
3	WORK.ENDPOINT	5.8277	0.09373	62.17	<.0001	0.05	5.6440	6.0115
4	WORK.ENDPOINT	5.9366	0.09279	63.98	<.0001	0.05	5.7548	6.1185

Differences of TRTPN Least Squares Means

Planned Treatment (N)	Planned Treatment (N)	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
2	4	WORK.ENDPOINT	-0.1744	0.1323	-1.32	0.1876	0.05	-0.4337	0.08498
3	4	WORK.ENDPOINT	-0.1089	0.1320	-0.82	0.4096	0.05	-0.3676	0.1499

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) / NovoRapid (meal)	WORK.ENDPOINT	-0.1744	0.1323	-1.32	0.1876	0.05	-0.4337	0.08498

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Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
TRTPN	Faster aspart (post) / NovoRapid (meal)	WORK.ENDPOINT	-0.1089	0.1320	-0.82	0.4096	0.05	-0.3676	0.1499

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
1	2	1.6950604	0.5277184	0.169902	0.3845918
2	1	1.6950604	0.5277184	0.169902	0.2256202
3	0	1.6950604	0.5277184	0.169902	0.0666486
4	0	1.6950604	0.5277184	0.169902	0.0666486
5	5	1.6950604	0.5277184	0.169902	0.8615066
6	1	1.4025693	0.3383058	0.140247	0.2514456
7	4	1.8098095	0.5932216	0.1661188	0.6748539
8	1	1.8589891	0.6200329	0.1661188	0.2131123
9	0	1.7595464	0.5650561	0.169902	0.0651494
10	0	0.2797956	-1.273696	0.135167	0.1006409
11	1	1.6766359	0.5167893	0.169902	0.2271087
12	4	1.8589891	0.6200329	0.1661188	0.6635879
13	1	1.8098095	0.5932216	0.1661188	0.2167304
14	3	1.9960223	0.6911564	0.1667636	0.4904962
15	2	1.6950604	0.5277184	0.169902	0.3845918
16	7	2.0289238	0.7075055	0.1667636	1.0529626

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
17	3	1.3949878	0.3328857	0.140247	0.6075537
18	0	1.5541807	0.4409485	0.1366784	0.0701457
19	0	1.6607225	0.5072527	0.135167	0.0674722
20	0	1.9960223	0.6911564	0.1667636	0.0601418
21	8	1.3949878	0.3328857	0.140247	1.4959853
22	0	0.3619161	-1.016343	0.1667636	0.1042475
23	0	1.8098095	0.5932216	0.1661188	0.0640225
24	1	1.4894232	0.3983889	0.1366784	0.2432682
25	0	1.878661	0.6305593	0.1661188	0.0625353
26	0	1.8098095	0.5932216	0.1661188	0.0640225
27	2	2.0163639	0.7012958	0.1661188	0.34475
28	14	1.4894232	0.3983889	0.1366784	2.471551
29	0	1.7042727	0.5331385	0.169902	0.0664306
30	0	1.7148765	0.539341	0.135167	0.0661813
31	0	1.4894232	0.3983889	0.1366784	0.0718618
32	0	1.6950604	0.5277184	0.169902	0.0666486
33	0	1.8098095	0.5932216	0.1661188	0.0640225
34	0	1.6516968	0.5018031	0.135167	0.0676917
35	1	1.9376765	0.6614896	0.1661188	0.2075484
36	0	2.0179566	0.7020854	0.1667636	0.0597132
37	3	2.0179566	0.7020854	0.1667636	0.4870007
38	4	1.8098095	0.5932216	0.1661188	0.6748539
39	0	1.8098095	0.5932216	0.1661188	0.0640225
40	0	1.7803018	0.5767829	0.1661188	0.0646797
41	2	1.8098095	0.5932216	0.1661188	0.3694382

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
42	2	1.5056126	0.4091998	0.1366784	0.4121603
43	0	1.4894232	0.3983889	0.1366784	0.0718618
44	5	1.6607225	0.5072527	0.135167	0.8721533
45	0	1.3949878	0.3328857	0.140247	0.0744947
46	0	1.4556395	0.3754453	0.140247	0.0727856
47	0	1.3949878	0.3328857	0.140247	0.0744947
48	4	1.5137072	0.4145618	0.1366784	0.7506159
49	9	1.6516968	0.5018031	0.135167	1.5208298
50	0	1.4101507	0.3436966	0.140247	0.0740612
51	0	1.4101507	0.3436966	0.140247	0.0740612
52	0	1.4894232	0.3983889	0.1366784	0.0718618
53	0	1.5056126	0.4091998	0.1366784	0.0714261
54	0	1.6787738	0.5180636	0.135167	0.067037
55	0	1.4732338	0.3874598	0.1366784	0.072302
56	0	1.4101507	0.3436966	0.140247	0.0740612
57	26	1.6594117	0.5064631	0.1366784	4.2538179
58	8	1.4253137	0.3543919	0.140247	1.4786605
59	0	1.6697481	0.5126728	0.135167	0.067254
60	3	1.4894232	0.3983889	0.1366784	0.5860809
61	3	1.6877995	0.5234256	0.135167	0.5449717
62	6	1.4253137	0.3543919	0.140247	1.1274034
63	6	1.4732338	0.3874598	0.1366784	1.1070405
64	1	1.6607225	0.5072527	0.135167	0.2284084
65	5	1.5298966	0.4252002	0.1366784	0.914922
66	0	1.5137072	0.4145618	0.1366784	0.0712099

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
67	0	1.4894232	0.3983889	0.1366784	0.0718618
68	0	1.4732338	0.3874598	0.1366784	0.072302
69	0	1.3722435	0.316447	0.140247	0.0751526
70	0	1.3949878	0.3328857	0.140247	0.0744947
71	0	1.4632209	0.3806401	0.140247	0.0725766
72	0	1.6607225	0.5072527	0.135167	0.0674722
73	7	1.4894232	0.3983889	0.1366784	1.2717064
74	0	1.6607225	0.5072527	0.135167	0.0674722
75	3	1.4025693	0.3383058	0.140247	0.605782
76	6	1.6607225	0.5072527	0.135167	1.0330896
77	0	1.4894232	0.3983889	0.1366784	0.0718618
78	0	1.6607225	0.5072527	0.135167	0.0674722
79	2	1.3949878	0.3328857	0.140247	0.4298673
80	8	1.4025693	0.3383058	0.140247	1.491623
81	0	1.6607225	0.5072527	0.135167	0.0674722
82	2	1.3949878	0.3328857	0.140247	0.4298673
83	0	1.6607225	0.5072527	0.135167	0.0674722
84	0	1.6336455	0.490814	0.135167	0.0681345
85	1	1.3949878	0.3328857	0.140247	0.252181
86	0	1.4813285	0.3929393	0.1366784	0.0720813
87	4	1.3949878	0.3328857	0.140247	0.78524
88	0	1.4894232	0.3983889	0.1366784	0.0718618
89	2	1.6877995	0.5234256	0.135167	0.3855882
90	0	1.4651391	0.3819502	0.1366784	0.0725238
91	7	1.6516968	0.5018031	0.135167	1.1979102

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
92	9	1.6607225	0.5072527	0.135167	1.5158982
93	23	1.6336455	0.490814	0.135167	3.8060021
94	0	1.6516968	0.5018031	0.135167	0.0676917
95	0	1.3949878	0.3328857	0.140247	0.0744947
96	0	1.6336455	0.490814	0.135167	0.0681345
97	0	1.4894232	0.3983889	0.1366784	0.0718618
98	1	2.0179566	0.7020854	0.1667636	0.2021423
99	4	1.3949878	0.3328857	0.140247	0.78524
100	0	1.7803018	0.5767829	0.1661188	0.0646797
101	0	1.6607225	0.5072527	0.135167	0.0674722
102	0	1.6858482	0.5222688	0.169902	0.0668678
103	1	1.8393173	0.6093945	0.1661188	0.2145462
104	1	1.6607225	0.5072527	0.135167	0.2284084
105	0	1.9960223	0.6911564	0.1667636	0.0601418
106	0	1.9850552	0.6856467	0.1667636	0.0603582
107	4	1.6607225	0.5072527	0.135167	0.7112171
108	2	1.4975179	0.403809	0.1366784	0.4134142
109	3	1.4732338	0.3874598	0.1366784	0.5896712
110	0	1.6950604	0.5277184	0.169902	0.0666486
111	2	1.9960223	0.6911564	0.1667636	0.3470447
112	1	2.0179566	0.7020854	0.1667636	0.2021423
113	0	2.0179566	0.7020854	0.1667636	0.0597132
114	0	2.0179566	0.7020854	0.1667636	0.0597132
115	0	1.6950604	0.5277184	0.169902	0.0666486
116	3	1.8098095	0.5932216	0.1661188	0.5221461

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
117	0	2.0289238	0.7075055	0.1667636	0.059501
118	0	1.6950604	0.5277184	0.169902	0.0666486
119	0	2.0179566	0.7020854	0.1667636	0.0597132
120	0	1.6950604	0.5277184	0.169902	0.0666486
121	0	2.0179566	0.7020854	0.1667636	0.0597132
122	0	1.6950604	0.5277184	0.169902	0.0666486
123	0	1.7803018	0.5767829	0.1661188	0.0646797
124	3	2.0179566	0.7020854	0.1667636	0.4870007
125	4	1.6950604	0.5277184	0.169902	0.702535
126	0	1.7999736	0.587772	0.1661188	0.0642402
127	0	1.8098095	0.5932216	0.1661188	0.0640225
128	0	1.8393173	0.6093945	0.1661188	0.0633773
129	0	1.4894232	0.3983889	0.1366784	0.0718618
130	0	1.7595464	0.5650561	0.169902	0.0651494
131	0	1.4708024	0.3858081	0.140247	0.0723685
132	0	1.8098095	0.5932216	0.1661188	0.0640225
133	0	2.1442309	0.7627809	0.1661188	0.0573528
134	0	1.7058508	0.534064	0.135167	0.0663934
135	0	2.0289238	0.7075055	0.1667636	0.059501
136	0	2.259234	0.8150258	0.1667636	0.0553511
137	0	1.1704746	0.1574093	0.1661188	0.081407
138	2	1.8231844	0.6005847	0.135167	0.3677421
139	1	1.713485	0.5385293	0.169902	0.224149
140	2	1.9960223	0.6911564	0.1667636	0.3470447
141	1	1.878661	0.6305593	0.1661188	0.2116958

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
142	1	1.7901377	0.5822925	0.1661188	0.2182091
143	1	1.6607225	0.5072527	0.135167	0.2284084
144	2	1.3949878	0.3328857	0.140247	0.4298673
145	5	1.3949878	0.3328857	0.140247	0.9629263
146	0	1.7058508	0.534064	0.135167	0.0663934
147	0	1.6027488	0.4717202	0.1366784	0.0689044
148	0	1.9427259	0.6640921	0.1366784	0.0612074
149	0	1.6697481	0.5126728	0.135167	0.067254
150	2	1.3722435	0.316447	0.140247	0.4336638
151	6	1.4894232	0.3983889	0.1366784	1.1003
152	8	1.6607225	0.5072527	0.135167	1.354962
153	1	1.6336455	0.490814	0.135167	0.2306505
154	0	1.4813285	0.3929393	0.1366784	0.0720813
155	0	1.6426711	0.4963237	0.135167	0.0679125
156	0	0.9931707	-0.006853	0.140247	0.0875063
157	0	1.2303931	0.2073337	0.1366784	0.0794707
158	0	1.4894232	0.3983889	0.1366784	0.0718618
159	2	1.4101507	0.3436966	0.140247	0.4273663
160	0	1.4177322	0.3490586	0.140247	0.0738461
161	3	1.3949878	0.3328857	0.140247	0.6075537
162	0	1.4894232	0.3983889	0.1366784	0.0718618
163	0	1.4894232	0.3983889	0.1366784	0.0718618
164	0	1.4894232	0.3983889	0.1366784	0.0718618
165	1	1.1282082	0.1206307	0.135167	0.280338
166	0	1.4732338	0.3874598	0.1366784	0.072302

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
167	1	1.6607225	0.5072527	0.135167	0.2284084
168	4	1.6787738	0.5180636	0.135167	0.7066293
169	12	1.6426711	0.4963237	0.135167	2.0117488
170	2	1.3874064	0.3274361	0.140247	0.4311268
171	0	1.4813285	0.3929393	0.1366784	0.0720813
172	0	1.4177322	0.3490586	0.140247	0.0738461
173	0	1.4025693	0.3383058	0.140247	0.0742774
174	0	1.6336455	0.490814	0.135167	0.0681345
175	1	1.6787738	0.5180636	0.135167	0.2269351
176	0	1.6516968	0.5018031	0.135167	0.0676917
177	5	1.546086	0.4357266	0.1366784	0.9094337
178	0	1.4177322	0.3490586	0.140247	0.0738461
179	0	1.4894232	0.3983889	0.1366784	0.0718618
180	2	1.6516968	0.5018031	0.135167	0.3906113
181	0	1.3722435	0.316447	0.140247	0.0751526
182	0	1.6426711	0.4963237	0.135167	0.0679125
183	1	1.4894232	0.3983889	0.1366784	0.2432682
184	0	1.4894232	0.3983889	0.1366784	0.0718618
185	2	1.5137072	0.4145618	0.1366784	0.4109129
186	1	1.6516968	0.5018031	0.135167	0.2291515
187	0	1.3949878	0.3328857	0.140247	0.0744947
188	3	1.4025693	0.3383058	0.140247	0.605782
189	0	0.8094691	-0.211377	0.1366784	0.0942407
190	2	1.3722435	0.316447	0.140247	0.4336638
191	5	1.9411865	0.6632994	0.1667636	0.7915776

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The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
192	11	1.6426711	0.4963237	0.135167	1.8497625
193	0	1.3949878	0.3328857	0.140247	0.0744947
194	2	1.6607225	0.5072527	0.135167	0.3893447
195	1	1.5218019	0.4198951	0.1366784	0.2403334
196	4	2.0508581	0.7182583	0.1667636	0.6227645
197	0	1.6607225	0.5072527	0.135167	0.0674722
198	1	1.6336455	0.490814	0.135167	0.2306505
199	0	1.3949878	0.3328857	0.140247	0.0744947
200	0	1.6697481	0.5126728	0.135167	0.067254
201	0	1.4101507	0.3436966	0.140247	0.0740612
202	0	0.5234886	-0.64724	0.135167	0.1035306
203	0	0.7770904	-0.252199	0.1366784	0.0954346
204	2	1.3949878	0.3328857	0.140247	0.4298673
205	2	1.4975179	0.403809	0.1366784	0.4134142
206	0	1.448058	0.3702234	0.140247	0.0729957
207	0	1.3949878	0.3328857	0.140247	0.0744947
208	5	1.4975179	0.403809	0.1366784	0.9260704
209	3	1.3722435	0.316447	0.140247	0.6129194
210	0	1.6607225	0.5072527	0.135167	0.0674722
211	4	1.878661	0.6305593	0.1661188	0.6591773
212	0	1.4732338	0.3874598	0.1366784	0.072302
213	0	1.4894232	0.3983889	0.1366784	0.0718618
214	0	1.8098095	0.5932216	0.1661188	0.0640225
215	0	0.0566628	-2.870637	0.1366784	0.0439733
216	0	1.6950604	0.5277184	0.169902	0.0666486

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The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
217	0	1.9960223	0.6911564	0.1667636	0.0601418
218	0	1.7042727	0.5331385	0.169902	0.0664306
219	0	2.0289238	0.7075055	0.1667636	0.059501
220	0	1.9960223	0.6911564	0.1667636	0.0601418
221	0	1.6516968	0.5018031	0.135167	0.0676917
222	1	1.3949878	0.3328857	0.140247	0.252181
223	1	1.4894232	0.3983889	0.1366784	0.2432682
224	0	1.546086	0.4357266	0.1366784	0.0703563
225	0	1.3949878	0.3328857	0.140247	0.0744947
226	6	1.3949878	0.3328857	0.140247	1.1406126
227	1	1.4894232	0.3983889	0.1366784	0.2432682
228	0	1.6607225	0.5072527	0.135167	0.0674722
229	0	1.7239021	0.5445904	0.135167	0.0659705
230	0	1.4894232	0.3983889	0.1366784	0.0718618
231	0	1.4975179	0.403809	0.1366784	0.0716434
232	0	1.6968251	0.5287589	0.135167	0.0666067
233	0	1.4894232	0.3983889	0.1366784	0.0718618
234	3	1.4177322	0.3490586	0.140247	0.6022641
235	1	1.4894232	0.3983889	0.1366784	0.2432682
236	5	1.4975179	0.403809	0.1366784	0.9260704
237	0	1.4894232	0.3983889	0.1366784	0.0718618
238	1	1.6607225	0.5072527	0.135167	0.2284084
239	1	1.4894232	0.3983889	0.1366784	0.2432682
240	0	1.3949878	0.3328857	0.140247	0.0744947
241	0	1.3949878	0.3328857	0.140247	0.0744947

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The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
242	2	1.3949878	0.3328857	0.140247	0.4298673
243	0	1.6607225	0.5072527	0.135167	0.0674722
244	0	1.5975428	0.4684667	0.135167	0.0690356
245	0	1.546086	0.4357266	0.1366784	0.0703563
246	0	1.2889087	0.2537959	0.169683	0.0776442
247	0	1.2889087	0.2537959	0.169683	0.0776442
248	0	1.1559611	0.1449321	0.177559	0.0818859
249	7	1.4220025	0.3520661	0.169683	1.3046847
250	4	1.1559611	0.1449321	0.177559	0.86315
251	0	1.2889087	0.2537959	0.169683	0.0776442
252	0	1.123857	0.1167665	0.1733041	0.0829588
253	0	1.1810907	0.1664383	0.177559	0.0810591
254	0	1.1622435	0.1503522	0.177559	0.0816781
255	1	1.0826685	0.0794289	0.1733041	0.2855836
256	0	1.1685259	0.155743	0.177559	0.081471
257	0	1.0826685	0.0794289	0.1733041	0.0843619
258	0	1.1559611	0.1449321	0.177559	0.0818859
259	0	1.1936554	0.1770204	0.177559	0.08065
260	0	1.1622435	0.1503522	0.177559	0.0816781
261	0	1.2889087	0.2537959	0.169683	0.0776442
262	0	1.1559611	0.1449321	0.177559	0.0818859
263	0	1.0826685	0.0794289	0.1733041	0.0843619
264	0	1.2959136	0.259216	0.169683	0.0774298
265	0	1.2959136	0.259216	0.169683	0.0774298
266	1	1.2889087	0.2537959	0.169683	0.2628428

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The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
267	0	1.2889087	0.2537959	0.169683	0.0776442
268	0	1.3309383	0.2858842	0.169683	0.0763715
269	0	1.1062048	0.1009351	0.1733041	0.0835565
270	0	1.1559611	0.1449321	0.177559	0.0818859
271	0	1.0826685	0.0794289	0.1733041	0.0843619
272	1	1.1685259	0.155743	0.177559	0.2757976
273	2	1.1371139	0.1284934	0.177559	0.4761396
274	0	1.1003208	0.0956017	0.1733041	0.0837569
275	1	1.4079927	0.3421651	0.169683	0.2509217
276	0	1.1622435	0.1503522	0.177559	0.0816781
277	0	1.1685259	0.155743	0.177559	0.081471
278	0	1.1559611	0.1449321	0.177559	0.0818859
279	0	1.1003208	0.0956017	0.1733041	0.0837569
280	0	1.0885526	0.0848489	0.1733041	0.0841596
281	0	1.1622435	0.1503522	0.177559	0.0816781
282	0	1.0885526	0.0848489	0.1733041	0.0841596
283	0	1.0650163	0.0629901	0.1733041	0.084972
284	0	1.0826685	0.0794289	0.1733041	0.0843619
285	0	1.1433963	0.134003	0.177559	0.0823036
286	0	1.2959136	0.259216	0.169683	0.0774298
287	0	1.2959136	0.259216	0.169683	0.0774298
288	0	1.3029186	0.2646068	0.169683	0.0772163
289	0	1.2959136	0.259216	0.169683	0.0774298
290	0	1.2889087	0.2537959	0.169683	0.0776442
291	0	1.3099235	0.2699688	0.169683	0.0770038

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
292	0	1.1559611	0.1449321	0.177559	0.0818859
293	0	1.0826685	0.0794289	0.1733041	0.0843619
294	0	1.2889087	0.2537959	0.169683	0.0776442
295	0	1.1622435	0.1503522	0.177559	0.0816781
296	0	1.2678939	0.2373572	0.169683	0.0782928
297	0	1.2819038	0.2483463	0.169683	0.0778595
298	7	1.1559611	0.1449321	0.177559	1.449098
299	0	0.7590448	-0.275694	0.1733041	0.0960955
300	0	1.0826685	0.0794289	0.1733041	0.0843619
301	0	1.2889087	0.2537959	0.169683	0.0776442
302	1	1.1559611	0.1449321	0.177559	0.2772019
303	0	1.1685259	0.155743	0.177559	0.081471
304	1	1.3029186	0.2646068	0.169683	0.2613945
305	8	1.1297411	0.1219885	0.1733041	1.661983
306	0	1.0826685	0.0794289	0.1733041	0.0843619
307	0	1.2748988	0.2428668	0.169683	0.0780757
308	5	1.0826685	0.0794289	0.1733041	1.0904707
309	1	1.0885526	0.0848489	0.1733041	0.284899
310	3	1.0885526	0.0848489	0.1733041	0.6863779
311	3	1.1685259	0.155743	0.177559	0.6644506
312	7	1.3029186	0.2646068	0.169683	1.3664632
313	4	1.2889087	0.2537959	0.169683	0.8184388
314	9	1.1936554	0.1770204	0.177559	1.8119639
315	0	1.0709004	0.0684998	0.1733041	0.0847681
316	0	1.3029186	0.2646068	0.169683	0.0772163

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The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
317	1	1.1622435	0.1503522	0.177559	0.2764985
318	1	1.0767845	0.0739793	0.1733041	0.2862702
319	3	1.1496787	0.1394825	0.177559	0.6695344
320	2	1.0944367	0.0902398	0.1733041	0.4844749
321	0	1.3099235	0.2699688	0.169683	0.0770038
322	0	1.1810907	0.1664383	0.177559	0.0810591
323	0	1.1297411	0.1219885	0.1733041	0.0827608
324	0	1.3099235	0.2699688	0.169683	0.0770038
325	4	1.0826685	0.0794289	0.1733041	0.889249
326	5	1.0944367	0.0902398	0.1733041	1.0852503
327	0	1.3099235	0.2699688	0.169683	0.0770038
328	0	1.2889087	0.2537959	0.169683	0.0776442
329	0	1.2959136	0.259216	0.169683	0.0774298
330	0	1.1622435	0.1503522	0.177559	0.0816781
331	0	1.2889087	0.2537959	0.169683	0.0776442
332	0	1.0944367	0.0902398	0.1733041	0.083958
333	0	1.1748083	0.1611049	0.177559	0.0812647
334	3	1.123857	0.1167665	0.1733041	0.6765841
335	0	1.0826685	0.0794289	0.1733041	0.0843619
336	0	0.1611136	-1.825646	0.169683	0.0840769
337	0	1.2889087	0.2537959	0.169683	0.0776442
338	0	1.0885526	0.0848489	0.1733041	0.0841596
339	0	1.3379433	0.2911336	0.169683	0.0761626
340	0	1.1748083	0.1611049	0.177559	0.0812647
341	0	1.1062048	0.1009351	0.1733041	0.0835565

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
342	1	1.2889087	0.2537959	0.169683	0.2628428
343	4	1.0826685	0.0794289	0.1733041	0.889249
344	4	1.3099235	0.2699688	0.169683	0.8116882
345	3	1.0826685	0.0794289	0.1733041	0.6880272
346	0	1.1559611	0.1449321	0.177559	0.0818859
347	1	1.3099235	0.2699688	0.169683	0.2606749
348	0	1.0944367	0.0902398	0.1733041	0.083958
349	4	1.4969248	0.4034128	0.1358727	0.7553533
350	0	1.4020138	0.3379096	0.1393917	0.0742933
351	0	1.3866912	0.3269205	0.1393917	0.0747336
352	0	1.4096751	0.3433592	0.1393917	0.0740748
353	0	1.4096751	0.3433592	0.1393917	0.0740748
354	0	1.4020138	0.3379096	0.1393917	0.0742933
355	1	1.6782075	0.5177263	0.1366555	0.226981
356	0	1.6782075	0.5177263	0.1366555	0.0670506
357	9	1.712907	0.5381919	0.1355674	1.4879336
358	4	1.8288643	0.6036952	0.1308697	0.6704478
359	0	2.0613681	0.7233699	0.1340363	0.0588815
360	1	1.712907	0.5381919	0.1355674	0.2241949
361	2	1.8984406	0.6410328	0.1308697	0.3584581
362	1	1.712907	0.5381919	0.1355674	0.2241949
363	7	2.0170376	0.7016299	0.1340363	1.0570331
364	5	1.7408349	0.5543648	0.1355674	0.8476701
365	0	1.712907	0.5381919	0.1355674	0.0662275
366	0	1.6942885	0.5272629	0.1355674	0.0666669

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
367	0	1.6849792	0.5217532	0.1355674	0.0668885
368	3	2.0392028	0.712559	0.1340363	0.4836588
369	8	1.6849792	0.5217532	0.1355674	1.3432402
370	0	2.1056986	0.7446473	0.1340363	0.0580543
371	1	1.6849792	0.5217532	0.1355674	0.2264325
372	1	1.8388037	0.6091152	0.1308697	0.2145838
373	13	1.9282591	0.6566176	0.1308697	1.9685699
374	4	1.8388037	0.6091152	0.1308697	0.6681702
375	1	1.712907	0.5381919	0.1355674	0.2241949
376	1	1.8288643	0.6036952	0.1308697	0.2153153
377	1	1.8288643	0.6036952	0.1308697	0.2153153
378	0	1.8288643	0.6036952	0.1308697	0.0636045
379	1	2.0392028	0.712559	0.1340363	0.2007552
380	0	1.8487432	0.6145061	0.1308697	0.0631737
381	0	1.8288643	0.6036952	0.1308697	0.0636045
382	0	1.8288643	0.6036952	0.1308697	0.0636045
383	0	2.0392028	0.712559	0.1340363	0.0593034
384	0	1.4096751	0.3433592	0.1393917	0.0740748
385	0	2.0392028	0.712559	0.1340363	0.0593034
386	0	1.8189248	0.5982455	0.1308697	0.0638219
387	0	1.712907	0.5381919	0.1355674	0.0662275
388	1	1.8288643	0.6036952	0.1308697	0.2153153
389	0	1.8288643	0.6036952	0.1308697	0.0636045
390	0	1.8487432	0.6145061	0.1308697	0.0631737
391	0	2.0392028	0.712559	0.1340363	0.0593034

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
392	1	1.5051047	0.4088625	0.1358727	0.2418392
393	3	1.5541842	0.4409508	0.1358727	0.572084
394	0	1.4020138	0.3379096	0.1393917	0.0742933
395	3	1.4862879	0.3962816	0.1393917	0.5867733
396	6	1.5132846	0.4142825	0.1358727	1.0904913
397	0	1.6942885	0.5272629	0.1355674	0.0666669
398	1	1.4173364	0.3487793	0.1393917	0.2500234
399	0	1.4096751	0.3433592	0.1393917	0.0740748
400	0	1.4556427	0.3754476	0.1393917	0.0727855
401	1	1.4249976	0.3541702	0.1393917	0.2492907
402	0	1.5051047	0.4088625	0.1358727	0.0714397
403	0	1.6873282	0.5231463	0.1366555	0.0668325
404	0	1.5296444	0.4250353	0.1358727	0.0707876
405	0	1.4173364	0.3487793	0.1393917	0.0738573
406	7	1.5214645	0.4196734	0.1358727	1.2565229
407	1	1.4173364	0.3487793	0.1393917	0.2500234
408	0	1.4096751	0.3433592	0.1393917	0.0740748
409	0	1.8089853	0.5927661	0.1308697	0.0640407
410	0	1.6849792	0.5217532	0.1355674	0.0668885
411	0	1.8189248	0.5982455	0.1308697	0.0638219
412	12	1.7222163	0.543612	0.1355674	1.9553856
413	0	1.8785617	0.6305064	0.1308697	0.0625374
414	0	2.0613681	0.7233699	0.1340363	0.0588815
415	0	1.8089853	0.5927661	0.1308697	0.0640407
416	0	2.0281202	0.7071094	0.1340363	0.0595165

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Nocturnal hypoglycaemic episodes - treatment emergent - statistical analysis - on-treatment - full analysis set

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The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
417	1	2.0392028	0.712559	0.1340363	0.2007552
418	0	1.8288643	0.6036952	0.1308697	0.0636045
419	1	1.8089853	0.5927661	0.1308697	0.2167919
420	9	1.6782075	0.5177263	0.1366555	1.5064248
421	2	1.5051047	0.4088625	0.1358727	0.4122388
422	0	1.6873282	0.5231463	0.1366555	0.0668325
423	7	1.6873282	0.5231463	0.1366555	1.1827044
424	0	1.4173364	0.3487793	0.1393917	0.0738573
425	1	1.3943525	0.3324302	0.1393917	0.2522428
426	4	1.5214645	0.4196734	0.1358727	0.7484433
427	0	1.4173364	0.3487793	0.1393917	0.0738573
428	0	1.4173364	0.3487793	0.1393917	0.0738573
429	4	1.5460043	0.4356737	0.1358727	0.7416407
430	0	1.7876558	0.5809052	0.1366555	0.0645148
431	0	1.5460043	0.4356737	0.1358727	0.0703585
432	0	1.6782075	0.5177263	0.1366555	0.0670506
433	0	1.4096751	0.3433592	0.1393917	0.0740748
434	1	1.6964489	0.5285372	0.1366555	0.2255087
435	0	1.6782075	0.5177263	0.1366555	0.0670506
436	0	1.6690868	0.5122767	0.1366555	0.0672699
437	1	1.712907	0.5381919	0.1355674	0.2241949
438	0	1.7146903	0.5392325	0.1366555	0.0661857
439	1	1.7222163	0.543612	0.1355674	0.2234578
440	0	2.0502855	0.717979	0.1340363	0.0590917
441	0	1.4326589	0.3595321	0.1393917	0.0734255

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Nocturnal hypoglycaemic episodes - treatment emergent - statistical analysis - on-treatment - full analysis set

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The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
442	13	1.712907	0.5381919	0.1355674	2.119803
443	0	1.6782075	0.5177263	0.1366555	0.0670506
444	2	1.7055696	0.5338991	0.1366555	0.3831578
445	1	1.712907	0.5381919	0.1355674	0.2241949
446	12	1.7222163	0.543612	0.1355674	1.9553856
447	0	1.5051047	0.4088625	0.1358727	0.0714397
448	1	1.7990458	0.5872564	0.1308697	0.2175372
449	1	2.0392028	0.712559	0.1340363	0.2007552
450	1	1.4096751	0.3433592	0.1393917	0.2507596
451	6	1.6782075	0.5177263	0.1366555	1.0266334
452	2	1.7785351	0.5757901	0.1366555	0.3734602
453	2	1.8388037	0.6091152	0.1308697	0.3657793
454	1	1.7873812	0.5807516	0.1355674	0.2184177
455	8	2.0475328	0.7166356	0.1308697	1.1877202
456	8	1.7694144	0.5706487	0.1366555	1.3038163
457	8	1.6942885	0.5272629	0.1355674	1.3387894
458	0	1.8586827	0.619868	0.1308697	0.0629603
459	0	1.8984406	0.6410328	0.1308697	0.0621197
460	3	1.6690868	0.5122767	0.1366555	0.548631
461	3	1.9244662	0.6546486	0.1366555	0.5022301
462	3	1.7408349	0.5543648	0.1355674	0.5348333
463	7	2.0392028	0.712559	0.1340363	1.049466
464	0	1.4096751	0.3433592	0.1393917	0.0740748
465	0	2.0281202	0.7071094	0.1340363	0.0595165
466	0	1.668703	0.5120467	0.1358727	0.0672792

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Nocturnal hypoglycaemic episodes - treatment emergent - statistical analysis - on-treatment - full analysis set

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The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
467	0	1.7329317	0.5498146	0.1366555	0.0657607
468	1	1.5214645	0.4196734	0.1358727	0.2403637
469	0	1.5051047	0.4088625	0.1358727	0.0714397
470	2	1.8288643	0.6036952	0.1308697	0.3670261
471	2	1.5322555	0.4267408	0.1393917	0.4080788
472	1	1.5541842	0.4409508	0.1358727	0.2374584
473	0	1.778072	0.5755296	0.1355674	0.0647299
474	0	1.5378244	0.4303687	0.1358727	0.0705725
475	0	1.4969248	0.4034128	0.1358727	0.0716594
476	1	1.4249976	0.3541702	0.1393917	0.2492907
477	4	1.7146903	0.5392325	0.1366555	0.6976562
478	0	1.5214645	0.4196734	0.1358727	0.0710038
479	0	1.3943525	0.3324302	0.1393917	0.0745129
480	0	1.5296444	0.4250353	0.1358727	0.0707876
481	14	1.7055696	0.5338991	0.1366555	2.2837042
482	2	1.5132846	0.4142825	0.1358727	0.4109779
483	1	1.4887448	0.3979334	0.1358727	0.2433303
484	0	1.4969248	0.4034128	0.1358727	0.0716594
485	0	1.6599661	0.5067972	0.1366555	0.0674906
486	0	1.3866912	0.3269205	0.1393917	0.0747336
487	2	1.4969248	0.4034128	0.1358727	0.4135063
488	0	1.4096751	0.3433592	0.1393917	0.0740748
489	0	1.4173364	0.3487793	0.1393917	0.0738573
490	3	1.5296444	0.4250353	0.1358727	0.5773198
491	1	1.5132846	0.4142825	0.1358727	0.2410995

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Nocturnal hypoglycaemic episodes - treatment emergent - statistical analysis - on-treatment - full analysis set

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The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
492	0	1.6690868	0.5122767	0.1366555	0.0672699
493	2	1.6964489	0.5285372	0.1366555	0.3844018
494	9	1.3637074	0.310207	0.1393917	1.6940552
495	0	1.4096751	0.3433592	0.1393917	0.0740748
496	0	1.7055696	0.5338991	0.1366555	0.0664
497	0	1.5051047	0.4088625	0.1358727	0.0714397
498	0	1.5051047	0.4088625	0.1358727	0.0714397
499	4	1.7055696	0.5338991	0.1366555	0.6999155
500	0	1.6782075	0.5177263	0.1366555	0.0670506
501	5	1.6599661	0.5067972	0.1366555	0.8723905
502	5	1.5214645	0.4196734	0.1358727	0.9178031
503	0	1.4096751	0.3433592	0.1393917	0.0740748
504	0	1.4887448	0.3979334	0.1358727	0.0718802
505	0	1.7055696	0.5338991	0.1366555	0.0664
506	0	1.7055696	0.5338991	0.1366555	0.0664
507	0	1.4887448	0.3979334	0.1358727	0.0718802
508	0	0.2453975	-1.404876	0.1358727	0.097641
509	3	1.4805649	0.3924237	0.1358727	0.5880408
510	0	1.5051047	0.4088625	0.1358727	0.0714397
511	0	1.6782075	0.5177263	0.1366555	0.0670506
512	1	1.5051047	0.4088625	0.1358727	0.2418392
513	5	1.6782075	0.5177263	0.1366555	0.8667029
514	0	1.5132846	0.4142825	0.1358727	0.0712212
515	0	1.4096751	0.3433592	0.1393917	0.0740748
516	0	1.4096751	0.3433592	0.1393917	0.0740748

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The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
517	2	1.5051047	0.4088625	0.1358727	0.4122388
518	0	1.5132846	0.4142825	0.1358727	0.0712212
519	0	1.6964489	0.5285372	0.1366555	0.0666156
520	1	1.5296444	0.4250353	0.1358727	0.2396316
521	2	1.4096751	0.3433592	0.1393917	0.4274444
522	0	1.6782075	0.5177263	0.1366555	0.0670506
523	0	1.6782075	0.5177263	0.1366555	0.0670506
524	0	1.5051047	0.4088625	0.1358727	0.0714397
525	0	1.4173364	0.3487793	0.1393917	0.0738573
526	0	1.4173364	0.3487793	0.1393917	0.0738573
527	0	1.5214645	0.4196734	0.1358727	0.0710038
528	0	1.4173364	0.3487793	0.1393917	0.0738573
529	0	1.4096751	0.3433592	0.1393917	0.0740748
530	1	1.4403202	0.3648654	0.1393917	0.2478359
531	0	1.6873282	0.5231463	0.1366555	0.0668325
532	0	1.4479815	0.3701705	0.1393917	0.0729978
533	2	1.5051047	0.4088625	0.1358727	0.4122388
534	7	1.4887448	0.3979334	0.1358727	1.2720312
535	2	1.4096751	0.3433592	0.1393917	0.4274444
536	3	1.6782075	0.5177263	0.1366555	0.546842
537	4	1.6873282	0.5231463	0.1366555	0.7044736
538	0	1.6873282	0.5231463	0.1366555	0.0668325
539	0	1.4173364	0.3487793	0.1393917	0.0738573
540	0	1.7055696	0.5338991	0.1366555	0.0664
541	0	1.4020138	0.3379096	0.1393917	0.0742933

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The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
542	0	1.6964489	0.5285372	0.1366555	0.0666156
543	0	1.6417247	0.4957474	0.1366555	0.0679357
544	0	1.4403202	0.3648654	0.1393917	0.0732111
545	0	1.4479815	0.3701705	0.1393917	0.0729978
546	0	1.4096751	0.3433592	0.1393917	0.0740748
547	3	1.4249976	0.3541702	0.1393917	0.6005903
548	0	1.5132846	0.4142825	0.1358727	0.0712212
549	1	1.4020138	0.3379096	0.1393917	0.2514994
550	1	1.6782075	0.5177263	0.1366555	0.226981
551	0	1.6782075	0.5177263	0.1366555	0.0670506
552	0	1.4096751	0.3433592	0.1393917	0.0740748
553	0	1.4173364	0.3487793	0.1393917	0.0738573
554	0	1.6964489	0.5285372	0.1366555	0.0666156
555	2	1.4096751	0.3433592	0.1393917	0.4274444
556	0	1.4479815	0.3701705	0.1393917	0.0729978
557	2	1.6873282	0.5231463	0.1366555	0.385653
558	1	1.4173364	0.3487793	0.1393917	0.2500234
559	4	1.4096751	0.3433592	0.1393917	0.780814
560	1	1.7055696	0.5338991	0.1366555	0.2247789
561	1	1.5051047	0.4088625	0.1358727	0.2418392
562	1	1.6873282	0.5231463	0.1366555	0.2262427
563	11	2.0392028	0.712559	0.1340363	1.6152732
564	8	1.5214645	0.4196734	0.1358727	1.4258827
565	0	1.7055696	0.5338991	0.1366555	0.0664
566	0	1.4096751	0.3433592	0.1393917	0.0740748

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The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
567	3	2.0613681	0.7233699	0.1340363	0.4802177
568	2	1.5051047	0.4088625	0.1358727	0.4122388
569	0	1.6508454	0.5012875	0.1366555	0.0677125
570	3	1.5132846	0.4142825	0.1358727	0.5808562
571	0	1.4173364	0.3487793	0.1393917	0.0738573
572	1	1.5541842	0.4409508	0.1358727	0.2374584
573	0	1.4403202	0.3648654	0.1393917	0.0732111
574	2	1.5296444	0.4250353	0.1358727	0.4084757
575	1	1.5051047	0.4088625	0.1358727	0.2418392
576	0	1.4403202	0.3648654	0.1393917	0.0732111
577	0	1.6873282	0.5231463	0.1366555	0.0668325
578	0	1.6690868	0.5122767	0.1366555	0.0672699
579	6	1.5051047	0.4088625	0.1358727	1.093837
580	3	1.5051047	0.4088625	0.1358727	0.5826384
581	1	1.6873282	0.5231463	0.1366555	0.2262427
582	0	1.6782075	0.5177263	0.1366555	0.0670506
583	1	1.4096751	0.3433592	0.1393917	0.2507596
584	0	1.8089853	0.5927661	0.1308697	0.0640407
585	0	2.0502855	0.717979	0.1340363	0.0590917
586	0	2.1056986	0.7446473	0.1340363	0.0580543
587	3	2.0392028	0.712559	0.1340363	0.4836588
588	1	1.712907	0.5381919	0.1355674	0.2241949
589	0	1.7315256	0.5490029	0.1355674	0.0657933
590	2	1.8288643	0.6036952	0.1308697	0.3670261
591	0	2.0392028	0.712559	0.1340363	0.0593034

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The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
592	1	2.0392028	0.712559	0.1340363	0.2007552
593	4	1.8288643	0.6036952	0.1308697	0.6704478
594	1	1.7222163	0.543612	0.1355674	0.2234578
595	1	1.8288643	0.6036952	0.1308697	0.2153153
596	0	1.8432369	0.6115232	0.1355674	0.0632925
597	4	1.712907	0.5381919	0.1355674	0.6980969
598	3	1.712907	0.5381919	0.1355674	0.5401296
599	0	1.6849792	0.5217532	0.1355674	0.0668885
600	20	2.0281202	0.7071094	0.1340363	2.8987176
601	3	1.8487432	0.6145061	0.1308697	0.5152234
602	2	1.6942885	0.5272629	0.1355674	0.3846975
603	0	1.5132846	0.4142825	0.1358727	0.0712212
604	0	1.6849792	0.5217532	0.1355674	0.0668885
605	2	2.0392028	0.712559	0.1340363	0.342207
606	0	2.0392028	0.712559	0.1340363	0.0593034
607	5	1.8189248	0.5982455	0.1308697	0.824969
608	0	1.5296444	0.4250353	0.1358727	0.0707876
609	0	1.712907	0.5381919	0.1355674	0.0662275
610	3	1.8487432	0.6145061	0.1308697	0.5152234
611	1	2.094616	0.7393702	0.1340363	0.1972197
612	16	1.8288643	0.6036952	0.1308697	2.4909777
613	9	2.0502855	0.717979	0.1340363	1.327614
614	0	1.7222163	0.543612	0.1355674	0.0660098
615	3	1.7035977	0.5327423	0.1355674	0.5419159
616	3	1.712907	0.5381919	0.1355674	0.5401296

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Nocturnal hypoglycaemic episodes - treatment emergent - statistical analysis - on-treatment - full analysis set

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The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
617	2	1.7990458	0.5872564	0.1308697	0.3708135
618	4	2.0502855	0.717979	0.1340363	0.6228794
619	5	1.8288643	0.6036952	0.1308697	0.8221586
620	0	1.7501441	0.5596981	0.1355674	0.0653642
621	6	1.8885011	0.6357835	0.1308697	0.9543228
622	4	1.7035977	0.5327423	0.1355674	0.7004057
623	0	1.8288643	0.6036952	0.1308697	0.0636045
624	5	2.0392028	0.712559	0.1340363	0.7665624
625	0	2.0170376	0.7016299	0.1340363	0.059731
626	1	1.712907	0.5381919	0.1355674	0.2241949
627	0	1.1032822	0.0982896	0.1308697	0.083656
628	0	2.1167812	0.7498966	0.1340363	0.0578508
629	0	1.7408349	0.5543648	0.1355674	0.0655781
630	0	2.0502855	0.717979	0.1340363	0.0590917
631	0	1.8089853	0.5927661	0.1308697	0.0640407
632	0	1.7222163	0.543612	0.1355674	0.0660098
633	0	2.0281202	0.7071094	0.1340363	0.0595165
634	1	1.8586827	0.619868	0.1308697	0.2131345
635	0	2.0392028	0.712559	0.1340363	0.0593034
636	4	1.7408349	0.5543648	0.1355674	0.6912517
637	1	1.7035977	0.5327423	0.1355674	0.2249363
638	1	2.2386901	0.8058909	0.1340363	0.1885531
639	1	1.8189248	0.5982455	0.1308697	0.2160513
640	0	1.6942885	0.5272629	0.1355674	0.0666669
641	0	1.8288643	0.6036952	0.1308697	0.0636045

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The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
642	0	1.6873282	0.5231463	0.1366555	0.0668325
643	0	1.7222163	0.543612	0.1355674	0.0660098
644	0	1.6690868	0.5122767	0.1366555	0.0672699
645	6	1.712907	0.5381919	0.1355674	1.0140316
646	5	1.5051047	0.4088625	0.1358727	0.9234375
647	0	1.712907	0.5381919	0.1355674	0.0662275
648	4	1.5051047	0.4088625	0.1358727	0.7530379
649	6	1.7329317	0.5498146	0.1366555	1.0068845
650	0	1.5214645	0.4196734	0.1358727	0.0710038
651	0	2.0392028	0.712559	0.1340363	0.0593034
652	0	1.8288643	0.6036952	0.1308697	0.0636045
653	6	1.8288643	0.6036952	0.1308697	0.9738694
654	2	1.5296444	0.4250353	0.1358727	0.4084757
655	0	1.6599661	0.5067972	0.1366555	0.0674906
656	0	1.5214645	0.4196734	0.1358727	0.0710038
657	2	1.6964489	0.5285372	0.1366555	0.3844018
658	0	1.6690868	0.5122767	0.1366555	0.0672699
659	2	1.6768829	0.5169367	0.1358727	0.3870949
660	0	1.4096751	0.3433592	0.1393917	0.0740748
661	1	1.7315256	0.5490029	0.1355674	0.222725
662	0	1.2024478	0.1843593	0.1358727	0.0803655
663	1	2.316656	0.8401248	0.1366555	0.1841574
664	1	1.7146903	0.5392325	0.1366555	0.2240533
665	0	1.7785351	0.5757901	0.1366555	0.0647195
666	0	1.4479815	0.3701705	0.1393917	0.0729978

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The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
667	1	1.4249976	0.3541702	0.1393917	0.2492907
668	0	1.0032762	0.0032709	0.1366555	0.0871452
669	4	1.5231557	0.4207843	0.1366555	0.747971
670	3	1.7594534	0.5650032	0.1355674	0.5313541
671	0	1.8089853	0.5927661	0.1308697	0.0640407
672	0	1.7501441	0.5596981	0.1355674	0.0653642
673	3	1.712907	0.5381919	0.1355674	0.5401296
674	0	1.8288643	0.6036952	0.1308697	0.0636045
675	2	1.8288643	0.6036952	0.1308697	0.3670261
676	2	2.0392028	0.712559	0.1340363	0.342207
677	10	2.0170376	0.7016299	0.1340363	1.4844483
678	5	1.8432369	0.6115232	0.1355674	0.8181255
679	4	1.8189248	0.5982455	0.1308697	0.6727396
680	5	2.0392028	0.712559	0.1340363	0.7665624
681	2	1.8388037	0.6091152	0.1308697	0.3657793
682	7	1.8288643	0.6036952	0.1308697	1.1255803
683	0	2.1056986	0.7446473	0.1340363	0.0580543
684	0	1.9948723	0.6905801	0.1340363	0.0601644
685	0	1.712907	0.5381919	0.1355674	0.0662275
686	0	1.8586827	0.619868	0.1308697	0.0629603
687	0	1.7873812	0.5807516	0.1355674	0.0645209
688	4	2.005955	0.6961202	0.1340363	0.6318944
689	0	2.0392028	0.712559	0.1340363	0.0593034
690	5	2.0392028	0.712559	0.1340363	0.7665624
691	0	2.0170376	0.7016299	0.1340363	0.059731

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The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
692	2	1.8388037	0.6091152	0.1308697	0.3657793
693	5	1.712907	0.5381919	0.1355674	0.8560642
694	1	1.2889087	0.2537959	0.169683	0.2628428
695	3	1.3169285	0.2753021	0.169683	0.626291
696	3	1.0826685	0.0794289	0.1733041	0.6880272
697	13	1.260889	0.231817	0.169683	2.5129667
698	0	1.0709004	0.0684998	0.1733041	0.0847681
699	17	1.2678939	0.2373572	0.169683	3.2529708
700	7	1.123857	0.1167665	0.1733041	1.4680845
701	0	1.1559611	0.1449321	0.177559	0.0818859
702	0	1.2889087	0.2537959	0.169683	0.0776442
703	0	1.2398741	0.2150099	0.169683	0.0791704
704	0	1.1559611	0.1449321	0.177559	0.0818859
705	0	1.2819038	0.2483463	0.169683	0.0778595
706	0	1.2748988	0.2428668	0.169683	0.0780757
707	0	1.1433963	0.134003	0.177559	0.0823036
708	3	1.0944367	0.0902398	0.1733041	0.6847334
709	1	1.2889087	0.2537959	0.169683	0.2628428
710	0	1.1559611	0.1449321	0.177559	0.0818859
711	0	1.0650163	0.0629901	0.1733041	0.084972
712	0	1.0650163	0.0629901	0.1733041	0.084972
713	3	1.2889087	0.2537959	0.169683	0.6332401
714	1	1.2678939	0.2373572	0.169683	0.2650386
715	0	1.2118544	0.1921517	0.169683	0.0800627
716	0	1.0826685	0.0794289	0.1733041	0.0843619

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Nocturnal hypoglycaemic episodes - treatment emergent - statistical analysis - on-treatment - full analysis set

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The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
717	3	1.1496787	0.1394825	0.177559	0.6695344
718	1	1.2819038	0.2483463	0.169683	0.2635717
719	0	1.1559611	0.1449321	0.177559	0.0818859
720	0	1.2889087	0.2537959	0.169683	0.0776442
721	2	1.2889087	0.2537959	0.169683	0.4480415
722	3	1.1496787	0.1394825	0.177559	0.6695344
723	0	1.1496787	0.1394825	0.177559	0.0820944
724	0	1.1559611	0.1449321	0.177559	0.0818859
725	5	2.3646307	0.8606218	0.1266674	0.6932228
726	0	2.0560074	0.7207659	0.1505808	0.058983
727	2	2.0071573	0.6967194	0.1458727	0.3457851
728	1	2.0233724	0.7047656	0.1505808	0.2017871
729	0	2.1192321	0.7510538	0.1458727	0.057806
730	0	1.9689806	0.677516	0.1505808	0.0606781
731	6	2.1647909	0.7723238	0.1505808	0.8725155
732	5	2.3646307	0.8606218	0.1266674	0.6932228
733	0	2.697166	0.9922016	0.1326609	0.0488135
734	0	2.697166	0.9922016	0.1326609	0.0488135
735	4	2.2779688	0.8232842	0.1266674	0.5801437
736	1	2.3660868	0.8612374	0.1309861	0.1814702
737	1	1.7827582	0.5781617	0.1266674	0.2187685
738	0	1.8645167	0.6230019	0.1458727	0.0628356
739	2	2.697166	0.9922016	0.1326609	0.2816754
740	0	2.7561205	1.0138241	0.1326609	0.0480454
741	3	2.3398701	0.8500954	0.1266674	0.4406085

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The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
742	0	1.8848939	0.6338715	0.1458727	0.0624038
743	0	1.8848939	0.6338715	0.1458727	0.0624038
744	1	2.7119046	0.9976512	0.1326609	0.1645869
745	0	2.697166	0.9922016	0.1326609	0.0488135
746	2	2.4718337	0.9049602	0.1309861	0.2999508
747	0	1.8747053	0.6284515	0.1458727	0.062619
748	0	2.7413819	1.0084621	0.1326609	0.0482352
749	0	2.0016157	0.6939547	0.1505808	0.0600319
750	4	2.5114887	0.9208757	0.1309861	0.5417477
751	5	2.2318225	0.8028185	0.1499687	0.7214849
752	8	1.8747053	0.6284515	0.1458727	1.2575008
753	6	2.4453969	0.8942075	0.1309861	0.8019791
754	1	1.8645167	0.6230019	0.1458727	0.2127125
755	1	2.5247071	0.9261251	0.1309861	0.1733317
756	5	2.4321786	0.8887874	0.1309861	0.6796436
757	2	2.4189602	0.8833378	0.1309861	0.3045732
758	5	2.7119046	0.9976512	0.1326609	0.6284577
759	0	2.2779688	0.8232842	0.1266674	0.0550374
760	0	2.7119046	0.9976512	0.1326609	0.0486192
761	0	2.4453969	0.8942075	0.1309861	0.0523781
762	4	2.697166	0.9922016	0.1326609	0.5145373
763	0	2.4321786	0.8887874	0.1309861	0.0525791
764	0	2.4718337	0.9049602	0.1309861	0.0519805
765	0	2.697166	0.9922016	0.1326609	0.0488135
766	1	2.2560814	0.8136294	0.1499687	0.1875554

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The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
767	1	2.7119046	0.9976512	0.1326609	0.1645869
768	1	2.2655885	0.8178346	0.1266674	0.1870143
769	2	2.4453969	0.8942075	0.1309861	0.3022451
770	5	2.8150749	1.0349889	0.1326609	0.6114111
771	7	2.4453969	0.8942075	0.1309861	0.9269125
772	0	2.7266432	1.0030713	0.1326609	0.0484265
773	5	2.3925235	0.8723487	0.1309861	0.6875532
774	18	2.4586153	0.8995983	0.1309861	2.2924151
775	1	2.7119046	0.9976512	0.1326609	0.1645869
776	0	2.4321786	0.8887874	0.1309861	0.0525791
777	8	2.2779688	0.8232842	0.1266674	1.1052499
778	1	2.4453969	0.8942075	0.1309861	0.1773116
779	0	0.7180554	-0.331209	0.1266674	0.097577
780	0	2.2779688	0.8232842	0.1266674	0.0550374
781	0	1.8747053	0.6284515	0.1458727	0.062619
782	8	2.4586153	0.8995983	0.1309861	1.0478393
783	7	2.7119046	0.9976512	0.1326609	0.8603931
784	3	2.3646307	0.8606218	0.1266674	0.4373856
785	3	2.4057419	0.8778583	0.1309861	0.4321325
786	2	1.8747053	0.6284515	0.1458727	0.3613394
787	2	1.8747053	0.6284515	0.1458727	0.3613394
788	1	2.485052	0.9102936	0.1309861	0.1753
789	1	1.8747053	0.6284515	0.1458727	0.2119792
790	12	2.8150749	1.0349889	0.1326609	1.4011661
791	3	2.8022927	1.0304379	0.1309861	0.3870686

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The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
792	0	2.3522504	0.8553725	0.1266674	0.0538265
793	0	2.7119046	0.9976512	0.1326609	0.0486192
794	3	2.7266432	1.0030713	0.1326609	0.3949505
795	4	2.7413819	1.0084621	0.1326609	0.5084424
796	1	2.2779688	0.8232842	0.1266674	0.186314
797	0	2.4321786	0.8887874	0.1309861	0.0525791
798	0	2.2779688	0.8232842	0.1266674	0.0550374
799	2	2.3045993	0.8349068	0.1499687	0.3150514
800	2	1.9765915	0.6813739	0.1458727	0.3492633
801	0	1.9969687	0.6916304	0.1458727	0.0601232
802	3	1.8645167	0.6230019	0.1458727	0.5124663
803	0	2.0016157	0.6939547	0.1505808	0.0600319
804	0	2.2318225	0.8028185	0.1499687	0.0558161
805	0	2.2924698	0.8296298	0.1499687	0.054797
806	1	2.0886424	0.7365143	0.1505808	0.1975952
807	10	2.2560814	0.8136294	0.1499687	1.3769169
808	0	2.3531172	0.8557409	0.1499687	0.0538127
809	0	2.0233724	0.7047656	0.1505808	0.0596082
810	5	2.0451291	0.7154609	0.1505808	0.7650971
811	0	2.3167288	0.8401562	0.1499687	0.0543992
812	2	2.3770109	0.8658438	0.1266674	0.3083386
813	1	2.3274899	0.8447904	0.1266674	0.183562
814	0	2.630454	0.9671565	0.1309861	0.0497116
815	4	2.191307	0.7844981	0.1266674	0.5957404
816	3	2.2903491	0.8287042	0.1266674	0.4471919

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
817	1	2.0016157	0.6939547	0.1505808	0.2032214
818	0	2.240828	0.8068454	0.1266674	0.0556625
819	0	2.697166	0.9922016	0.1326609	0.0488135
820	0	2.8298135	1.0402108	0.1326609	0.0471177
821	1	2.8150749	1.0349889	0.1326609	0.1601226
822	1	2.5907989	0.9519663	0.1309861	0.170144
823	0	2.4057419	0.8778583	0.1309861	0.0529856
824	0	2.2903491	0.8287042	0.1266674	0.0548321
825	2	2.2903491	0.8287042	0.1266674	0.3164053
826	5	2.6676888	0.9812125	0.1326609	0.6360479
827	0	1.8747053	0.6284515	0.1458727	0.062619
828	1	2.5008136	0.9166161	0.1266674	0.1745126
829	5	2.4189602	0.8833378	0.1309861	0.6822607
830	7	2.5247071	0.9261251	0.1309861	0.9061073
831	4	2.8445521	1.0454056	0.1326609	0.4947505
832	1	2.7119046	0.9976512	0.1326609	0.1645869
833	0	2.4321786	0.8887874	0.1309861	0.0525791
834	1	2.4321786	0.8887874	0.1309861	0.177992
835	4	2.3522504	0.8553725	0.1266674	0.5673797
836	0	2.3167288	0.8401562	0.1499687	0.0543992
837	4	2.3167288	0.8401562	0.1499687	0.5734161
838	0	1.8747053	0.6284515	0.1458727	0.062619
839	5	1.8543281	0.6175224	0.1458727	0.8150377
840	0	2.2318225	0.8028185	0.1499687	0.0558161
841	0	2.0451291	0.7154609	0.1505808	0.05919

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Nocturnal hypoglycaemic episodes - treatment emergent - statistical analysis - on-treatment - full analysis set

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The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
842	0	2.3288582	0.8453781	0.1499687	0.0542024
843	0	2.219693	0.7973689	0.1499687	0.0560242
844	7	1.8747053	0.6284515	0.1458727	1.1081406
845	1	2.3895056	0.8710865	0.1499687	0.180223
846	5	1.8848939	0.6338715	0.1458727	0.8066378
847	1	2.2318225	0.8028185	0.1499687	0.1889498
848	1	2.0016157	0.6939547	0.1505808	0.2032214
849	0	2.0233724	0.7047656	0.1505808	0.0596082
850	10	1.8747053	0.6284515	0.1458727	1.5562212
851	1	1.8950825	0.6392624	0.1458727	0.2105265
852	6	2.0016157	0.6939547	0.1505808	0.9191688
853	6	2.0016157	0.6939547	0.1505808	0.9191688
854	0	2.7119046	0.9976512	0.1326609	0.0486192
855	4	2.7119046	0.9976512	0.1326609	0.51249
856	0	2.4321786	0.8887874	0.1309861	0.0525791
857	0	2.4321786	0.8887874	0.1309861	0.0525791
858	0	2.4884333	0.9116533	0.1266674	0.0517338
859	1	2.4512925	0.8966154	0.1266674	0.1770098
860	0	2.0016157	0.6939547	0.1505808	0.0600319
861	0	1.8950825	0.6392624	0.1458727	0.0621899
862	0	2.219693	0.7973689	0.1499687	0.0560242
863	0	2.3925235	0.8723487	0.1309861	0.053191
864	0	2.0016157	0.6939547	0.1505808	0.0600319
865	0	2.4718337	0.9049602	0.1309861	0.0519805
866	1	2.4718337	0.9049602	0.1309861	0.1759657

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Nocturnal hypoglycaemic episodes - treatment emergent - statistical analysis - on-treatment - full analysis set

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The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
867	2	2.697166	0.9922016	0.1326609	0.2816754
868	1	2.4017715	0.8762066	0.1266674	0.1795763
869	4	2.4718337	0.9049602	0.1309861	0.5479211
870	5	2.6824274	0.9867221	0.1326609	0.6334983
871	0	1.8747053	0.6284515	0.1458727	0.062619
872	0	2.3027293	0.8340951	0.1266674	0.0546281
873	3	2.7413819	1.0084621	0.1326609	0.3933906
874	0	2.7266432	1.0030713	0.1326609	0.0484265
875	0	2.3151096	0.839457	0.1266674	0.0544256
876	1	2.3027293	0.8340951	0.1266674	0.1849283
877	3	2.7413819	1.0084621	0.1326609	0.3933906
878	4	2.3925235	0.8723487	0.1309861	0.5606808
879	0	2.2655885	0.8178346	0.1266674	0.0552443
880	0	2.4321786	0.8887874	0.1309861	0.0525791
881	0	2.2655885	0.8178346	0.1266674	0.0552443
882	0	0.7056751	-0.3486	0.1266674	0.098017
883	2	2.2532083	0.8123551	0.1266674	0.3199865
884	7	2.7119046	0.9976512	0.1326609	0.8603931
885	0	2.697166	0.9922016	0.1326609	0.0488135
886	3	2.4718337	0.9049602	0.1309861	0.423936
887	0	2.7119046	0.9976512	0.1326609	0.0486192
888	2	2.2779688	0.8232842	0.1266674	0.3175906
889	4	2.7119046	0.9976512	0.1326609	0.51249
890	0	2.5114887	0.9208757	0.1309861	0.0513949
891	1	2.4189602	0.8833378	0.1309861	0.1786774

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Nocturnal hypoglycaemic episodes - treatment emergent - statistical analysis - on-treatment - full analysis set

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The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
892	7	2.6824274	0.9867221	0.1326609	0.8672939
893	5	2.4453969	0.8942075	0.1309861	0.6770456
894	1	2.4189602	0.8833378	0.1309861	0.1786774
895	3	2.8298135	1.0402108	0.1326609	0.3842764
896	1	2.7119046	0.9976512	0.1326609	0.1645869
897	1	1.9907373	0.6885051	0.1505808	0.2039457
898	1	2.3027293	0.8340951	0.1266674	0.1849283
899	0	2.3528684	0.8556352	0.1309861	0.0538167
900	8	2.4321786	0.8887874	0.1309861	1.0558822
901	1	2.2655885	0.8178346	0.1266674	0.1870143
902	1	2.2655885	0.8178346	0.1266674	0.1870143
903	9	2.3027293	0.8340951	0.1266674	1.2273296
904	7	2.4189602	0.8833378	0.1309861	0.9340524
905	0	2.2318225	0.8028185	0.1499687	0.0558161
906	0	2.3409877	0.8505729	0.1499687	0.0540069
907	0	2.4321786	0.8887874	0.1309861	0.0525791
908	0	1.8747053	0.6284515	0.1458727	0.062619
909	0	2.0016157	0.6939547	0.1505808	0.0600319
910	1	2.219693	0.7973689	0.1499687	0.1896544
911	0	2.3925235	0.8723487	0.1309861	0.053191
912	0	2.3045993	0.8349068	0.1499687	0.0545974
913	0	2.012494	0.6993748	0.1505808	0.0598194
914	0	2.0233724	0.7047656	0.1505808	0.0596082
915	3	1.9052711	0.6446243	0.1458727	0.5054663
916	12	2.219693	0.7973689	0.1499687	1.6595867

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The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
917	0	2.219693	0.7973689	0.1499687	0.0560242
918	0	2.2903491	0.8287042	0.1266674	0.0548321
919	0	2.3027293	0.8340951	0.1266674	0.0546281
920	0	1.8645167	0.6230019	0.1458727	0.0628356
921	1	2.7266432	1.0030713	0.1326609	0.1639345
922	0	1.935837	0.6605398	0.1458727	0.0613476
923	0	2.2903491	0.8287042	0.1266674	0.0548321
924	0	2.4586153	0.8995983	0.1309861	0.0521786
925	4	1.8747053	0.6284515	0.1458727	0.6600599
926	1	2.4321786	0.8887874	0.1309861	0.177992
927	0	2.7266432	1.0030713	0.1326609	0.0484265
928	2	2.0016157	0.6939547	0.1505808	0.3464109
929	4	2.2903491	0.8287042	0.1266674	0.5779786
930	2	1.8645167	0.6230019	0.1458727	0.3625894
931	3	1.979859	0.6830256	0.1505808	0.493102
932	0	2.4453969	0.8942075	0.1309861	0.0523781
933	0	1.419148	0.3500567	0.1499687	0.073806
934	8	1.8950825	0.6392624	0.1458727	1.248883
935	0	1.8747053	0.6284515	0.1458727	0.062619
936	3	2.7119046	0.9976512	0.1326609	0.3965223
937	24	1.8747053	0.6284515	0.1458727	3.6472644
938	0	2.1321558	0.7571336	0.1505808	0.0575709
939	0	2.4453969	0.8942075	0.1309861	0.0523781
940	16	2.2779688	0.8232842	0.1266674	2.1554623
941	0	2.1954341	0.7863798	0.1499687	0.0564449

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The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
942	5	2.3770109	0.8658438	0.1266674	0.6906954
943	8	2.4057419	0.8778583	0.1309861	1.0640442
944	3	2.2779688	0.8232842	0.1266674	0.4488671
945	1	2.2532083	0.8123551	0.1266674	0.1877196
946	1	1.8747053	0.6284515	0.1458727	0.2119792
947	0	2.7626376	1.0161859	0.1309861	0.047962
948	1	2.5247071	0.9261251	0.1309861	0.1733317
949	4	2.4453969	0.8942075	0.1309861	0.5521121
950	1	2.3288582	0.8453781	0.1499687	0.1834871
951	1	2.2903491	0.8287042	0.1266674	0.1856187
952	1	2.1497979	0.7653738	0.1458727	0.1938132
953	1	2.7119046	0.9976512	0.1326609	0.1645869
954	1	2.8003363	1.0297395	0.1326609	0.1607459
955	5	2.4189602	0.8833378	0.1309861	0.6822607
956	0	2.2779688	0.8232842	0.1266674	0.0550374
957	0	1.8747053	0.6284515	0.1458727	0.062619
958	1	2.240828	0.8068454	0.1266674	0.1884299
959	4	2.4321786	0.8887874	0.1309861	0.5542307
960	0	2.4321786	0.8887874	0.1309861	0.0525791
961	0	2.2779688	0.8232842	0.1266674	0.0550374
962	0	1.8747053	0.6284515	0.1458727	0.062619
963	0	2.2779688	0.8232842	0.1266674	0.0550374
964	0	2.8150749	1.0349889	0.1326609	0.0473005
965	1	1.8848939	0.6338715	0.1458727	0.2112506
966	1	2.7119046	0.9976512	0.1326609	0.1645869

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Nocturnal hypoglycaemic episodes - treatment emergent - statistical analysis - on-treatment - full analysis set

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The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
967	1	2.2903491	0.8287042	0.1266674	0.1856187
968	0	0.606633	-0.499831	0.1266674	0.1013151
969	5	2.2036872	0.790132	0.1266674	0.7277546
970	2	2.7708591	1.0191574	0.1326609	0.2761566
971	9	2.2318225	0.8028185	0.1499687	1.2540199
972	4	2.4321786	0.8887874	0.1309861	0.5542307
973	6	2.0342507	0.7101275	0.1505808	0.9094694
974	4	2.2318225	0.8028185	0.1499687	0.5883511
975	0	1.9907373	0.6885051	0.1505808	0.0602459
976	0	1.8747053	0.6284515	0.1458727	0.062619
977	0	2.7561205	1.0138241	0.1326609	0.0480454
978	1	2.219693	0.7973689	0.1499687	0.1896544
979	0	2.3646307	0.8606218	0.1266674	0.0536296
980	4	2.2924698	0.8296298	0.1499687	0.5776092
981	1	1.8543281	0.6175224	0.1458727	0.2134504
982	0	2.0071573	0.6967194	0.1458727	0.0599235
983	0	2.8740294	1.055715	0.1326609	0.0465776
984	3	2.2655885	0.8178346	0.1266674	0.4505542
985	0	2.697166	0.9922016	0.1326609	0.0488135
986	2	2.012494	0.6993748	0.1505808	0.3451844
987	1	2.4321786	0.8887874	0.1309861	0.177992
988	1	2.6824274	0.9867221	0.1326609	0.165907
989	17	2.6824274	0.9867221	0.1326609	2.036272
990	1	2.3027293	0.8340951	0.1266674	0.1849283
991	7	2.7119046	0.9976512	0.1326609	0.8603931

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The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
992	9	2.5939957	0.9531994	0.1326609	1.1282051
993	2	2.4321786	0.8887874	0.1309861	0.3034049
994	1	2.7413819	1.0084621	0.1326609	0.163287
995	11	2.4321786	0.8887874	0.1309861	1.4321209
996	3	2.4453969	0.8942075	0.1309861	0.4271786
997	1	1.6654632	0.5101033	0.1326609	0.2280199
998	3	1.8339508	0.6064726	0.1458727	0.5178338
999	0	2.8298135	1.0402108	0.1326609	0.0471177
1000	8	2.2903491	0.8287042	0.1266674	1.1011251
1001	4	1.9664028	0.6762059	0.1458727	0.6401448
1002	6	1.9907373	0.6885051	0.1505808	0.9224449
1003	0	2.3139621	0.8389612	0.1326609	0.0544443
1004	0	0.9252853	-0.077653	0.1309861	0.0899652
1005	9	2.7266432	1.0030713	0.1326609	1.0879984
1006	7	2.2779688	0.8232842	0.1266674	0.9739733
1007	2	2.2903491	0.8287042	0.1266674	0.3164053
1008	2	2.7119046	0.9976512	0.1326609	0.2805546
1009	1	2.7855977	1.0244625	0.1326609	0.161374
1010	2	2.4057419	0.8778583	0.1309861	0.3057502
1011	5	2.5503347	0.9362246	0.1266674	0.6570773
1012	2	2.2655885	0.8178346	0.1266674	0.3187842
1013	3	2.3027293	0.8340951	0.1266674	0.4455286
1014	0	2.4586153	0.8995983	0.1309861	0.0521786
1015	0	2.2903491	0.8287042	0.1266674	0.0548321
1016	5	2.4982704	0.9155986	0.1309861	0.6668411

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Parameter Code=HYNOCSEX Parameter=Nocturnal severe or BG confirmed hypoglycaemic episodes Study Identifier=NN1218-4131

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
1017	0	2.4189602	0.8833378	0.1309861	0.0527816
1018	7	2.7119046	0.9976512	0.1326609	0.8603931
1019	0	1.8747053	0.6284515	0.1458727	0.062619
1020	8	2.3151096	0.839457	0.1266674	1.0929627
1021	6	2.4586153	0.8995983	0.1309861	0.7989241
1022	7	2.2779688	0.8232842	0.1266674	0.9739733
1023	4	2.7119046	0.9976512	0.1326609	0.51249
1024	6	2.7119046	0.9976512	0.1326609	0.7444254
1025	0	2.7119046	0.9976512	0.1326609	0.0486192

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33: Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=H12HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 1-2 hours after meal

The GENMOD Procedure

Model Information

Data Set	WORK.ENDPOINT	
Distribution	Negative Binomial	
Link Function	Log	
Dependent Variable	AVAL	Analysis Value
Offset Variable	log_offset	

Number of Observations Read	1025
Number of Observations Used	1025

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Parameter Information

Parameter	Effect	TRTPN	REGION1	BOLAD1
Prm1	Intercept			
Prm2	TRTPN	2		
Prm3	TRTPN	3		
Prm4	TRTPN	4		
Prm5	REGION1		ASIA (EXCLUDING JAPAN)	
Prm6	REGION1		EUROPE	

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Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=H12HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 1-2 hours after meal

The GENMOD Procedure

Parameter Information

Parameter	Effect	TRTPN	REGION1	BOLAD1
Prm7	REGION1		JAPAN	
Prm8	REGION1		NORTH AMERICA	
Prm9	BOLAD1			BOLUS INSULIN ALGORITHM (SLIDING SCALE)
Prm10	BOLAD1			CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Criteria For Assessing Goodness Of Fit

Criterion	DF	Value	Value/DF
Deviance	1018	715.2060	0.7026
Scaled Deviance	1018	715.2060	0.7026
Pearson Chi-Square	1018	1011.0318	0.9932
Scaled Pearson X2	1018	1011.0318	0.9932
Log Likelihood		-43.3006	
Full Log Likelihood		-1300.6565	
AIC (smaller is better)		2617.3131	
AICC (smaller is better)		2617.4548	
BIC (smaller is better)		2656.7726	

Algorithm converged.

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Analysis Of Maximum Likelihood Parameter Estimates

Parameter		DF	Estimate	Standard Error	Wald 95% Confidence Limits		Wald Chi-Square
Intercept		1	5.0493	0.1759	4.7045	5.3940	824.03
TRTPN	2	1	-0.2899	0.1801	-0.6429	0.0630	2.59
TRTPN	3	1	-0.0121	0.1784	-0.3618	0.3376	0.00
TRTPN	4	0	0.0000	0.0000	0.0000	0.0000	.
REGION1	ASIA (EXCLUDING JAPAN)	1	-0.5154	0.2795	-1.0632	0.0324	3.40
REGION1	EUROPE	1	0.5351	0.1914	0.1600	0.9102	7.82
REGION1	JAPAN	1	0.3155	0.2104	-0.0970	0.7280	2.25
REGION1	NORTH AMERICA	0	0.0000	0.0000	0.0000	0.0000	.
BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	1	0.3314	0.1635	0.0110	0.6518	4.11
BOLAD1	CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY	0	0.0000	0.0000	0.0000	0.0000	.
Dispersion		1	4.3717	0.3555	3.7276	5.1272	

Analysis Of Maximum Likelihood Parameter Estimates

Parameter		Pr > ChiSq
Intercept		<.0001
TRTPN	2	0.1074
TRTPN	3	0.9460
TRTPN	4	.
REGION1	ASIA (EXCLUDING JAPAN)	0.0652
REGION1	EUROPE	0.0052
REGION1	JAPAN	0.1338
REGION1	NORTH AMERICA	.
BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.0426
BOLAD1	CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY	.
Dispersion		

NOTE: The negative binomial dispersion parameter was estimated by maximum likelihood.

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Coefficients for TRTPN Least Squares Means Using WORK.ENDPOINT Margins

Parameter	Geographic Region Grouping Method 1
Intercept	
Planned Treatment (N) 2	
Planned Treatment (N) 3	
Planned Treatment (N) 4	
Geographic Region Grouping Method 1 ASIA (EXCLUDING JAPAN)	ASIA (EXCLUDING JAPAN)
Geographic Region Grouping Method 1 EUROPE	EUROPE
Geographic Region Grouping Method 1 JAPAN	JAPAN
Geographic Region Grouping Method 1 NORTH AMERICA	NORTH AMERICA
Bolus Adjustment Method at Timepoint 1 BOLUS INSULIN ALGORITHM (SLIDING SCALE)	
Bolus Adjustment Method at Timepoint 1 CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY	

Coefficients for TRTPN Least Squares Means Using WORK.ENDPOINT Margins

Bolus Adjustment Method at Timepoint 1	Planned Treatment (N)	Row1	Row2	Row3
	1	1	1	1
	2	1		
	3		1	
	4			1
		0.1307	0.1307	0.1307
		0.3366	0.3366	0.3366
		0.239	0.239	0.239
BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.2937	0.2937	0.2937
CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0.5824	0.5824	0.5824
		0.4176	0.4176	0.4176

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TRTPN Least Squares Means

Planned Treatment (N)	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
2	WORK.ENDPOINT	5.1405	0.1287	39.94	<.0001	0.05	4.8882	5.3928
3	WORK.ENDPOINT	5.4184	0.1259	43.03	<.0001	0.05	5.1716	5.6651
4	WORK.ENDPOINT	5.4305	0.1257	43.22	<.0001	0.05	5.1842	5.6767

Differences of TRTPN Least Squares Means

Planned Treatment (N)	Planned Treatment (N)	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
2	4	WORK.ENDPOINT	-0.2899	0.1801	-1.61	0.1074	0.05	-0.6429	0.06304
3	4	WORK.ENDPOINT	-0.01209	0.1784	-0.07	0.9460	0.05	-0.3618	0.3376

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) / NovoRapid (meal)	WORK.ENDPOINT	-0.2899	0.1801	-1.61	0.1074	0.05	-0.6429	0.06304

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Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
TRTPN	Faster aspart (post) / NovoRapid (meal)	WORK.ENDPOINT	-0.01209	0.1784	-0.07	0.9460	0.05	-0.3618	0.3376

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
1	0	0.8057563	-0.215974	0.2174991	0.0393944
2	0	0.8057563	-0.215974	0.2174991	0.0393944
3	0	0.8057563	-0.215974	0.2174991	0.0393944
4	0	0.8057563	-0.215974	0.2174991	0.0393944
5	0	0.8057563	-0.215974	0.2174991	0.0393944
6	2	1.128495	0.1208849	0.1885977	0.3123152
7	1	1.0638172	0.0618635	0.2170105	0.1789666
8	0	1.0927252	0.0886748	0.2170105	0.0327407
9	0	0.8364101	-0.178636	0.2174991	0.0385732
10	0	0.2526985	-1.375558	0.1805406	0.0570438
11	0	0.7969981	-0.226903	0.2174991	0.0396344
12	1	1.0927252	0.0886748	0.2170105	0.1758749
13	1	1.0638172	0.0618635	0.2170105	0.1789666
14	2	1.0650509	0.0630226	0.2025481	1.7797862
15	0	0.8057563	-0.215974	0.2174991	0.0393944
16	0	1.0826066	0.0793717	0.2025481	0.0329401

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
17	1	1.122395	0.1154648	0.1885977	0.1728035
18	0	1.5462953	0.4358619	0.189572	0.0256784
19	1	1.4998879	0.4053904	0.1805406	0.1410784
20	7	1.0650509	0.0630226	0.2025481	1.05208
21	0	1.122395	0.1154648	0.1885977	0.032169
22	0	0.1931136	-1.644477	0.2025481	0.0567775
23	0	1.0638172	0.0618635	0.2170105	0.0333163
24	0	1.4818663	0.3933023	0.189572	0.0264971
25	0	1.1042885	0.0992012	0.2170105	0.0325157
26	0	1.0638172	0.0618635	0.2170105	0.0333163
27	0	1.1852311	0.1699378	0.2170105	0.0310178
28	6	1.4818663	0.3933023	0.189572	0.7215282
29	3	0.8101354	-0.210554	0.2174991	0.5543801
30	25	1.5487973	0.4374787	0.1805406	2.828765
31	2	1.4818663	0.3933023	0.189572	0.2581741
32	1	0.8057563	-0.215974	0.2174991	0.2116167
33	0	1.0638172	0.0618635	0.2170105	0.0333163
34	0	1.4917364	0.3999408	0.1805406	0.0263684
35	0	1.1389782	0.1301315	0.2170105	0.0318574
36	1	1.0767547	0.0739516	0.2025481	0.1775706
37	0	1.0767547	0.0739516	0.2025481	0.0330564
38	1	1.0638172	0.0618635	0.2170105	0.1789666
39	1	1.0638172	0.0618635	0.2170105	0.1789666
40	0	1.0464723	0.0454248	0.2170105	0.0336706
41	4	1.0638172	0.0618635	0.2170105	0.6159174

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
42	7	1.4979735	0.4041132	0.189572	0.8307501
43	2	1.4818663	0.3933023	0.189572	0.2581741
44	5	1.4998879	0.4053904	0.1805406	0.6003397
45	0	1.122395	0.1154648	0.1885977	0.032169
46	0	1.1711948	0.1580245	0.1885977	0.0312682
47	1	1.122395	0.1154648	0.1885977	0.1728035
48	0	1.5060272	0.4094752	0.189572	0.0261842
49	3	1.4917364	0.3999408	0.1805406	0.3721963
50	1	1.134595	0.1262758	0.1885977	0.1715695
51	5	1.134595	0.1262758	0.1885977	0.7300907
52	0	1.4818663	0.3933023	0.189572	0.0264971
53	0	1.4979735	0.4041132	0.189572	0.0262877
54	0	1.5161911	0.4162013	0.1805406	0.0260547
55	1	1.465759	0.3823732	0.189572	0.1434777
56	3	1.134595	0.1262758	0.1885977	0.4508301
57	0	1.6509923	0.5013765	0.189572	0.0244479
58	4	1.1467949	0.136971	0.1885977	0.5862699
59	7	1.5080395	0.4108105	0.1805406	0.8266662
60	0	1.4818663	0.3933023	0.189572	0.0264971
61	0	1.5243426	0.4215632	0.1805406	0.0259518
62	2	1.1467949	0.136971	0.1885977	0.3089912
63	0	1.465759	0.3823732	0.189572	0.0267097
64	0	1.4998879	0.4053904	0.1805406	0.026263
65	7	1.5221344	0.4201136	0.189572	0.8210127
66	4	1.5060272	0.4094752	0.189572	0.4840672

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Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
67	0	1.4818663	0.3933023	0.189572	0.0264971
68	7	1.465759	0.3823732	0.189572	0.8440861
69	0	1.1040951	0.0990261	0.1885977	0.0325194
70	0	1.122395	0.1154648	0.1885977	0.032169
71	7	1.1772948	0.1632193	0.1885977	0.9846905
72	0	1.4998879	0.4053904	0.1805406	0.026263
73	0	1.4818663	0.3933023	0.189572	0.0264971
74	0	1.4998879	0.4053904	0.1805406	0.026263
75	2	1.128495	0.1208849	0.1885977	0.3123152
76	6	1.4998879	0.4053904	0.1805406	0.715155
77	0	1.4818663	0.3933023	0.189572	0.0264971
78	1	1.4998879	0.4053904	0.1805406	0.1410784
79	0	1.122395	0.1154648	0.1885977	0.032169
80	1	1.128495	0.1208849	0.1885977	0.1721845
81	0	1.4998879	0.4053904	0.1805406	0.026263
82	0	1.122395	0.1154648	0.1885977	0.032169
83	0	1.4998879	0.4053904	0.1805406	0.026263
84	0	1.4754332	0.3889517	0.1805406	0.0265816
85	4	1.122395	0.1154648	0.1885977	0.5947073
86	0	1.4738127	0.3878527	0.189572	0.026603
87	3	1.122395	0.1154648	0.1885977	0.4540727
88	0	1.4818663	0.3933023	0.189572	0.0264971
89	0	1.5243426	0.4215632	0.1805406	0.0259518
90	0	1.4577054	0.3768636	0.189572	0.0268172
91	0	1.4917364	0.3999408	0.1805406	0.0263684

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Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
92	1	1.4998879	0.4053904	0.1805406	0.1410784
93	1	1.4754332	0.3889517	0.1805406	0.1427896
94	0	1.4917364	0.3999408	0.1805406	0.0263684
95	0	1.122395	0.1154648	0.1885977	0.032169
96	5	1.4754332	0.3889517	0.1805406	0.6076218
97	0	1.4818663	0.3933023	0.189572	0.0264971
98	1	1.0767547	0.0739516	0.2025481	0.1775706
99	0	1.122395	0.1154648	0.1885977	0.032169
100	0	1.0464723	0.0454248	0.2170105	0.0336706
101	0	1.4998879	0.4053904	0.1805406	0.026263
102	0	0.8013772	-0.221424	0.2174991	0.0395141
103	1	1.081162	0.0780364	0.2170105	0.1770996
104	2	1.4998879	0.4053904	0.1805406	0.2558937
105	4	1.0650509	0.0630226	0.2025481	0.6154563
106	0	1.0591989	0.0575129	0.2025481	0.0334099
107	9	1.4998879	0.4053904	0.1805406	1.059601
108	8	1.4899199	0.3987224	0.189572	0.9494248
109	1	1.465759	0.3823732	0.189572	0.1434777
110	0	0.8057563	-0.215974	0.2174991	0.0393944
111	0	1.0650509	0.0630226	0.2025481	0.0332913
112	14	1.0767547	0.0739516	0.2025481	2.0562548
113	0	1.0767547	0.0739516	0.2025481	0.0330564
114	0	1.0767547	0.0739516	0.2025481	0.0330564
115	0	0.8057563	-0.215974	0.2174991	0.0393944
116	6	1.0638172	0.0618635	0.2170105	0.907218

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Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
117	0	1.0826066	0.0793717	0.2025481	0.0329401
118	0	0.8057563	-0.215974	0.2174991	0.0393944
119	0	1.0767547	0.0739516	0.2025481	0.0330564
120	1	0.8057563	-0.215974	0.2174991	0.2116167
121	0	1.0767547	0.0739516	0.2025481	0.0330564
122	0	0.8057563	-0.215974	0.2174991	0.0393944
123	0	1.0464723	0.0454248	0.2170105	0.0336706
124	0	1.0767547	0.0739516	0.2025481	0.0330564
125	5	0.8057563	-0.215974	0.2174991	0.9005061
126	3	1.0580355	0.0564139	0.2170105	0.4719237
127	0	1.0638172	0.0618635	0.2170105	0.0333163
128	0	1.081162	0.0780364	0.2170105	0.0329687
129	5	1.4818663	0.3933023	0.189572	0.6056897
130	0	0.8364101	-0.178636	0.2174991	0.0385732
131	0	1.1833948	0.1683872	0.1885977	0.0310503
132	0	1.0638172	0.0618635	0.2170105	0.0333163
133	0	1.2603921	0.2314228	0.2170105	0.0297391
134	1	1.5406458	0.4322016	0.1805406	0.1383128
135	0	1.0826066	0.0793717	0.2025481	0.0329401
136	0	1.2054971	0.186892	0.2025481	0.0306629
137	0	0.6880122	-0.373949	0.2170105	0.0428332
138	0	1.6466161	0.4987223	0.1805406	0.0244971
139	1	0.8145145	-0.205163	0.2174991	0.2103403
140	5	1.0650509	0.0630226	0.2025481	0.7609975
141	0	1.1042885	0.0992012	0.2170105	0.0325157

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142	0	1.0522539	0.0509345	0.2170105	0.0335517
143	2	1.4998879	0.4053904	0.1805406	0.2558937
144	2	1.122395	0.1154648	0.1885977	0.3134381
145	1	1.122395	0.1154648	0.1885977	0.1728035
146	0	1.5406458	0.4322016	0.1805406	0.0257482
147	1	1.594617	0.4666336	0.189572	0.1348086
148	0	1.9328691	0.6590055	0.189572	0.021644
149	0	1.5080395	0.4108105	0.1805406	0.0261585
150	0	1.1040951	0.0990261	0.1885977	0.0325194
151	5	1.4818663	0.3933023	0.189572	0.6056897
152	0	1.4998879	0.4053904	0.1805406	0.026263
153	0	1.4754332	0.3889517	0.1805406	0.0265816
154	0	1.4738127	0.3878527	0.189572	0.026603
155	6	1.4835848	0.3944613	0.1805406	0.7209157
156	0	0.7990965	-0.224274	0.1885977	0.0395767
157	0	1.2241504	0.2022471	0.189572	0.030343
158	0	1.4818663	0.3933023	0.189572	0.0264971
159	6	1.134595	0.1262758	0.1885977	0.869721
160	0	1.140695	0.1316377	0.1885977	0.0318255
161	1	1.122395	0.1154648	0.1885977	0.1728035
162	0	1.4818663	0.3933023	0.189572	0.0264971
163	1	1.4818663	0.3933023	0.189572	0.1423356
164	3	1.4818663	0.3933023	0.189572	0.3740126
165	0	1.0189456	0.0187684	0.1805406	0.0342475
166	2	1.465759	0.3823732	0.189572	0.2602458

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Parameter Code=H12HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 1-2 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
167	4	1.4998879	0.4053904	0.1805406	0.4855244
168	0	1.5161911	0.4162013	0.1805406	0.0260547
169	0	1.4835848	0.3944613	0.1805406	0.0264746
170	1	1.1162951	0.1100152	0.1885977	0.1734268
171	0	1.4738127	0.3878527	0.189572	0.026603
172	0	1.140695	0.1316377	0.1885977	0.0318255
173	0	1.128495	0.1208849	0.1885977	0.0320537
174	0	1.4754332	0.3889517	0.1805406	0.0265816
175	0	1.5161911	0.4162013	0.1805406	0.0260547
176	0	1.4917364	0.3999408	0.1805406	0.0263684
177	0	1.5382416	0.43064	0.189572	0.025778
178	0	1.140695	0.1316377	0.1885977	0.0318255
179	0	1.4818663	0.3933023	0.189572	0.0264971
180	0	1.4917364	0.3999408	0.1805406	0.0263684
181	1	1.1040951	0.0990261	0.1885977	0.174686
182	0	1.4835848	0.3944613	0.1805406	0.0264746
183	0	1.4818663	0.3933023	0.189572	0.0264971
184	0	1.4818663	0.3933023	0.189572	0.0264971
185	2	1.5060272	0.4094752	0.189572	0.2551257
186	0	1.4917364	0.3999408	0.1805406	0.0263684
187	0	1.122395	0.1154648	0.1885977	0.032169
188	0	1.128495	0.1208849	0.1885977	0.0320537
189	0	0.8053621	-0.216463	0.189572	0.0394051
190	5	1.1040951	0.0990261	0.1885977	0.7433523
191	2	1.0357912	0.0351656	0.2025481	0.3302301

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Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=H12HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 1-2 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
192	0	1.4835848	0.3944613	0.1805406	0.0264746
193	0	1.122395	0.1154648	0.1885977	0.032169
194	1	1.4998879	0.4053904	0.1805406	0.1410784
195	3	1.5140808	0.4148085	0.189572	0.3681468
196	4	1.0943105	0.0901245	0.2025481	0.6047039
197	0	1.4998879	0.4053904	0.1805406	0.026263
198	1	1.4754332	0.3889517	0.1805406	0.1427896
199	0	1.122395	0.1154648	0.1885977	0.032169
200	0	1.5080395	0.4108105	0.1805406	0.0261585
201	0	1.134595	0.1262758	0.1885977	0.0319392
202	0	0.4727908	-0.749102	0.1805406	0.0502647
203	0	0.7731476	-0.257285	0.189572	0.0403007
204	10	1.122395	0.1154648	0.1885977	1.4385149
205	0	1.4899199	0.3987224	0.189572	0.026392
206	0	1.1650949	0.1528025	0.1885977	0.0313782
207	1	1.122395	0.1154648	0.1885977	0.1728035
208	0	1.4899199	0.3987224	0.189572	0.026392
209	0	1.1040951	0.0990261	0.1885977	0.0325194
210	1	1.4998879	0.4053904	0.1805406	0.1410784
211	0	1.1042885	0.0992012	0.2170105	0.0325157
212	0	1.465759	0.3823732	0.189572	0.0267097
213	0	1.4818663	0.3933023	0.189572	0.0264971
214	0	1.0638172	0.0618635	0.2170105	0.0333163
215	0	0.0563753	-2.875723	0.189572	0.0362855
216	0	0.8057563	-0.215974	0.2174991	0.0393944

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Parameter Code=H12HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 1-2 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
217	0	1.0650509	0.0630226	0.2025481	0.0332913
218	0	0.8101354	-0.210554	0.2174991	0.0392753
219	0	1.0826066	0.0793717	0.2025481	0.0329401
220	0	1.0650509	0.0630226	0.2025481	0.0332913
221	0	1.4917364	0.3999408	0.1805406	0.0263684
222	3	1.122395	0.1154648	0.1885977	0.4540727
223	2	1.4818663	0.3933023	0.189572	0.2581741
224	0	1.5382416	0.43064	0.189572	0.025778
225	1	1.122395	0.1154648	0.1885977	0.1728035
226	1	1.122395	0.1154648	0.1885977	0.1728035
227	0	1.4818663	0.3933023	0.189572	0.0264971
228	1	1.4998879	0.4053904	0.1805406	0.1410784
229	1	1.5569489	0.4427281	0.1805406	0.1372358
230	0	1.4818663	0.3933023	0.189572	0.0264971
231	0	1.4899199	0.3987224	0.189572	0.026392
232	1	1.5324942	0.4268966	0.1805406	0.1388575
233	0	1.4818663	0.3933023	0.189572	0.0264971
234	0	1.140695	0.1316377	0.1885977	0.0318255
235	0	1.4818663	0.3933023	0.189572	0.0264971
236	0	1.4899199	0.3987224	0.189572	0.026392
237	0	1.4818663	0.3933023	0.189572	0.0264971
238	1	1.4998879	0.4053904	0.1805406	0.1410784
239	1	1.4818663	0.3933023	0.189572	0.1423356
240	0	1.122395	0.1154648	0.1885977	0.032169
241	0	1.122395	0.1154648	0.1885977	0.032169

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Parameter Code=H12HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 1-2 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
242	0	1.122395	0.1154648	0.1885977	0.032169
243	0	1.4998879	0.4053904	0.1805406	0.026263
244	0	1.442827	0.3666044	0.1805406	0.0270182
245	0	1.5382416	0.43064	0.189572	0.025778
246	0	0.6534383	-0.425507	0.240882	0.0439319
247	1	0.6534383	-0.425507	0.240882	0.2359912
248	0	0.645587	-0.437595	0.2438292	0.0441871
249	0	0.7209129	-0.327237	0.240882	0.0418255
250	0	0.645587	-0.437595	0.2438292	0.0441871
251	0	0.6534383	-0.425507	0.240882	0.0439319
252	0	0.507583	-0.678095	0.2342711	0.0489845
253	0	0.6596215	-0.416089	0.2438292	0.0437324
254	0	0.6490956	-0.432175	0.2438292	0.0440728
255	0	0.4889805	-0.715433	0.2342711	0.0496671
256	0	0.6526043	-0.426784	0.2438292	0.0439589
257	0	0.4889805	-0.715433	0.2342711	0.0496671
258	0	0.645587	-0.437595	0.2438292	0.0441871
259	0	0.6666388	-0.405507	0.2438292	0.0435076
260	0	0.6490956	-0.432175	0.2438292	0.0440728
261	0	0.6534383	-0.425507	0.240882	0.0439319
262	0	0.645587	-0.437595	0.2438292	0.0441871
263	0	0.4889805	-0.715433	0.2342711	0.0496671
264	2	0.6569896	-0.420087	0.240882	0.4269326
265	0	0.6569896	-0.420087	0.240882	0.0438172
266	0	0.6534383	-0.425507	0.240882	0.0439319

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Parameter Code=H12HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 1-2 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
267	0	0.6534383	-0.425507	0.240882	0.0439319
268	2	0.6747461	-0.393419	0.240882	0.4214059
269	1	0.4996105	-0.693927	0.2342711	0.2647003
270	0	0.645587	-0.437595	0.2438292	0.0441871
271	0	0.4889805	-0.715433	0.2342711	0.0496671
272	1	0.6526043	-0.426784	0.2438292	0.2361363
273	0	0.6350611	-0.454034	0.2438292	0.0445324
274	0	0.496953	-0.69926	0.2342711	0.0493739
275	0	0.7138103	-0.337138	0.240882	0.0420399
276	0	0.6490956	-0.432175	0.2438292	0.0440728
277	0	0.6526043	-0.426784	0.2438292	0.0439589
278	0	0.645587	-0.437595	0.2438292	0.0441871
279	0	0.496953	-0.69926	0.2342711	0.0493739
280	0	0.491638	-0.710013	0.2342711	0.0495693
281	1	0.6490956	-0.432175	0.2438292	0.2367479
282	5	0.491638	-0.710013	0.2342711	1.1330912
283	1	0.481008	-0.731871	0.2342711	0.2683784
284	0	0.4889805	-0.715433	0.2342711	0.0496671
285	0	0.6385698	-0.448524	0.2438292	0.0444169
286	0	0.6569896	-0.420087	0.240882	0.0438172
287	0	0.6569896	-0.420087	0.240882	0.0438172
288	0	0.6605409	-0.414696	0.240882	0.0437029
289	0	0.6569896	-0.420087	0.240882	0.0438172
290	0	0.6534383	-0.425507	0.240882	0.0439319
291	0	0.6640922	-0.409334	0.240882	0.043589

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Parameter Code=H12HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 1-2 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
292	0	0.645587	-0.437595	0.2438292	0.0441871
293	0	0.4889805	-0.715433	0.2342711	0.0496671
294	0	0.6534383	-0.425507	0.240882	0.0439319
295	0	0.6490956	-0.432175	0.2438292	0.0440728
296	0	0.6427844	-0.441946	0.240882	0.0442787
297	0	0.649887	-0.430957	0.240882	0.0440471
298	6	0.645587	-0.437595	0.2438292	1.2032357
299	0	0.3428178	-1.070556	0.2342711	0.0549074
300	0	0.4889805	-0.715433	0.2342711	0.0496671
301	0	0.6534383	-0.425507	0.240882	0.0439319
302	0	0.645587	-0.437595	0.2438292	0.0441871
303	0	0.6526043	-0.426784	0.2438292	0.0439589
304	2	0.6605409	-0.414696	0.240882	0.4258189
305	4	0.5102405	-0.672873	0.2342711	0.9037811
306	0	0.4889805	-0.715433	0.2342711	0.0496671
307	0	0.6463357	-0.436436	0.240882	0.0441627
308	0	0.4889805	-0.715433	0.2342711	0.0496671
309	0	0.491638	-0.710013	0.2342711	0.0495693
310	0	0.491638	-0.710013	0.2342711	0.0495693
311	0	0.6526043	-0.426784	0.2438292	0.0439589
312	0	0.6605409	-0.414696	0.240882	0.0437029
313	0	0.6534383	-0.425507	0.240882	0.0439319
314	0	0.6666388	-0.405507	0.2438292	0.0435076
315	0	0.4836655	-0.726362	0.2342711	0.049863
316	0	0.6605409	-0.414696	0.240882	0.0437029

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Parameter Code=H12HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 1-2 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
317	5	0.6490956	-0.432175	0.2438292	1.0074485
318	0	0.486323	-0.720882	0.2342711	0.049765
319	0	0.6420784	-0.443045	0.2438292	0.0443018
320	3	0.4942955	-0.704622	0.2342711	0.6983029
321	0	0.6640922	-0.409334	0.240882	0.043589
322	0	0.6596215	-0.416089	0.2438292	0.0437324
323	0	0.5102405	-0.672873	0.2342711	0.0488874
324	1	0.6640922	-0.409334	0.240882	0.2341492
325	0	0.4889805	-0.715433	0.2342711	0.0496671
326	0	0.4942955	-0.704622	0.2342711	0.0494715
327	0	0.6640922	-0.409334	0.240882	0.043589
328	0	0.6534383	-0.425507	0.240882	0.0439319
329	0	0.6569896	-0.420087	0.240882	0.0438172
330	0	0.6490956	-0.432175	0.2438292	0.0440728
331	0	0.6534383	-0.425507	0.240882	0.0439319
332	0	0.4942955	-0.704622	0.2342711	0.0494715
333	0	0.6561129	-0.421422	0.2438292	0.0438455
334	1	0.507583	-0.678095	0.2342711	0.2631322
335	1	0.4889805	-0.715433	0.2342711	0.2667992
336	1	0.0816798	-2.504949	0.240882	0.2382413
337	3	0.6534383	-0.425507	0.240882	0.6201097
338	0	0.491638	-0.710013	0.2342711	0.0495693
339	0	0.6782974	-0.38817	0.240882	0.0431378
340	0	0.6561129	-0.421422	0.2438292	0.0438455
341	0	0.4996105	-0.693927	0.2342711	0.0492764

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Parameter Code=H12HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 1-2 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
342	0	0.6534383	-0.425507	0.240882	0.0439319
343	0	0.4889805	-0.715433	0.2342711	0.0496671
344	5	0.6640922	-0.409334	0.240882	0.9963899
345	8	0.4889805	-0.715433	0.2342711	1.7867236
346	0	0.645587	-0.437595	0.2438292	0.0441871
347	1	0.6640922	-0.409334	0.240882	0.2341492
348	2	0.4942955	-0.704622	0.2342711	0.4820257
349	1	1.8357829	0.607471	0.1602293	0.1210561
350	0	1.3904585	0.3296336	0.1776056	0.027749
351	0	1.3752623	0.3186445	0.1776056	0.0279682
352	0	1.3980567	0.3350832	0.1776056	0.0276406
353	0	1.3980567	0.3350832	0.1776056	0.0276406
354	0	1.3904585	0.3296336	0.1776056	0.027749
355	0	1.8682623	0.6250087	0.1793431	0.0222295
356	0	1.8682623	0.6250087	0.1793431	0.0222295
357	9	1.0036511	0.0036444	0.1968176	1.3949929
358	9	1.325092	0.2814819	0.1796833	1.1585758
359	0	1.3557854	0.3043809	0.189872	0.0282541
360	0	1.0036511	0.0036444	0.1968176	0.034576
361	2	1.3755031	0.3188195	0.1796833	0.2724739
362	0	1.0036511	0.0036444	0.1968176	0.034576
363	0	1.3266287	0.2826409	0.189872	0.0286927
364	0	1.0200149	0.0198173	0.1968176	0.0342248
365	0	1.0036511	0.0036444	0.1968176	0.034576
366	0	0.9927418	-0.007285	0.1968176	0.0348138

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The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
367	0	0.9872872	-0.012794	0.1968176	0.0349338
368	2	1.341207	0.29357	0.189872	0.2774148
369	2	0.9872872	-0.012794	0.1968176	0.3403772
370	0	1.384942	0.3256583	0.189872	0.0278282
371	1	0.9872872	-0.012794	0.1968176	0.1876555
372	0	1.3322936	0.2869019	0.1796833	0.0286065
373	2	1.3971079	0.3344043	0.1796833	0.2694473
374	2	1.3322936	0.2869019	0.1796833	0.2787271
375	0	1.0036511	0.0036444	0.1968176	0.034576
376	6	1.325092	0.2814819	0.1796833	0.7819559
377	0	1.325092	0.2814819	0.1796833	0.0287162
378	0	1.325092	0.2814819	0.1796833	0.0287162
379	0	1.341207	0.29357	0.189872	0.0284718
380	0	1.3394952	0.2922928	0.1796833	0.0284976
381	0	1.325092	0.2814819	0.1796833	0.0287162
382	0	1.325092	0.2814819	0.1796833	0.0287162
383	0	1.341207	0.29357	0.189872	0.0284718
384	0	1.3980567	0.3350832	0.1776056	0.0276406
385	0	1.341207	0.29357	0.189872	0.0284718
386	0	1.3178904	0.2760323	0.1796833	0.0288267
387	0	1.0036511	0.0036444	0.1968176	0.034576
388	0	1.325092	0.2814819	0.1796833	0.0287162
389	1	1.325092	0.2814819	0.1796833	0.1542561
390	0	1.3394952	0.2922928	0.1796833	0.0284976
391	0	1.341207	0.29357	0.189872	0.0284718

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Parameter Code=H12HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 1-2 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
392	0	1.8458145	0.6129206	0.1602293	0.0224402
393	5	1.9060041	0.645009	0.1602293	0.5002345
394	0	1.3904585	0.3296336	0.1776056	0.027749
395	1	1.474038	0.3880056	0.1776056	0.1428885
396	0	1.8558461	0.6183407	0.1602293	0.0223456
397	0	0.9927418	-0.007285	0.1968176	0.0348138
398	1	1.4056548	0.3405032	0.1776056	0.1479004
399	0	1.3980567	0.3350832	0.1776056	0.0276406
400	0	1.4436455	0.3671715	0.1776056	0.027007
401	0	1.4132529	0.3458941	0.1776056	0.0274262
402	0	1.8458145	0.6129206	0.1602293	0.0224402
403	0	1.8784159	0.6304288	0.1793431	0.0221354
404	2	1.8759093	0.6290935	0.1602293	0.2159018
405	0	1.4056548	0.3405032	0.1776056	0.027533
406	0	1.8658777	0.6237316	0.1602293	0.0222517
407	1	1.4056548	0.3405032	0.1776056	0.1479004
408	0	1.3980567	0.3350832	0.1776056	0.0276406
409	0	1.3106888	0.2705528	0.1796833	0.0289381
410	0	0.9872872	-0.012794	0.1968176	0.0349338
411	0	1.3178904	0.2760323	0.1796833	0.0288267
412	1	1.0091057	0.0090645	0.1968176	0.1851007
413	0	1.3610999	0.3082931	0.1796833	0.0281755
414	0	1.3557854	0.3043809	0.189872	0.0282541
415	0	1.3106888	0.2705528	0.1796833	0.0289381
416	2	1.3339179	0.2881204	0.189872	0.2784871

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Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=H12HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 1-2 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
417	0	1.341207	0.29357	0.189872	0.0284718
418	0	1.325092	0.2814819	0.1796833	0.0287162
419	0	1.3106888	0.2705528	0.1796833	0.0289381
420	15	1.8682623	0.6250087	0.1793431	1.4799543
421	1	1.8458145	0.6129206	0.1602293	0.1205433
422	2	1.8784159	0.6304288	0.1793431	0.2156763
423	5	1.8784159	0.6304288	0.1793431	0.5059876
424	1	1.4056548	0.3405032	0.1776056	0.1479004
425	0	1.3828604	0.3241541	0.1776056	0.0278582
426	4	1.8658777	0.6237316	0.1602293	0.4113666
427	0	1.4056548	0.3405032	0.1776056	0.027533
428	1	1.4056548	0.3405032	0.1776056	0.1479004
429	0	1.8959725	0.6397319	0.1602293	0.0219746
430	0	1.9901055	0.6881876	0.1793431	0.02115
431	0	1.8959725	0.6397319	0.1602293	0.0219746
432	0	1.8682623	0.6250087	0.1793431	0.0222295
433	0	1.3980567	0.3350832	0.1776056	0.0276406
434	0	1.8885695	0.6358197	0.1793431	0.0220421
435	0	1.8682623	0.6250087	0.1793431	0.0222295
436	0	1.8581087	0.6195591	0.1793431	0.0223243
437	0	1.0036511	0.0036444	0.1968176	0.034576
438	0	1.9088767	0.6465149	0.1793431	0.0218578
439	0	1.0091057	0.0090645	0.1968176	0.0344582
440	1	1.3484962	0.29899	0.189872	0.1523564
441	0	1.4208511	0.351256	0.1776056	0.0273203

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Parameter Code=H12HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 1-2 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
442	0	1.0036511	0.0036444	0.1968176	0.034576
443	0	1.8682623	0.6250087	0.1793431	0.0222295
444	1	1.8987231	0.6411816	0.1793431	0.1179077
445	0	1.0036511	0.0036444	0.1968176	0.034576
446	6	1.0091057	0.0090645	0.1968176	0.9383131
447	0	1.8458145	0.6129206	0.1602293	0.0224402
448	0	1.3034872	0.2650432	0.1796833	0.0290502
449	0	1.341207	0.29357	0.189872	0.0284718
450	0	1.3980567	0.3350832	0.1776056	0.0276406
451	0	1.8682623	0.6250087	0.1793431	0.0222295
452	0	1.9799519	0.6830725	0.1793431	0.021236
453	0	1.3322936	0.2869019	0.1796833	0.0286065
454	1	1.0472881	0.046204	0.1968176	0.1807799
455	3	1.4835269	0.3944223	0.1796833	0.3737059
456	0	1.9697983	0.6779311	0.1793431	0.0213227
457	1	0.9927418	-0.007285	0.1968176	0.1870108
458	0	1.3466967	0.2976547	0.1796833	0.0283894
459	0	1.3755031	0.3188195	0.1796833	0.0279647
460	1	1.8581087	0.6195591	0.1793431	0.1199206
461	0	2.1424095	0.7619311	0.1793431	0.0199376
462	3	1.0200149	0.0198173	0.1968176	0.4830913
463	0	1.341207	0.29357	0.189872	0.0284718
464	0	1.3980567	0.3350832	0.1776056	0.0276406
465	0	1.3339179	0.2881204	0.189872	0.0285818
466	0	2.0464465	0.7161049	0.1602293	0.020685

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Parameter Code=H12HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 1-2 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
467	0	1.9291839	0.6570971	0.1793431	0.0216766
468	3	1.8658777	0.6237316	0.1602293	0.3140879
469	0	1.8458145	0.6129206	0.1602293	0.0224402
470	0	1.325092	0.2814819	0.1796833	0.0287162
471	1	1.5196268	0.4184648	0.1776056	0.1397258
472	0	1.9060041	0.645009	0.1602293	0.0218837
473	0	1.0418334	0.0409821	0.1968176	0.0337666
474	0	1.8859409	0.6344268	0.1602293	0.0220662
475	0	1.8357829	0.607471	0.1602293	0.0225357
476	4	1.4132529	0.3458941	0.1776056	0.5070287
477	0	1.9088767	0.6465149	0.1793431	0.0218578
478	0	1.8658777	0.6237316	0.1602293	0.0222517
479	0	1.3828604	0.3241541	0.1776056	0.0278582
480	0	1.8759093	0.6290935	0.1602293	0.0221586
481	3	1.8987231	0.6411816	0.1793431	0.309824
482	3	1.8558461	0.6183407	0.1602293	0.3154132
483	5	1.8257513	0.6019916	0.1602293	0.517338
484	0	1.8357829	0.607471	0.1602293	0.0225357
485	0	1.8479551	0.6140797	0.1793431	0.02242
486	0	1.3752623	0.3186445	0.1776056	0.0279682
487	0	1.8357829	0.607471	0.1602293	0.0225357
488	0	1.3980567	0.3350832	0.1776056	0.0276406
489	10	1.4056548	0.3405032	0.1776056	1.2312069
490	0	1.8759093	0.6290935	0.1602293	0.0221586
491	0	1.8558461	0.6183407	0.1602293	0.0223456

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
492	0	1.8581087	0.6195591	0.1793431	0.0223243
493	0	1.8885695	0.6358197	0.1793431	0.0220421
494	4	1.3524679	0.301931	0.1776056	0.523244
495	0	1.3980567	0.3350832	0.1776056	0.0276406
496	4	1.8987231	0.6411816	0.1793431	0.4057822
497	0	1.8458145	0.6129206	0.1602293	0.0224402
498	0	1.8458145	0.6129206	0.1602293	0.0224402
499	0	1.8987231	0.6411816	0.1793431	0.0219496
500	0	1.8682623	0.6250087	0.1793431	0.0222295
501	8	1.8479551	0.6140797	0.1793431	0.8065357
502	1	1.8658777	0.6237316	0.1602293	0.1195304
503	0	1.3980567	0.3350832	0.1776056	0.0276406
504	0	1.8257513	0.6019916	0.1602293	0.022632
505	0	1.8987231	0.6411816	0.1793431	0.0219496
506	0	1.8987231	0.6411816	0.1793431	0.0219496
507	0	1.8257513	0.6019916	0.1602293	0.022632
508	0	0.300948	-1.200818	0.1602293	0.0561227
509	2	1.8157197	0.5964819	0.1602293	0.2214602
510	1	1.8458145	0.6129206	0.1602293	0.1205433
511	4	1.8682623	0.6250087	0.1793431	0.4109561
512	2	1.8458145	0.6129206	0.1602293	0.2186464
513	11	1.8682623	0.6250087	0.1793431	1.0912277
514	6	1.8558461	0.6183407	0.1602293	0.6084808
515	3	1.3980567	0.3350832	0.1776056	0.3901536
516	0	1.3980567	0.3350832	0.1776056	0.0276406

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Parameter Code=H12HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 1-2 hours after meal

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
517	14	1.8458145	0.6129206	0.1602293	1.3958833
518	1	1.8558461	0.6183407	0.1602293	0.1200348
519	1	1.8885695	0.6358197	0.1793431	0.1184047
520	0	1.8759093	0.6290935	0.1602293	0.0221586
521	0	1.3980567	0.3350832	0.1776056	0.0276406
522	1	1.8682623	0.6250087	0.1793431	0.1194111
523	0	1.8682623	0.6250087	0.1793431	0.0222295
524	0	1.8458145	0.6129206	0.1602293	0.0224402
525	3	1.4056548	0.3405032	0.1776056	0.3886352
526	0	1.4056548	0.3405032	0.1776056	0.027533
527	0	1.8658777	0.6237316	0.1602293	0.0222517
528	0	1.4056548	0.3405032	0.1776056	0.027533
529	0	1.3980567	0.3350832	0.1776056	0.0276406
530	0	1.4284492	0.3565894	0.1776056	0.0272151
531	0	1.8784159	0.6304288	0.1793431	0.0221354
532	1	1.4360473	0.3618944	0.1776056	0.1456317
533	14	1.8458145	0.6129206	0.1602293	1.3958833
534	9	1.8257513	0.6019916	0.1602293	0.9131029
535	0	1.3980567	0.3350832	0.1776056	0.0276406
536	3	1.8682623	0.6250087	0.1793431	0.3137744
537	0	1.8784159	0.6304288	0.1793431	0.0221354
538	0	1.8784159	0.6304288	0.1793431	0.0221354
539	0	1.4056548	0.3405032	0.1776056	0.027533
540	0	1.8987231	0.6411816	0.1793431	0.0219496
541	0	1.3904585	0.3296336	0.1776056	0.027749

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Parameter Code=H12HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 1-2 hours after meal

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
542	0	1.8885695	0.6358197	0.1793431	0.0220421
543	0	1.8276479	0.6030298	0.1793431	0.0226137
544	2	1.4284492	0.3565894	0.1776056	0.26517
545	0	1.4360473	0.3618944	0.1776056	0.0271107
546	1	1.3980567	0.3350832	0.1776056	0.1484782
547	0	1.4132529	0.3458941	0.1776056	0.0274262
548	42	1.8558461	0.6183407	0.1602293	4.1252918
549	3	1.3904585	0.3296336	0.1776056	0.3916834
550	23	1.8682623	0.6250087	0.1793431	2.2574076
551	6	1.8682623	0.6250087	0.1793431	0.6053194
552	8	1.3980567	0.3350832	0.1776056	0.9943419
553	0	1.4056548	0.3405032	0.1776056	0.027533
554	0	1.8885695	0.6358197	0.1793431	0.0220421
555	0	1.3980567	0.3350832	0.1776056	0.0276406
556	0	1.4360473	0.3618944	0.1776056	0.0271107
557	3	1.8784159	0.6304288	0.1793431	0.3124467
558	0	1.4056548	0.3405032	0.1776056	0.027533
559	0	1.3980567	0.3350832	0.1776056	0.0276406
560	0	1.8987231	0.6411816	0.1793431	0.0219496
561	4	1.8458145	0.6129206	0.1602293	0.4148525
562	0	1.8784159	0.6304288	0.1793431	0.0221354
563	11	1.341207	0.29357	0.189872	1.3976582
564	3	1.8658777	0.6237316	0.1602293	0.3140879
565	0	1.8987231	0.6411816	0.1793431	0.0219496
566	0	1.3980567	0.3350832	0.1776056	0.0276406

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
567	8	1.3557854	0.3043809	0.189872	1.0164126
568	0	1.8458145	0.6129206	0.1602293	0.0224402
569	2	1.8378015	0.60857	0.1793431	0.2193887
570	1	1.8558461	0.6183407	0.1602293	0.1200348
571	0	1.4056548	0.3405032	0.1776056	0.027533
572	8	1.9060041	0.645009	0.1602293	0.7872449
573	2	1.4284492	0.3565894	0.1776056	0.26517
574	10	1.8759093	0.6290935	0.1602293	0.9908749
575	8	1.8458145	0.6129206	0.1602293	0.8072648
576	5	1.4284492	0.3565894	0.1776056	0.6221024
577	0	1.8784159	0.6304288	0.1793431	0.0221354
578	4	1.8581087	0.6195591	0.1793431	0.4127096
579	12	1.8458145	0.6129206	0.1602293	1.1996771
580	22	1.8458145	0.6129206	0.1602293	2.1807078
581	7	1.8784159	0.6304288	0.1793431	0.6995284
582	0	1.8682623	0.6250087	0.1793431	0.0222295
583	11	1.3980567	0.3350832	0.1776056	1.3568549
584	0	1.3106888	0.2705528	0.1796833	0.0289381
585	0	1.3484962	0.29899	0.189872	0.0283625
586	0	1.384942	0.3256583	0.189872	0.0278282
587	0	1.341207	0.29357	0.189872	0.0284718
588	0	1.0036511	0.0036444	0.1968176	0.034576
589	0	1.0145603	0.0144553	0.1968176	0.0343411
590	0	1.325092	0.2814819	0.1796833	0.0287162
591	1	1.341207	0.29357	0.189872	0.1529433

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The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
592	5	1.341207	0.29357	0.189872	0.6508292
593	3	1.325092	0.2814819	0.1796833	0.4053361
594	1	1.0091057	0.0090645	0.1968176	0.1851007
595	1	1.325092	0.2814819	0.1796833	0.1542561
596	0	1.0800158	0.0769757	0.1968176	0.0329915
597	1	1.0036511	0.0036444	0.1968176	0.1857334
598	0	1.0036511	0.0036444	0.1968176	0.034576
599	0	0.9872872	-0.012794	0.1968176	0.0349338
600	0	1.3339179	0.2881204	0.189872	0.0285818
601	0	1.3394952	0.2922928	0.1796833	0.0284976
602	0	0.9927418	-0.007285	0.1968176	0.0348138
603	0	1.8558461	0.6183407	0.1602293	0.0223456
604	1	0.9872872	-0.012794	0.1968176	0.1876555
605	1	1.341207	0.29357	0.189872	0.1529433
606	0	1.341207	0.29357	0.189872	0.0284718
607	0	1.3178904	0.2760323	0.1796833	0.0288267
608	0	1.8759093	0.6290935	0.1602293	0.0221586
609	0	1.0036511	0.0036444	0.1968176	0.034576
610	0	1.3394952	0.2922928	0.1796833	0.0284976
611	2	1.3776529	0.3203812	0.189872	0.2721699
612	5	1.325092	0.2814819	0.1796833	0.656416
613	0	1.3484962	0.29899	0.189872	0.0283625
614	0	1.0091057	0.0090645	0.1968176	0.0344582
615	0	0.9981964	-0.001805	0.1968176	0.0346945
616	0	1.0036511	0.0036444	0.1968176	0.034576

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
617	1	1.3034872	0.2650432	0.1796833	0.1560504
618	0	1.3484962	0.29899	0.189872	0.0283625
619	0	1.325092	0.2814819	0.1796833	0.0287162
620	1	1.0254696	0.0251506	0.1968176	0.1832259
621	19	1.3683015	0.3135702	0.1796833	2.3596323
622	1	0.9981964	-0.001805	0.1968176	0.1863701
623	1	1.325092	0.2814819	0.1796833	0.1542561
624	0	1.341207	0.29357	0.189872	0.0284718
625	0	1.3266287	0.2826409	0.189872	0.0286927
626	1	1.0036511	0.0036444	0.1968176	0.1857334
627	0	0.7993761	-0.223924	0.1796833	0.039569
628	0	1.3922312	0.3309076	0.189872	0.0277236
629	5	1.0200149	0.0198173	0.1968176	0.7823356
630	0	1.3484962	0.29899	0.189872	0.0283625
631	0	1.3106888	0.2705528	0.1796833	0.0289381
632	0	1.0091057	0.0090645	0.1968176	0.0344582
633	2	1.3339179	0.2881204	0.189872	0.2784871
634	0	1.3466967	0.2976547	0.1796833	0.0283894
635	0	1.341207	0.29357	0.189872	0.0284718
636	1	1.0200149	0.0198173	0.1968176	0.183847
637	0	0.9981964	-0.001805	0.1968176	0.0346945
638	0	1.4724121	0.3869019	0.189872	0.0266215
639	2	1.3178904	0.2760323	0.1796833	0.280873
640	8	0.9927418	-0.007285	0.1968176	1.2523899
641	0	1.325092	0.2814819	0.1796833	0.0287162

Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=H12HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 1-2 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
642	0	1.8784159	0.6304288	0.1793431	0.0221354
643	0	1.0091057	0.0090645	0.1968176	0.0344582
644	0	1.8581087	0.6195591	0.1793431	0.0223243
645	0	1.0036511	0.0036444	0.1968176	0.034576
646	0	1.8458145	0.6129206	0.1602293	0.0224402
647	0	1.0036511	0.0036444	0.1968176	0.034576
648	0	1.8458145	0.6129206	0.1602293	0.0224402
649	3	1.9291839	0.6570971	0.1793431	0.3059701
650	0	1.8658777	0.6237316	0.1602293	0.0222517
651	0	1.341207	0.29357	0.189872	0.0284718
652	0	1.325092	0.2814819	0.1796833	0.0287162
653	10	1.325092	0.2814819	0.1796833	1.2841157
654	1	1.8759093	0.6290935	0.1602293	0.1190302
655	8	1.8479551	0.6140797	0.1793431	0.8065357
656	0	1.8658777	0.6237316	0.1602293	0.0222517
657	0	1.8885695	0.6358197	0.1793431	0.0220421
658	0	1.8581087	0.6195591	0.1793431	0.0223243
659	1	2.0564781	0.7209949	0.1602293	0.1106811
660	1	1.3980567	0.3350832	0.1776056	0.1484782
661	2	1.0145603	0.0144553	0.1968176	0.3346026
662	0	1.4746453	0.3884175	0.1602293	0.026592
663	0	2.5790142	0.9474072	0.1793431	0.0171169
664	0	1.9088767	0.6465149	0.1793431	0.0218578
665	2	1.9799519	0.6830725	0.1793431	0.2069133
666	0	1.4360473	0.3618944	0.1776056	0.0271107

Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=H12HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 1-2 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
667	0	1.4132529	0.3458941	0.1776056	0.0274262
668	0	1.1168959	0.1105533	0.1793431	0.0322735
669	0	1.6956511	0.5280668	0.1793431	0.0239574
670	0	1.0309242	0.0304557	0.1968176	0.0339943
671	0	1.3106888	0.2705528	0.1796833	0.0289381
672	1	1.0254696	0.0251506	0.1968176	0.1832259
673	0	1.0036511	0.0036444	0.1968176	0.034576
674	0	1.325092	0.2814819	0.1796833	0.0287162
675	6	1.325092	0.2814819	0.1796833	0.7819559
676	2	1.341207	0.29357	0.189872	0.2774148
677	1	1.3266287	0.2826409	0.189872	0.15413
678	0	1.0800158	0.0769757	0.1968176	0.0329915
679	1	1.3178904	0.2760323	0.1796833	0.1548498
680	2	1.341207	0.29357	0.189872	0.2774148
681	3	1.3322936	0.2869019	0.1796833	0.4037874
682	1	1.325092	0.2814819	0.1796833	0.1542561
683	0	1.384942	0.3256583	0.189872	0.0278282
684	0	1.3120503	0.2715911	0.189872	0.0289169
685	0	1.0036511	0.0036444	0.1968176	0.034576
686	0	1.3466967	0.2976547	0.1796833	0.0283894
687	0	1.0472881	0.046204	0.1968176	0.0336538
688	0	1.3193395	0.2771312	0.189872	0.0288044
689	0	1.341207	0.29357	0.189872	0.0284718
690	0	1.341207	0.29357	0.189872	0.0284718
691	0	1.3266287	0.2826409	0.189872	0.0286927

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
692	0	1.3322936	0.2869019	0.1796833	0.0286065
693	0	1.0036511	0.0036444	0.1968176	0.034576
694	0	0.6534383	-0.425507	0.240882	0.0439319
695	0	0.6676435	-0.404001	0.240882	0.0434756
696	0	0.4889805	-0.715433	0.2342711	0.0496671
697	0	0.6392331	-0.447486	0.240882	0.0443951
698	1	0.4836655	-0.726362	0.2342711	0.2678516
699	0	0.6427844	-0.441946	0.240882	0.0442787
700	1	0.507583	-0.678095	0.2342711	0.2631322
701	0	0.645587	-0.437595	0.2438292	0.0441871
702	0	0.6534383	-0.425507	0.240882	0.0439319
703	2	0.6285792	-0.464293	0.240882	0.4359915
704	6	0.645587	-0.437595	0.2438292	1.2032357
705	0	0.649887	-0.430957	0.240882	0.0440471
706	0	0.6463357	-0.436436	0.240882	0.0441627
707	0	0.6385698	-0.448524	0.2438292	0.0444169
708	2	0.4942955	-0.704622	0.2342711	0.4820257
709	2	0.6534383	-0.425507	0.240882	0.4280505
710	0	0.645587	-0.437595	0.2438292	0.0441871
711	0	0.481008	-0.731871	0.2342711	0.0499611
712	0	0.481008	-0.731871	0.2342711	0.0499611
713	0	0.6534383	-0.425507	0.240882	0.0439319
714	0	0.6427844	-0.441946	0.240882	0.0442787
715	0	0.614374	-0.487151	0.240882	0.0452219
716	2	0.4889805	-0.715433	0.2342711	0.4839312

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Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=H12HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 1-2 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
717	1	0.6420784	-0.443045	0.2438292	0.237978
718	1	0.649887	-0.430957	0.240882	0.2366098
719	0	0.645587	-0.437595	0.2438292	0.0441871
720	0	0.6534383	-0.425507	0.240882	0.0439319
721	0	0.6534383	-0.425507	0.240882	0.0439319
722	0	0.6420784	-0.443045	0.2438292	0.0443018
723	0	0.6420784	-0.443045	0.2438292	0.0443018
724	1	0.645587	-0.437595	0.2438292	0.2373619
725	0	0.6100943	-0.494142	0.1785645	0.0453662
726	3	1.1102754	0.1046081	0.2085841	0.4573375
727	3	0.8765402	-0.131773	0.2017996	0.5299124
728	15	1.0926519	0.0886077	0.2085841	2.1798492
729	0	0.9254841	-0.077438	0.2017996	0.0363477
730	1	1.0632796	0.0613581	0.2085841	0.179025
731	0	1.1690201	0.1561659	0.2085841	0.0313073
732	3	0.6100943	-0.494142	0.1785645	0.6403556
733	2	0.781138	-0.247003	0.1758966	0.390475
734	4	0.781138	-0.247003	0.1758966	0.7408746
735	0	0.5877348	-0.531479	0.1785645	0.0461301
736	0	0.7548835	-0.281192	0.1846315	0.0408235
737	3	0.4599664	-0.776602	0.1785645	0.7161998
738	0	0.814248	-0.20549	0.2017996	0.039164
739	2	0.781138	-0.247003	0.1758966	0.390475
740	0	0.798212	-0.225381	0.1758966	0.039601
741	0	0.6037059	-0.504668	0.1785645	0.0455829

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Parameter Code=H12HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 1-2 hours after meal

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Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
742	0	0.8231469	-0.194621	0.2017996	0.0389249
743	2	0.8231469	-0.194621	0.2017996	0.3792649
744	0	0.7854065	-0.241554	0.1758966	0.039956
745	0	0.781138	-0.247003	0.1758966	0.0400755
746	0	0.7886213	-0.237469	0.1846315	0.0398664
747	0	0.8186975	-0.200041	0.2017996	0.0390441
748	1	0.7939435	-0.230743	0.1758966	0.2133591
749	0	1.080903	0.0777968	0.2085841	0.0329738
750	0	0.8012729	-0.221554	0.1846315	0.039517
751	2	1.0940484	0.0898849	0.2075654	0.3187568
752	0	0.8186975	-0.200041	0.2017996	0.0390441
753	1	0.7801868	-0.248222	0.1846315	0.2154187
754	3	0.814248	-0.20549	0.2017996	0.5528089
755	0	0.8054902	-0.216304	0.1846315	0.0394016
756	0	0.7759696	-0.253642	0.1846315	0.0402209
757	1	0.7717524	-0.259092	0.1846315	0.2166978
758	2	0.7854065	-0.241554	0.1758966	0.3893108
759	0	0.5877348	-0.531479	0.1785645	0.0461301
760	0	0.7854065	-0.241554	0.1758966	0.039956
761	0	0.7801868	-0.248222	0.1846315	0.0401022
762	0	0.781138	-0.247003	0.1758966	0.0400755
763	1	0.7759696	-0.253642	0.1846315	0.2160567
764	0	0.7886213	-0.237469	0.1846315	0.0398664
765	0	0.781138	-0.247003	0.1758966	0.0400755
766	2	1.1059402	0.1006958	0.2075654	0.3165052

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
767	1	0.7854065	-0.241554	0.1758966	0.2146334
768	0	0.5845406	-0.536929	0.1785645	0.0462404
769	0	0.7801868	-0.248222	0.1846315	0.0401022
770	0	0.8152861	-0.204216	0.1758966	0.0391359
771	0	0.7801868	-0.248222	0.1846315	0.0401022
772	2	0.789675	-0.236134	0.1758966	0.3881523
773	0	0.7633179	-0.270081	0.1846315	0.0405807
774	1	0.784404	-0.242831	0.1846315	0.2147838
775	1	0.7854065	-0.241554	0.1758966	0.2146334
776	0	0.7759696	-0.253642	0.1846315	0.0402209
777	0	0.5877348	-0.531479	0.1785645	0.0461301
778	11	0.7801868	-0.248222	0.1846315	1.9685841
779	0	0.1852642	-1.685972	0.1785645	0.0565547
780	0	0.5877348	-0.531479	0.1785645	0.0461301
781	0	0.8186975	-0.200041	0.2017996	0.0390441
782	1	0.784404	-0.242831	0.1846315	0.2147838
783	5	0.7854065	-0.241554	0.1758966	0.913343
784	0	0.6100943	-0.494142	0.1785645	0.0453662
785	0	0.7675351	-0.264571	0.1846315	0.0404602
786	0	0.8186975	-0.200041	0.2017996	0.0390441
787	0	0.8186975	-0.200041	0.2017996	0.0390441
788	0	0.7928385	-0.232136	0.1846315	0.0397493
789	1	0.8186975	-0.200041	0.2017996	0.2097352
790	0	0.8152861	-0.204216	0.1758966	0.0391359
791	1	0.8940519	-0.111991	0.1846315	0.1993281

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
792	0	0.6069001	-0.499391	0.1785645	0.0454744
793	0	0.7854065	-0.241554	0.1758966	0.039956
794	0	0.789675	-0.236134	0.1758966	0.0398371
795	0	0.7939435	-0.230743	0.1758966	0.0397188
796	0	0.5877348	-0.531479	0.1785645	0.0461301
797	0	0.7759696	-0.253642	0.1846315	0.0402209
798	0	0.5877348	-0.531479	0.1785645	0.0461301
799	3	1.1297238	0.1219732	0.2075654	0.4521196
800	1	0.8631919	-0.147118	0.2017996	0.2034794
801	0	0.8720908	-0.136862	0.2017996	0.0376538
802	2	0.814248	-0.20549	0.2017996	0.3815939
803	0	1.080903	0.0777968	0.2085841	0.0329738
804	0	1.0940484	0.0898849	0.2075654	0.0327148
805	0	1.1237779	0.1166962	0.2075654	0.0321428
806	0	1.1278988	0.1203564	0.2085841	0.0320649
807	5	1.1059402	0.1006958	0.2075654	0.7425373
808	0	1.1535075	0.1428073	0.2075654	0.0315891
809	0	1.0926519	0.0886077	0.2085841	0.0327422
810	0	1.1044009	0.099303	0.2085841	0.0325135
811	0	1.1356698	0.1272226	0.2075654	0.0319191
812	2	0.6132885	-0.48892	0.1785645	0.4409753
813	0	0.6005117	-0.509973	0.1785645	0.0456917
814	0	0.839228	-0.175273	0.1846315	0.0384992
815	0	0.5653753	-0.570265	0.1785645	0.0469092
816	3	0.590929	-0.526059	0.1785645	0.6495833

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
817	0	1.080903	0.0777968	0.2085841	0.0329738
818	0	0.5781522	-0.547918	0.1785645	0.0464622
819	1	0.781138	-0.247003	0.1758966	0.2152752
820	0	0.8195546	-0.198994	0.1758966	0.0390211
821	0	0.8152861	-0.204216	0.1758966	0.0391359
822	0	0.8265763	-0.190463	0.1846315	0.0388335
823	0	0.7675351	-0.264571	0.1846315	0.0404602
824	0	0.590929	-0.526059	0.1785645	0.04602
825	1	0.590929	-0.526059	0.1785645	0.2472078
826	0	0.772601	-0.257993	0.1758966	0.0403162
827	0	0.8186975	-0.200041	0.2017996	0.0390441
828	1	0.6452306	-0.438147	0.1785645	0.2374243
829	3	0.7717524	-0.259092	0.1846315	0.5694129
830	0	0.8054902	-0.216304	0.1846315	0.0394016
831	2	0.8238231	-0.193799	0.1758966	0.3790889
832	0	0.7854065	-0.241554	0.1758966	0.039956
833	0	0.7759696	-0.253642	0.1846315	0.0402209
834	0	0.7759696	-0.253642	0.1846315	0.0402209
835	0	0.6069001	-0.499391	0.1785645	0.0454744
836	0	1.1356698	0.1272226	0.2075654	0.0319191
837	0	1.1356698	0.1272226	0.2075654	0.0319191
838	0	0.8186975	-0.200041	0.2017996	0.0390441
839	0	0.8097986	-0.21097	0.2017996	0.0392844
840	0	1.0940484	0.0898849	0.2075654	0.0327148
841	0	1.1044009	0.099303	0.2085841	0.0325135

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
842	0	1.1416157	0.1324445	0.2075654	0.0318084
843	0	1.0881024	0.0844353	0.2075654	0.0328315
844	0	0.8186975	-0.200041	0.2017996	0.0390441
845	0	1.1713452	0.1581529	0.2075654	0.0312655
846	0	0.8231469	-0.194621	0.2017996	0.0389249
847	0	1.0940484	0.0898849	0.2075654	0.0327148
848	0	1.080903	0.0777968	0.2085841	0.0329738
849	1	1.0926519	0.0886077	0.2085841	0.1758826
850	9	0.8186975	-0.200041	0.2017996	1.5752641
851	0	0.8275964	-0.18923	0.2017996	0.0388063
852	0	1.080903	0.0777968	0.2085841	0.0329738
853	0	1.080903	0.0777968	0.2085841	0.0329738
854	0	0.7854065	-0.241554	0.1758966	0.039956
855	0	0.7854065	-0.241554	0.1758966	0.039956
856	0	0.7759696	-0.253642	0.1846315	0.0402209
857	3	0.7759696	-0.253642	0.1846315	0.5677282
858	0	0.6420364	-0.44311	0.1785645	0.0443032
859	0	0.6324538	-0.458148	0.1785645	0.0446185
860	1	1.080903	0.0777968	0.2085841	0.1771272
861	0	0.8275964	-0.18923	0.2017996	0.0388063
862	0	1.0881024	0.0844353	0.2075654	0.0328315
863	1	0.7633179	-0.270081	0.1846315	0.2179895
864	1	1.080903	0.0777968	0.2085841	0.1771272
865	0	0.7886213	-0.237469	0.1846315	0.0398664
866	0	0.7886213	-0.237469	0.1846315	0.0398664

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Parameter Code=H12HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 1-2 hours after meal

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
867	0	0.781138	-0.247003	0.1758966	0.0400755
868	0	0.6196769	-0.478557	0.1785645	0.0450438
869	0	0.7886213	-0.237469	0.1846315	0.0398664
870	0	0.7768695	-0.252483	0.1758966	0.0401955
871	0	0.8186975	-0.200041	0.2017996	0.0390441
872	1	0.5941232	-0.520669	0.1785645	0.2466182
873	0	0.7939435	-0.230743	0.1758966	0.0397188
874	0	0.789675	-0.236134	0.1758966	0.0398371
875	0	0.5973175	-0.515307	0.1785645	0.0458008
876	2	0.5941232	-0.520669	0.1785645	0.4473261
877	0	0.7939435	-0.230743	0.1758966	0.0397188
878	2	0.7633179	-0.270081	0.1846315	0.3953982
879	0	0.5845406	-0.536929	0.1785645	0.0462404
880	2	0.7759696	-0.253642	0.1846315	0.3918925
881	0	0.5845406	-0.536929	0.1785645	0.0462404
882	0	0.18207	-1.703364	0.1785645	0.0564473
883	1	0.5813464	-0.542408	0.1785645	0.2489867
884	0	0.7854065	-0.241554	0.1758966	0.039956
885	0	0.781138	-0.247003	0.1758966	0.0400755
886	1	0.7886213	-0.237469	0.1846315	0.214152
887	0	0.7854065	-0.241554	0.1758966	0.039956
888	4	0.5877348	-0.531479	0.1785645	0.8528061
889	2	0.7854065	-0.241554	0.1758966	0.3893108
890	0	0.8012729	-0.221554	0.1846315	0.039517
891	0	0.7717524	-0.259092	0.1846315	0.0403403

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Parameter Code=H12HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 1-2 hours after meal

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
892	4	0.7768695	-0.252483	0.1758966	0.7430946
893	0	0.7801868	-0.248222	0.1846315	0.0401022
894	0	0.7717524	-0.259092	0.1846315	0.0403403
895	4	0.8195546	-0.198994	0.1758966	0.7213831
896	1	0.7854065	-0.241554	0.1758966	0.2146334
897	1	1.0750285	0.0723472	0.2085841	0.1777556
898	0	0.5941232	-0.520669	0.1785645	0.0459102
899	0	0.7506662	-0.286794	0.1846315	0.0409458
900	7	0.7759696	-0.253642	0.1846315	1.2710713
901	0	0.5845406	-0.536929	0.1785645	0.0462404
902	0	0.5845406	-0.536929	0.1785645	0.0462404
903	2	0.5941232	-0.520669	0.1785645	0.4473261
904	0	0.7717524	-0.259092	0.1846315	0.0403403
905	0	1.0940484	0.0898849	0.2075654	0.0327148
906	0	1.1475616	0.1376393	0.2075654	0.0316984
907	0	0.7759696	-0.253642	0.1846315	0.0402209
908	1	0.8186975	-0.200041	0.2017996	0.2097352
909	0	1.080903	0.0777968	0.2085841	0.0329738
910	0	1.0881024	0.0844353	0.2075654	0.0328315
911	0	0.7633179	-0.270081	0.1846315	0.0405807
912	0	1.1297238	0.1219732	0.2075654	0.0320306
913	0	1.0867775	0.0832169	0.2085841	0.0328576
914	0	1.0926519	0.0886077	0.2085841	0.0327422
915	2	0.8320458	-0.183868	0.2017996	0.3769599
916	10	1.0881024	0.0844353	0.2075654	1.4681427

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Parameter Code=H12HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 1-2 hours after meal

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
917	0	1.0881024	0.0844353	0.2075654	0.0328315
918	0	0.590929	-0.526059	0.1785645	0.04602
919	1	0.5941232	-0.520669	0.1785645	0.2466182
920	1	0.814248	-0.20549	0.2017996	0.2103789
921	2	0.789675	-0.236134	0.1758966	0.3881523
922	0	0.8453941	-0.167952	0.2017996	0.0383381
923	0	0.590929	-0.526059	0.1785645	0.04602
924	1	0.784404	-0.242831	0.1846315	0.2147838
925	0	0.8186975	-0.200041	0.2017996	0.0390441
926	0	0.7759696	-0.253642	0.1846315	0.0402209
927	0	0.789675	-0.236134	0.1758966	0.0398371
928	0	1.080903	0.0777968	0.2085841	0.0329738
929	0	0.590929	-0.526059	0.1785645	0.04602
930	0	0.814248	-0.20549	0.2017996	0.039164
931	0	1.0691541	0.0668677	0.2085841	0.0332086
932	0	0.7801868	-0.248222	0.1846315	0.0401022
933	0	0.695672	-0.362877	0.2075654	0.0425953
934	0	0.8275964	-0.18923	0.2017996	0.0388063
935	0	0.8186975	-0.200041	0.2017996	0.0390441
936	0	0.7854065	-0.241554	0.1758966	0.039956
937	0	0.8186975	-0.200041	0.2017996	0.0390441
938	0	1.1513967	0.1409757	0.2085841	0.0316278
939	0	0.7801868	-0.248222	0.1846315	0.0401022
940	0	0.5877348	-0.531479	0.1785645	0.0461301
941	0	1.0762106	0.0734462	0.2075654	0.0330672

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
942	0	0.6132885	-0.48892	0.1785645	0.0452584
943	4	0.7675351	-0.264571	0.1846315	0.7479876
944	0	0.5877348	-0.531479	0.1785645	0.0461301
945	0	0.5813464	-0.542408	0.1785645	0.0463511
946	0	0.8186975	-0.200041	0.2017996	0.0390441
947	0	0.8814002	-0.126243	0.1846315	0.0374202
948	0	0.8054902	-0.216304	0.1846315	0.0394016
949	1	0.7801868	-0.248222	0.1846315	0.2154187
950	0	1.1416157	0.1324445	0.2075654	0.0318084
951	0	0.590929	-0.526059	0.1785645	0.04602
952	1	0.9388324	-0.063118	0.2017996	0.1935641
953	0	0.7854065	-0.241554	0.1758966	0.039956
954	1	0.8110176	-0.209466	0.1758966	0.2108484
955	0	0.7717524	-0.259092	0.1846315	0.0403403
956	0	0.5877348	-0.531479	0.1785645	0.0461301
957	0	0.8186975	-0.200041	0.2017996	0.0390441
958	0	0.5781522	-0.547918	0.1785645	0.0464622
959	0	0.7759696	-0.253642	0.1846315	0.0402209
960	0	0.7759696	-0.253642	0.1846315	0.0402209
961	0	0.5877348	-0.531479	0.1785645	0.0461301
962	0	0.8186975	-0.200041	0.2017996	0.0390441
963	0	0.5877348	-0.531479	0.1785645	0.0461301
964	0	0.8152861	-0.204216	0.1758966	0.0391359
965	0	0.8231469	-0.194621	0.2017996	0.0389249
966	0	0.7854065	-0.241554	0.1758966	0.039956

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
967	0	0.590929	-0.526059	0.1785645	0.04602
968	0	0.1565163	-1.854595	0.1785645	0.0551755
969	0	0.5685696	-0.564632	0.1785645	0.046797
970	0	0.8024806	-0.220048	0.1758966	0.0394839
971	0	1.0940484	0.0898849	0.2075654	0.0327148
972	0	0.7759696	-0.253642	0.1846315	0.0402209
973	0	1.0985264	0.0939697	0.2085841	0.0326274
974	1	1.0940484	0.0898849	0.2075654	0.1757358
975	0	1.0750285	0.0723472	0.2085841	0.0330908
976	0	0.8186975	-0.200041	0.2017996	0.0390441
977	0	0.798212	-0.225381	0.1758966	0.039601
978	0	1.0881024	0.0844353	0.2075654	0.0328315
979	0	0.6100943	-0.494142	0.1785645	0.0453662
980	1	1.1237779	0.1166962	0.2075654	0.1726628
981	0	0.8097986	-0.21097	0.2017996	0.0392844
982	0	0.8765402	-0.131773	0.2017996	0.0375418
983	3	0.8323601	-0.18349	0.1758966	0.5459784
984	1	0.5845406	-0.536929	0.1785645	0.248392
985	0	0.781138	-0.247003	0.1758966	0.0400755
986	1	1.0867775	0.0832169	0.2085841	0.1765029
987	0	0.7759696	-0.253642	0.1846315	0.0402209
988	0	0.7768695	-0.252483	0.1758966	0.0401955
989	6	0.7768695	-0.252483	0.1758966	1.0945441
990	0	0.5941232	-0.520669	0.1785645	0.0459102
991	1	0.7854065	-0.241554	0.1758966	0.2146334

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Parameter Code=H12HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 1-2 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
992	7	0.7512584	-0.286006	0.1758966	1.2934358
993	1	0.7759696	-0.253642	0.1846315	0.2160567
994	0	0.7939435	-0.230743	0.1758966	0.0397188
995	0	0.7759696	-0.253642	0.1846315	0.0402209
996	0	0.7801868	-0.248222	0.1846315	0.0401022
997	0	0.482342	-0.729102	0.1758966	0.0499118
998	9	0.8008997	-0.22202	0.2017996	1.594754
999	0	0.8195546	-0.198994	0.1758966	0.0390211
1000	4	0.590929	-0.526059	0.1785645	0.8507711
1001	0	0.8587425	-0.152286	0.2017996	0.0379933
1002	0	1.0750285	0.0723472	0.2085841	0.0330908
1003	0	0.6701566	-0.400244	0.1758966	0.0433955
1004	0	0.2952058	-1.220082	0.1846315	0.0562651
1005	0	0.789675	-0.236134	0.1758966	0.0398371
1006	0	0.5877348	-0.531479	0.1785645	0.0461301
1007	10	0.590929	-0.526059	0.1785645	2.0578978
1008	5	0.7854065	-0.241554	0.1758966	0.913343
1009	1	0.8067491	-0.214743	0.1758966	0.2114714
1010	0	0.7675351	-0.264571	0.1846315	0.0404602
1011	1	0.6580075	-0.418539	0.1785645	0.2351987
1012	0	0.5845406	-0.536929	0.1785645	0.0462404
1013	2	0.5941232	-0.520669	0.1785645	0.4473261
1014	0	0.784404	-0.242831	0.1846315	0.039984
1015	0	0.590929	-0.526059	0.1785645	0.04602
1016	0	0.7970557	-0.226831	0.1846315	0.0396329

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
1017	2	0.7717524	-0.259092	0.1846315	0.3930553
1018	0	0.7854065	-0.241554	0.1758966	0.039956
1019	0	0.8186975	-0.200041	0.2017996	0.0390441
1020	0	0.5973175	-0.515307	0.1785645	0.0458008
1021	0	0.784404	-0.242831	0.1846315	0.039984
1022	0	0.5877348	-0.531479	0.1785645	0.0461301
1023	1	0.7854065	-0.241554	0.1758966	0.2146334
1024	6	0.7854065	-0.241554	0.1758966	1.0880204
1025	0	0.7854065	-0.241554	0.1758966	0.039956

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Parameter Code=H23HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 2-3 hours after meal

The GENMOD Procedure

Model Information

Data Set	WORK.ENDPOINT	
Distribution	Negative Binomial	
Link Function	Log	
Dependent Variable	AVAL	Analysis Value
Offset Variable	log_offset	

Number of Observations Read	1025
Number of Observations Used	1025

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Parameter Information

Parameter	Effect	TRTPN	REGION1	BOLAD1
Prm1	Intercept			
Prm2	TRTPN	2		
Prm3	TRTPN	3		
Prm4	TRTPN	4		
Prm5	REGION1		ASIA (EXCLUDING JAPAN)	
Prm6	REGION1		EUROPE	

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Parameter Information

Parameter	Effect	TRTPN	REGION1	BOLAD1
Prm7	REGION1		JAPAN	
Prm8	REGION1		NORTH AMERICA	
Prm9	BOLAD1			BOLUS INSULIN ALGORITHM (SLIDING SCALE)
Prm10	BOLAD1			CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Criteria For Assessing Goodness Of Fit

Criterion	DF	Value	Value/DF
Deviance	1018	876.5225	0.8610
Scaled Deviance	1018	876.5225	0.8610
Pearson Chi-Square	1018	1018.0712	1.0001
Scaled Pearson X2	1018	1018.0712	1.0001
Log Likelihood		533.1194	
Full Log Likelihood		-1705.7068	
AIC (smaller is better)		3427.4136	
AICC (smaller is better)		3427.5553	
BIC (smaller is better)		3466.8732	

Algorithm converged.

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Analysis Of Maximum Likelihood Parameter Estimates

Parameter		DF	Estimate	Standard Error	Wald 95% Confidence Limits		Wald Chi-Square
Intercept		1	5.6417	0.1479	5.3517	5.9316	1454.25
TRTPN	2	1	-0.1535	0.1509	-0.4492	0.1422	1.04
TRTPN	3	1	0.1799	0.1487	-0.1115	0.4713	1.46
TRTPN	4	0	0.0000	0.0000	0.0000	0.0000	.
REGION1	ASIA (EXCLUDING JAPAN)	1	-0.4115	0.2294	-0.8611	0.0381	3.22
REGION1	EUROPE	1	0.3839	0.1559	0.0785	0.6894	6.07
REGION1	JAPAN	1	0.1784	0.1782	-0.1709	0.5276	1.00
REGION1	NORTH AMERICA	0	0.0000	0.0000	0.0000	0.0000	.
BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	1	0.1371	0.1379	-0.1332	0.4073	0.99
BOLAD1	CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY	0	0.0000	0.0000	0.0000	0.0000	.
Dispersion		1	3.2167	0.2234	2.8073	3.6858	

Analysis Of Maximum Likelihood Parameter Estimates

Parameter		Pr > ChiSq
Intercept		<.0001
TRTPN	2	0.3088
TRTPN	3	0.2264
TRTPN	4	.
REGION1	ASIA (EXCLUDING JAPAN)	0.0728
REGION1	EUROPE	0.0138
REGION1	JAPAN	0.3168
REGION1	NORTH AMERICA	.
BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.3202
BOLAD1	CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY	.
Dispersion		

NOTE: The negative binomial dispersion parameter was estimated by maximum likelihood.

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Coefficients for TRTPN Least Squares Means Using WORK.ENDPOINT Margins

Parameter	Geographic Region Grouping Method 1
Intercept	
Planned Treatment (N) 2	
Planned Treatment (N) 3	
Planned Treatment (N) 4	
Geographic Region Grouping Method 1 ASIA (EXCLUDING JAPAN)	ASIA (EXCLUDING JAPAN)
Geographic Region Grouping Method 1 EUROPE	EUROPE
Geographic Region Grouping Method 1 JAPAN	JAPAN
Geographic Region Grouping Method 1 NORTH AMERICA	NORTH AMERICA
Bolus Adjustment Method at Timepoint 1 BOLUS INSULIN ALGORITHM (SLIDING SCALE)	
Bolus Adjustment Method at Timepoint 1 CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY	

Coefficients for TRTPN Least Squares Means Using WORK.ENDPOINT Margins

Bolus Adjustment Method at Timepoint 1	Planned Treatment (N)	Row1	Row2	Row3
	1	1	1	1
	2	1		
	3		1	
	4			1
		0.1307	0.1307	0.1307
		0.3366	0.3366	0.3366
		0.239	0.239	0.239
		0.2937	0.2937	0.2937
BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.5824	0.5824	0.5824
CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0.4176	0.4176	0.4176

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TRTPN Least Squares Means

Planned Treatment (N)	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
2	WORK.ENDPOINT	5.6861	0.1073	52.99	<.0001	0.05	5.4758	5.8963
3	WORK.ENDPOINT	6.0194	0.1046	57.54	<.0001	0.05	5.8144	6.2245
4	WORK.ENDPOINT	5.8396	0.1058	55.19	<.0001	0.05	5.6322	6.0470

Differences of TRTPN Least Squares Means

Planned Treatment (N)	Planned Treatment (N)	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
2	4	WORK.ENDPOINT	-0.1535	0.1509	-1.02	0.3088	0.05	-0.4492	0.1422
3	4	WORK.ENDPOINT	0.1799	0.1487	1.21	0.2264	0.05	-0.1115	0.4713

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) / NovoRapid (meal)	WORK.ENDPOINT	-0.1535	0.1509	-1.02	0.3088	0.05	-0.4492	0.1422

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Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
TRTPN	Faster aspart (post) / NovoRapid (meal)	WORK.ENDPOINT	0.1799	0.1487	1.21	0.2264	0.05	-0.1115	0.4713

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
1	0	1.4560174	0.3757049	0.1853262	0.0450736
2	0	1.4560174	0.3757049	0.1853262	0.0450736
3	0	1.4560174	0.3757049	0.1853262	0.0450736
4	0	1.4560174	0.3757049	0.1853262	0.0450736
5	6	1.4560174	0.3757049	0.1853262	0.9150052
6	16	1.6789927	0.518194	0.1549431	2.1501329
7	4	2.0321617	0.7091001	0.1852031	0.4960819
8	2	2.0873834	0.7359113	0.1852031	0.2607203
9	0	1.5114094	0.4130426	0.1853262	0.0439871
10	0	0.3280308	-1.114648	0.1538871	0.0776632
11	3	1.4401912	0.3647759	0.1853262	0.4834433
12	0	2.0873834	0.7359113	0.1852031	0.0350741
13	0	2.0321617	0.7091001	0.1852031	0.0357747
14	11	1.6791752	0.5183027	0.1810451	1.4909113
15	0	1.4560174	0.3757049	0.1853262	0.0450736
16	0	1.7068539	0.5346519	0.1810451	0.0405179

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Parameter Code=H23HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 2-3 hours after meal

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
17	1	1.6699171	0.512774	0.1549431	0.1734469
18	0	2.432036	0.8887288	0.1557733	0.0312408
19	3	1.9470217	0.6663009	0.1538871	0.3930912
20	0	1.6791752	0.5183027	0.1810451	0.0409774
21	6	1.6699171	0.512774	0.1549431	0.8350153
22	0	0.3044658	-1.189196	0.1810451	0.0777108
23	0	2.0321617	0.7091001	0.1852031	0.0357747
24	0	2.3307011	0.8461691	0.1557733	0.0322802
25	0	2.1094722	0.7464378	0.1852031	0.0348012
26	1	2.0321617	0.7091001	0.1852031	0.1508515
27	3	2.2640932	0.8171743	0.1852031	0.3514644
28	5	2.3307011	0.8461691	0.1557733	0.5514604
29	1	1.4639306	0.381125	0.1853262	0.1893949
30	11	2.0105115	0.6983892	0.1538871	1.3118846
31	6	2.3307011	0.8461691	0.1557733	0.6552965
32	1	1.4560174	0.3757049	0.1853262	0.1900622
33	1	2.0321617	0.7091001	0.1852031	0.1508515
34	0	1.9364401	0.6608513	0.1538871	0.0370555
35	0	2.1757383	0.7773681	0.1852031	0.0340068
36	0	1.6976277	0.5292318	0.1810451	0.0406699
37	1	1.6976277	0.5292318	0.1810451	0.1714933
38	3	2.0321617	0.7091001	0.1852031	0.3810051
39	0	2.0321617	0.7091001	0.1852031	0.0357747
40	0	1.9990286	0.6926614	0.1852031	0.0362082
41	2	2.0321617	0.7091001	0.1852031	0.2659283

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
42	8	2.3560348	0.8569801	0.1557733	0.855854
43	8	2.3307011	0.8461691	0.1557733	0.8629685
44	6	1.9470217	0.6663009	0.1538871	0.7492729
45	0	1.6699171	0.512774	0.1549431	0.0411333
46	0	1.7425222	0.5553336	0.1549431	0.03994
47	3	1.6699171	0.512774	0.1549431	0.4380743
48	1	2.3687017	0.862342	0.1557733	0.1344397
49	6	1.9364401	0.6608513	0.1538871	0.752235
50	0	1.6880684	0.5235849	0.1549431	0.0408287
51	6	1.6880684	0.5235849	0.1549431	0.8288317
52	2	2.3307011	0.8461691	0.1557733	0.2399523
53	0	2.3560348	0.8569801	0.1557733	0.0320141
54	0	1.968185	0.6771118	0.1538871	0.036621
55	1	2.3053674	0.8352401	0.1557733	0.1372568
56	1	1.6880684	0.5235849	0.1549431	0.1721625
57	1	2.5967051	0.9542434	0.1557733	0.1251725
58	5	1.7062196	0.5342802	0.1549431	0.6923668
59	6	1.9576033	0.6717209	0.1538871	0.7463333
60	0	2.3307011	0.8461691	0.1557733	0.0322802
61	5	1.9787666	0.6824737	0.1538871	0.62318
62	6	1.7062196	0.5342802	0.1549431	0.8227345
63	0	2.3053674	0.8352401	0.1557733	0.0325507
64	1	1.9470217	0.6663009	0.1538871	0.1556368
65	7	2.3940354	0.8729804	0.1557733	0.7436731
66	8	2.3687017	0.862342	0.1557733	0.8523395

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
67	0	2.3307011	0.8461691	0.1557733	0.0322802
68	4	2.3053674	0.8352401	0.1557733	0.4513751
69	0	1.6426902	0.4963353	0.1549431	0.0415983
70	0	1.6699171	0.512774	0.1549431	0.0411333
71	5	1.7515978	0.5605284	0.1549431	0.6798479
72	0	1.9470217	0.6663009	0.1538871	0.0369096
73	2	2.3307011	0.8461691	0.1557733	0.2399523
74	0	1.9470217	0.6663009	0.1538871	0.0369096
75	3	1.6789927	0.518194	0.1549431	0.4364465
76	0	1.9470217	0.6663009	0.1538871	0.0369096
77	1	2.3307011	0.8461691	0.1557733	0.1361163
78	1	1.9470217	0.6663009	0.1538871	0.1556368
79	0	1.6699171	0.512774	0.1549431	0.0411333
80	9	1.6789927	0.518194	0.1549431	1.2273787
81	0	1.9470217	0.6663009	0.1538871	0.0369096
82	0	1.6699171	0.512774	0.1549431	0.0411333
83	0	1.9470217	0.6663009	0.1538871	0.0369096
84	1	1.9152768	0.6498621	0.1538871	0.1574967
85	0	1.6699171	0.512774	0.1549431	0.0411333
86	0	2.3180343	0.8407195	0.1557733	0.0324149
87	10	1.6699171	0.512774	0.1549431	1.3642699
88	0	2.3307011	0.8461691	0.1557733	0.0322802
89	0	1.9787666	0.6824737	0.1538871	0.0364784
90	0	2.2927006	0.8297304	0.1557733	0.0326876
91	0	1.9364401	0.6608513	0.1538871	0.0370555

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Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
92	6	1.9470217	0.6663009	0.1538871	0.7492729
93	3	1.9152768	0.6498621	0.1538871	0.3977889
94	0	1.9364401	0.6608513	0.1538871	0.0370555
95	0	1.6699171	0.512774	0.1549431	0.0411333
96	4	1.9152768	0.6498621	0.1538871	0.517935
97	0	2.3307011	0.8461691	0.1557733	0.0322802
98	0	1.6976277	0.5292318	0.1810451	0.0406699
99	2	1.6699171	0.512774	0.1549431	0.3057606
100	2	1.9990286	0.6926614	0.1852031	0.2691509
101	1	1.9470217	0.6663009	0.1538871	0.1556368
102	0	1.4481043	0.3702553	0.1853262	0.0452329
103	2	2.0652947	0.7252729	0.1852031	0.2627796
104	4	1.9470217	0.6663009	0.1538871	0.5118185
105	1	1.6791752	0.5183027	0.1810451	0.1727895
106	1	1.669949	0.5127931	0.1810451	0.1734447
107	29	1.9470217	0.6663009	0.1538871	3.4799993
108	20	2.343368	0.8515892	0.1557733	2.1002723
109	4	2.3053674	0.8352401	0.1557733	0.4513751
110	1	1.4560174	0.3757049	0.1853262	0.1900622
111	2	1.6791752	0.5183027	0.1810451	0.3046017
112	8	1.6976277	0.5292318	0.1810451	1.0872566
113	2	1.6976277	0.5292318	0.1810451	0.3023166
114	0	1.6976277	0.5292318	0.1810451	0.0406699
115	0	1.4560174	0.3757049	0.1853262	0.0450736
116	6	2.0321617	0.7091001	0.1852031	0.7262356

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
117	0	1.7068539	0.5346519	0.1810451	0.0405179
118	0	1.4560174	0.3757049	0.1853262	0.0450736
119	0	1.6976277	0.5292318	0.1810451	0.0406699
120	2	1.4560174	0.3757049	0.1853262	0.3350508
121	0	1.6976277	0.5292318	0.1810451	0.0406699
122	0	1.4560174	0.3757049	0.1853262	0.0450736
123	3	1.9990286	0.6926614	0.1852031	0.3856222
124	2	1.6976277	0.5292318	0.1810451	0.3023166
125	7	1.4560174	0.3757049	0.1853262	1.0599938
126	3	2.0211173	0.7036505	0.1852031	0.3825322
127	1	2.0321617	0.7091001	0.1852031	0.1508515
128	0	2.0652947	0.7252729	0.1852031	0.0353511
129	5	2.3307011	0.8461691	0.1557733	0.5514604
130	0	1.5114094	0.4130426	0.1853262	0.0439871
131	0	1.7606735	0.5656964	0.1549431	0.039652
132	0	2.0321617	0.7091001	0.1852031	0.0357747
133	0	2.4076698	0.8786594	0.1852031	0.0314847
134	0	1.9999299	0.6931121	0.1538871	0.0361963
135	0	1.7068539	0.5346519	0.1810451	0.0405179
136	0	1.9006049	0.6421722	0.1810451	0.037558
137	0	1.3142785	0.2732878	0.1852031	0.0480922
138	0	2.1374912	0.7596328	0.1538871	0.034461
139	4	1.4718437	0.3865158	0.1853262	0.6206534
140	1	1.6791752	0.5183027	0.1810451	0.1727895
141	0	2.1094722	0.7464378	0.1852031	0.0348012

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142	0	2.0100729	0.698171	0.1852031	0.0360626
143	1	1.9470217	0.6663009	0.1538871	0.1556368
144	1	1.6699171	0.512774	0.1549431	0.1734469
145	4	1.6699171	0.512774	0.1549431	0.5703879
146	0	1.9999299	0.6931121	0.1538871	0.0361963
147	1	2.5080371	0.9195004	0.1557733	0.1286236
148	0	3.040045	1.1118723	0.1557733	0.0261655
149	1	1.9576033	0.6717209	0.1538871	0.1550262
150	0	1.6426902	0.4963353	0.1549431	0.0415983
151	12	2.3307011	0.8461691	0.1557733	1.2783127
152	4	1.9470217	0.6663009	0.1538871	0.5118185
153	0	1.9152768	0.6498621	0.1538871	0.0373506
154	0	2.3180343	0.8407195	0.1557733	0.0324149
155	3	1.9258584	0.6553718	0.1538871	0.3962111
156	0	1.1889084	0.1730355	0.1549431	0.0510819
157	0	1.9253618	0.6551139	0.1557733	0.0372094
158	0	2.3307011	0.8461691	0.1557733	0.0322802
159	9	1.6880684	0.5235849	0.1549431	1.2228332
160	0	1.697144	0.5289468	0.1549431	0.040678
161	4	1.6699171	0.512774	0.1549431	0.5703879
162	1	2.3307011	0.8461691	0.1557733	0.1361163
163	0	2.3307011	0.8461691	0.1557733	0.0322802
164	6	2.3307011	0.8461691	0.1557733	0.6552965
165	1	1.322705	0.2796788	0.1538871	0.2019908
166	1	2.3053674	0.8352401	0.1557733	0.1372568

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
167	4	1.9470217	0.6663009	0.1538871	0.5118185
168	1	1.968185	0.6771118	0.1538871	0.1544202
169	1	1.9258584	0.6553718	0.1538871	0.156872
170	2	1.6608415	0.5073244	0.1549431	0.3069048
171	0	2.3180343	0.8407195	0.1557733	0.0324149
172	0	1.697144	0.5289468	0.1549431	0.040678
173	0	1.6789927	0.518194	0.1549431	0.0409804
174	1	1.9152768	0.6498621	0.1538871	0.1574967
175	0	1.968185	0.6771118	0.1538871	0.036621
176	0	1.9364401	0.6608513	0.1538871	0.0370555
177	0	2.4193691	0.8835068	0.1557733	0.0313672
178	0	1.697144	0.5289468	0.1549431	0.040678
179	0	2.3307011	0.8461691	0.1557733	0.0322802
180	2	1.9364401	0.6608513	0.1538871	0.2754486
181	0	1.6426902	0.4963353	0.1549431	0.0415983
182	0	1.9258584	0.6553718	0.1538871	0.0372025
183	1	2.3307011	0.8461691	0.1557733	0.1361163
184	0	2.3307011	0.8461691	0.1557733	0.0322802
185	7	2.3687017	0.862342	0.1557733	0.7497824
186	0	1.9364401	0.6608513	0.1538871	0.0370555
187	0	1.6699171	0.512774	0.1549431	0.0411333
188	0	1.6789927	0.518194	0.1549431	0.0409804
189	0	1.2666854	0.2364036	0.1557733	0.0491895
190	6	1.6426902	0.4963353	0.1549431	0.8444562
191	6	1.633044	0.4904458	0.1810451	0.8478496

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
192	0	1.9258584	0.6553718	0.1538871	0.0372025
193	0	1.6699171	0.512774	0.1549431	0.0411333
194	0	1.9470217	0.6663009	0.1538871	0.0369096
195	5	2.3813686	0.8676753	0.1557733	0.5424403
196	4	1.7253064	0.5454047	0.1810451	0.5576819
197	0	1.9470217	0.6663009	0.1538871	0.0369096
198	0	1.9152768	0.6498621	0.1538871	0.0373506
199	0	1.6699171	0.512774	0.1549431	0.0411333
200	0	1.9576033	0.6717209	0.1538871	0.0367647
201	0	1.6880684	0.5235849	0.1549431	0.0408287
202	0	0.6137351	-0.488192	0.1538871	0.0693807
203	1	1.216018	0.1955816	0.1557733	0.2125554
204	12	1.6699171	0.512774	0.1549431	1.6288973
205	1	2.343368	0.8515892	0.1557733	0.1355529
206	0	1.7334466	0.5501117	0.1549431	0.0400856
207	0	1.6699171	0.512774	0.1549431	0.0411333
208	0	2.343368	0.8515892	0.1557733	0.0321466
209	1	1.6426902	0.4963353	0.1549431	0.175408
210	11	1.9470217	0.6663009	0.1538871	1.3429091
211	2	2.1094722	0.7464378	0.1852031	0.258692
212	0	2.3053674	0.8352401	0.1557733	0.0325507
213	3	2.3307011	0.8461691	0.1557733	0.3437883
214	0	2.0321617	0.7091001	0.1852031	0.0357747
215	0	0.088668	-2.422856	0.1557733	0.05368
216	0	1.4560174	0.3757049	0.1853262	0.0450736

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
217	0	1.6791752	0.5183027	0.1810451	0.0409774
218	0	1.4639306	0.381125	0.1853262	0.0449154
219	0	1.7068539	0.5346519	0.1810451	0.0405179
220	0	1.6791752	0.5183027	0.1810451	0.0409774
221	1	1.9364401	0.6608513	0.1538871	0.156252
222	1	1.6699171	0.512774	0.1549431	0.1734469
223	6	2.3307011	0.8461691	0.1557733	0.6552965
224	0	2.4193691	0.8835068	0.1557733	0.0313672
225	0	1.6699171	0.512774	0.1549431	0.0411333
226	0	1.6699171	0.512774	0.1549431	0.0411333
227	1	2.3307011	0.8461691	0.1557733	0.1361163
228	0	1.9470217	0.6663009	0.1538871	0.0369096
229	0	2.0210932	0.7036385	0.1538871	0.0359184
230	0	2.3307011	0.8461691	0.1557733	0.0322802
231	0	2.343368	0.8515892	0.1557733	0.0321466
232	0	1.9893483	0.6878071	0.1538871	0.0363368
233	0	2.3307011	0.8461691	0.1557733	0.0322802
234	0	1.697144	0.5289468	0.1549431	0.040678
235	0	2.3307011	0.8461691	0.1557733	0.0322802
236	0	2.343368	0.8515892	0.1557733	0.0321466
237	0	2.3307011	0.8461691	0.1557733	0.0322802
238	5	1.9470217	0.6663009	0.1538871	0.6305457
239	0	2.3307011	0.8461691	0.1557733	0.0322802
240	0	1.6699171	0.512774	0.1549431	0.0411333
241	0	1.6699171	0.512774	0.1549431	0.0411333

Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=H23HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 2-3 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
242	0	1.6699171	0.512774	0.1549431	0.0411333
243	0	1.9470217	0.6663009	0.1538871	0.0369096
244	0	1.8729502	0.6275148	0.1538871	0.0379548
245	0	2.4193691	0.8835068	0.1557733	0.0313672
246	0	1.0794113	0.0764158	0.1995988	0.0539702
247	0	1.0794113	0.0764158	0.1995988	0.0539702
248	0	1.2921197	0.256284	0.1985305	0.0485976
249	0	1.1908722	0.174686	0.1995988	0.0510325
250	0	1.2921197	0.256284	0.1985305	0.0485976
251	0	1.0794113	0.0764158	0.1995988	0.0539702
252	1	0.9610071	-0.039773	0.1921581	0.2420928
253	0	1.3202093	0.2777902	0.1985305	0.0479585
254	0	1.2991421	0.2617041	0.1985305	0.0484364
255	0	0.925787	-0.077111	0.1921581	0.0585039
256	0	1.3061645	0.267095	0.1985305	0.0482761
257	0	0.925787	-0.077111	0.1921581	0.0585039
258	0	1.2921197	0.256284	0.1985305	0.0485976
259	3	1.334254	0.2883724	0.1985305	0.5074217
260	0	1.2991421	0.2617041	0.1985305	0.0484364
261	0	1.0794113	0.0764158	0.1995988	0.0539702
262	0	1.2921197	0.256284	0.1985305	0.0485976
263	0	0.925787	-0.077111	0.1921581	0.0585039
264	1	1.0852776	0.0818358	0.1995988	0.2268946
265	0	1.0852776	0.0818358	0.1995988	0.0538085
266	1	1.0794113	0.0764158	0.1995988	0.2275766

Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=H23HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 2-3 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
267	0	1.0794113	0.0764158	0.1995988	0.0539702
268	1	1.1146095	0.1085041	0.1995988	0.2235357
269	0	0.9459128	-0.055605	0.1921581	0.0578766
270	0	1.2921197	0.256284	0.1985305	0.0485976
271	0	0.925787	-0.077111	0.1921581	0.0585039
272	0	1.3061645	0.267095	0.1985305	0.0482761
273	0	1.2710525	0.2398453	0.1985305	0.049087
274	0	0.9408813	-0.060938	0.1921581	0.0580324
275	0	1.1791395	0.1647849	0.1995988	0.0513287
276	0	1.2991421	0.2617041	0.1985305	0.0484364
277	0	1.3061645	0.267095	0.1985305	0.0482761
278	0	1.2921197	0.256284	0.1985305	0.0485976
279	0	0.9408813	-0.060938	0.1921581	0.0580324
280	0	0.9308184	-0.071691	0.1921581	0.0583461
281	0	1.2991421	0.2617041	0.1985305	0.0484364
282	5	0.9308184	-0.071691	0.1921581	0.9967576
283	0	0.9106926	-0.09355	0.1921581	0.058981
284	1	0.925787	-0.077111	0.1921581	0.2466937
285	0	1.2780749	0.245355	0.1985305	0.0489228
286	0	1.0852776	0.0818358	0.1995988	0.0538085
287	0	1.0852776	0.0818358	0.1995988	0.0538085
288	0	1.091144	0.0872267	0.1995988	0.0536476
289	0	1.0852776	0.0818358	0.1995988	0.0538085
290	0	1.0794113	0.0764158	0.1995988	0.0539702
291	0	1.0970104	0.0925886	0.1995988	0.0534874

Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=H23HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 2-3 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
292	0	1.2921197	0.256284	0.1985305	0.0485976
293	0	0.925787	-0.077111	0.1921581	0.0585039
294	0	1.0794113	0.0764158	0.1995988	0.0539702
295	0	1.2991421	0.2617041	0.1985305	0.0484364
296	0	1.0618122	0.059977	0.1995988	0.0544603
297	0	1.0735449	0.0709662	0.1995988	0.0541328
298	7	1.2921197	0.256284	0.1985305	1.1428663
299	0	0.6490572	-0.432234	0.1921581	0.0680733
300	0	0.925787	-0.077111	0.1921581	0.0585039
301	0	1.0794113	0.0764158	0.1995988	0.0539702
302	0	1.2921197	0.256284	0.1985305	0.0485976
303	0	1.3061645	0.267095	0.1985305	0.0482761
304	0	1.091144	0.0872267	0.1995988	0.0536476
305	9	0.9660386	-0.034551	0.1921581	1.714941
306	0	0.925787	-0.077111	0.1921581	0.0585039
307	0	1.0676785	0.0654867	0.1995988	0.0542961
308	1	0.925787	-0.077111	0.1921581	0.2466937
309	0	0.9308184	-0.071691	0.1921581	0.0583461
310	0	0.9308184	-0.071691	0.1921581	0.0583461
311	0	1.3061645	0.267095	0.1985305	0.0482761
312	0	1.091144	0.0872267	0.1995988	0.0536476
313	0	1.0794113	0.0764158	0.1995988	0.0539702
314	0	1.334254	0.2883724	0.1985305	0.0476447
315	0	0.9157241	-0.08804	0.1921581	0.0588213
316	0	1.091144	0.0872267	0.1995988	0.0536476

Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=H23HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 2-3 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
317	3	1.2991421	0.2617041	0.1985305	0.5158532
318	1	0.9207555	-0.082561	0.1921581	0.2473617
319	2	1.2850973	0.2508344	0.1985305	0.3624512
320	2	0.9358499	-0.0663	0.1921581	0.4325426
321	0	1.0970104	0.0925886	0.1995988	0.0534874
322	0	1.3202093	0.2777902	0.1985305	0.0479585
323	0	0.9660386	-0.034551	0.1921581	0.0572594
324	4	1.0970104	0.0925886	0.1995988	0.7417013
325	0	0.925787	-0.077111	0.1921581	0.0585039
326	0	0.9358499	-0.0663	0.1921581	0.0581889
327	0	1.0970104	0.0925886	0.1995988	0.0534874
328	0	1.0794113	0.0764158	0.1995988	0.0539702
329	0	1.0852776	0.0818358	0.1995988	0.0538085
330	0	1.2991421	0.2617041	0.1985305	0.0484364
331	0	1.0794113	0.0764158	0.1995988	0.0539702
332	0	0.9358499	-0.0663	0.1921581	0.0581889
333	0	1.3131869	0.2724569	0.1985305	0.0481169
334	0	0.9610071	-0.039773	0.1921581	0.0574128
335	0	0.925787	-0.077111	0.1921581	0.0585039
336	0	0.1349264	-2.003026	0.1995988	0.0656126
337	0	1.0794113	0.0764158	0.1995988	0.0539702
338	0	0.9308184	-0.071691	0.1921581	0.0583461
339	0	1.1204758	0.1137534	0.1995988	0.052855
340	0	1.3131869	0.2724569	0.1985305	0.0481169
341	0	0.9459128	-0.055605	0.1921581	0.0578766

Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=H23HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 2-3 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
342	0	1.0794113	0.0764158	0.1995988	0.0539702
343	4	0.925787	-0.077111	0.1921581	0.8112632
344	4	1.0970104	0.0925886	0.1995988	0.7417013
345	7	0.925787	-0.077111	0.1921581	1.3758327
346	0	1.2921197	0.256284	0.1985305	0.0485976
347	3	1.0970104	0.0925886	0.1995988	0.5696478
348	17	0.9358499	-0.0663	0.1921581	3.2401947
349	2	2.8470705	1.0462906	0.1450956	0.2050943
350	0	2.039889	0.7128954	0.1525058	0.0356751
351	0	2.0175951	0.7019063	0.1525058	0.0359641
352	0	2.0510359	0.718345	0.1525058	0.0355322
353	0	2.0510359	0.718345	0.1525058	0.0355322
354	0	2.039889	0.7128954	0.1525058	0.0356751
355	0	2.3913831	0.8718719	0.1517889	0.0316499
356	0	2.3913831	0.8718719	0.1517889	0.0316499
357	10	1.7883188	0.5812759	0.1570993	1.3008377
358	19	2.4959542	0.9146711	0.1489004	1.9019297
359	0	2.1077347	0.7456137	0.1523802	0.0348225
360	0	1.7883188	0.5812759	0.1570993	0.0392208
361	7	2.590909	0.9520088	0.1489004	0.6993254
362	0	1.7883188	0.5812759	0.1570993	0.0392208
363	2	2.062407	0.7238738	0.1523802	0.2630512
364	0	1.8174761	0.5974488	0.1570993	0.0387756
365	0	1.7883188	0.5812759	0.1570993	0.0392208
366	0	1.7688805	0.5703469	0.1570993	0.039523

Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=H23HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 2-3 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
367	0	1.7591614	0.5648372	0.1570993	0.0396758
368	1	2.0850708	0.7348028	0.1523802	0.1480187
369	3	1.7591614	0.5648372	0.1570993	0.4225522
370	0	2.1530623	0.7668911	0.1523802	0.0342747
371	0	1.7591614	0.5648372	0.1570993	0.0396758
372	1	2.5095192	0.9200912	0.1489004	0.1285644
373	3	2.6316039	0.9675935	0.1489004	0.3128417
374	6	2.5095192	0.9200912	0.1489004	0.6189398
375	0	1.7883188	0.5812759	0.1570993	0.0392208
376	11	2.4959542	0.9146711	0.1489004	1.1140091
377	0	2.4959542	0.9146711	0.1489004	0.0306183
378	0	2.4959542	0.9146711	0.1489004	0.0306183
379	2	2.0850708	0.7348028	0.1523802	0.2609344
380	0	2.5230841	0.925482	0.1489004	0.0303613
381	0	2.4959542	0.9146711	0.1489004	0.0306183
382	0	2.4959542	0.9146711	0.1489004	0.0306183
383	0	2.0850708	0.7348028	0.1523802	0.0351029
384	0	2.0510359	0.718345	0.1525058	0.0355322
385	0	2.0850708	0.7348028	0.1523802	0.0351029
386	0	2.4823892	0.9092215	0.1489004	0.0307484
387	0	1.7883188	0.5812759	0.1570993	0.0392208
388	1	2.4959542	0.9146711	0.1489004	0.1291084
389	0	2.4959542	0.9146711	0.1489004	0.0306183
390	1	2.5230841	0.925482	0.1489004	0.1280249
391	0	2.0850708	0.7348028	0.1523802	0.0351029

Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=H23HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 2-3 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
392	0	2.8626282	1.0517402	0.1450956	0.0274703
393	3	2.9559748	1.0838285	0.1450956	0.2850843
394	0	2.039889	0.7128954	0.1525058	0.0356751
395	0	2.1625053	0.7712674	0.1525058	0.0341626
396	1	2.878186	1.0571602	0.1450956	0.1153302
397	0	1.7688805	0.5703469	0.1570993	0.039523
398	3	2.0621829	0.7237651	0.1525058	0.3769131
399	0	2.0510359	0.718345	0.1525058	0.0355322
400	0	2.1179175	0.7504333	0.1525058	0.034698
401	0	2.0733298	0.7291559	0.1525058	0.0352499
402	0	2.8626282	1.0517402	0.1450956	0.0274703
403	0	2.4043797	0.877292	0.1517889	0.031518
404	1	2.9093015	1.067913	0.1450956	0.114335
405	0	2.0621829	0.7237651	0.1525058	0.0353905
406	2	2.8937437	1.0625511	0.1450956	0.2024287
407	1	2.0621829	0.7237651	0.1525058	0.1492314
408	0	2.0510359	0.718345	0.1525058	0.0355322
409	0	2.4688243	0.903742	0.1489004	0.0308795
410	0	1.7591614	0.5648372	0.1570993	0.0396758
411	0	2.4823892	0.9092215	0.1489004	0.0307484
412	6	1.7980379	0.586696	0.1570993	0.7931565
413	0	2.563779	0.9414824	0.1489004	0.0299837
414	0	2.1077347	0.7456137	0.1523802	0.0348225
415	0	2.4688243	0.903742	0.1489004	0.0308795
416	2	2.0737389	0.7293532	0.1523802	0.2619886

Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=H23HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 2-3 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
417	0	2.0850708	0.7348028	0.1523802	0.0351029
418	0	2.4959542	0.9146711	0.1489004	0.0306183
419	0	2.4688243	0.903742	0.1489004	0.0308795
420	16	2.3913831	0.8718719	0.1517889	1.6605831
421	0	2.8626282	1.0517402	0.1450956	0.0274703
422	7	2.4043797	0.877292	0.1517889	0.7412064
423	9	2.4043797	0.877292	0.1517889	0.9439746
424	1	2.0621829	0.7237651	0.1525058	0.1492314
425	0	2.0287421	0.7074159	0.1525058	0.035819
426	3	2.8937437	1.0625511	0.1450956	0.2900269
427	0	2.0621829	0.7237651	0.1525058	0.0353905
428	6	2.0621829	0.7237651	0.1525058	0.7184358
429	0	2.940417	1.0785514	0.1450956	0.0268827
430	0	2.5473428	0.9350508	0.1517889	0.0301351
431	0	2.940417	1.0785514	0.1450956	0.0268827
432	0	2.3913831	0.8718719	0.1517889	0.0316499
433	0	2.0510359	0.718345	0.1525058	0.0355322
434	1	2.4173764	0.8826828	0.1517889	0.1323504
435	0	2.3913831	0.8718719	0.1517889	0.0316499
436	0	2.3783864	0.8664223	0.1517889	0.0317828
437	0	1.7883188	0.5812759	0.1570993	0.0392208
438	0	2.4433697	0.8933781	0.1517889	0.0311287
439	2	1.7980379	0.586696	0.1570993	0.290433
440	0	2.0964028	0.7402229	0.1523802	0.0349622
441	0	2.0844767	0.7345179	0.1525058	0.0351103

Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=H23HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 2-3 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
442	0	1.7883188	0.5812759	0.1570993	0.0392208
443	0	2.3913831	0.8718719	0.1517889	0.0316499
444	0	2.430373	0.8880447	0.1517889	0.0312574
445	2	1.7883188	0.5812759	0.1570993	0.2915441
446	3	1.7980379	0.586696	0.1570993	0.4161139
447	0	2.8626282	1.0517402	0.1450956	0.0274703
448	0	2.4552593	0.8982324	0.1489004	0.0310118
449	1	2.0850708	0.7348028	0.1523802	0.1480187
450	0	2.0510359	0.718345	0.1525058	0.0355322
451	1	2.3913831	0.8718719	0.1517889	0.1334582
452	0	2.5343462	0.9299357	0.1517889	0.0302559
453	0	2.5095192	0.9200912	0.1489004	0.0304893
454	1	1.8660718	0.6238356	0.1570993	0.1604657
455	4	2.7943835	1.0276115	0.1489004	0.3883685
456	3	2.5213495	0.9247943	0.1517889	0.3235255
457	4	1.7688805	0.5703469	0.1570993	0.5480588
458	0	2.5366491	0.930844	0.1489004	0.0302344
459	0	2.590909	0.9520088	0.1489004	0.0297371
460	2	2.3783864	0.8664223	0.1517889	0.236255
461	0	2.7422925	1.0087943	0.1517889	0.0284308
462	1	1.8174761	0.5974488	0.1570993	0.1635053
463	1	2.0850708	0.7348028	0.1523802	0.1480187
464	0	2.0510359	0.718345	0.1525058	0.0355322
465	0	2.0737389	0.7293532	0.1523802	0.0352447
466	0	3.1737835	1.1549244	0.1450956	0.02526

Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=H23HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 2-3 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
467	0	2.469363	0.9039602	0.1517889	0.0308743
468	2	2.8937437	1.0625511	0.1450956	0.2024287
469	0	2.8626282	1.0517402	0.1450956	0.0274703
470	0	2.4959542	0.9146711	0.1489004	0.0306183
471	0	2.2293869	0.8017266	0.1525058	0.0333891
472	0	2.9559748	1.0838285	0.1450956	0.0267682
473	2	1.8563526	0.6186136	0.1570993	0.283933
474	1	2.9248593	1.0732464	0.1450956	0.1138437
475	2	2.8470705	1.0462906	0.1450956	0.2050943
476	4	2.0733298	0.7291559	0.1525058	0.4888039
477	1	2.4433697	0.8933781	0.1517889	0.1312604
478	0	2.8937437	1.0625511	0.1450956	0.0272323
479	0	2.0287421	0.7074159	0.1525058	0.035819
480	1	2.9093015	1.067913	0.1450956	0.114335
481	6	2.430373	0.8880447	0.1517889	0.6345324
482	7	2.878186	1.0571602	0.1450956	0.6432067
483	3	2.8315127	1.0408111	0.1450956	0.2951412
484	0	2.8470705	1.0462906	0.1450956	0.0275909
485	0	2.3653898	0.8609428	0.1517889	0.0319169
486	0	2.0175951	0.7019063	0.1525058	0.0359641
487	0	2.8470705	1.0462906	0.1450956	0.0275909
488	0	2.0510359	0.718345	0.1525058	0.0355322
489	9	2.0621829	0.7237651	0.1525058	1.0599584
490	0	2.9093015	1.067913	0.1450956	0.0271148
491	0	2.878186	1.0571602	0.1450956	0.0273508

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Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=H23HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 2-3 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
492	0	2.3783864	0.8664223	0.1517889	0.0317828
493	1	2.4173764	0.8826828	0.1517889	0.1323504
494	5	1.9841543	0.6851928	0.1525058	0.6219463
495	1	2.0510359	0.718345	0.1525058	0.149829
496	6	2.430373	0.8880447	0.1517889	0.6345324
497	0	2.8626282	1.0517402	0.1450956	0.0274703
498	0	2.8626282	1.0517402	0.1450956	0.0274703
499	0	2.430373	0.8880447	0.1517889	0.0312574
500	0	2.3913831	0.8718719	0.1517889	0.0316499
501	10	2.3653898	0.8609428	0.1517889	1.0585904
502	3	2.8937437	1.0625511	0.1450956	0.2900269
503	0	2.0510359	0.718345	0.1525058	0.0355322
504	0	2.8315127	1.0408111	0.1450956	0.0277125
505	0	2.430373	0.8880447	0.1517889	0.0312574
506	0	2.430373	0.8880447	0.1517889	0.0312574
507	0	2.8315127	1.0408111	0.1450956	0.0277125
508	0	0.4667329	-0.761998	0.1450956	0.0745971
509	2	2.8159549	1.0353014	0.1450956	0.2069102
510	1	2.8626282	1.0517402	0.1450956	0.1158342
511	1	2.3913831	0.8718719	0.1517889	0.1334582
512	4	2.8626282	1.0517402	0.1450956	0.380926
513	12	2.3913831	0.8718719	0.1517889	1.2533498
514	1	2.878186	1.0571602	0.1450956	0.1153302
515	6	2.0510359	0.718345	0.1525058	0.7213128
516	0	2.0510359	0.718345	0.1525058	0.0355322

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Parameter Code=H23HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 2-3 hours after meal

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
517	7	2.8626282	1.0517402	0.1450956	0.6460177
518	1	2.878186	1.0571602	0.1450956	0.1153302
519	5	2.4173764	0.8826828	0.1517889	0.5362034
520	0	2.9093015	1.067913	0.1450956	0.0271148
521	1	2.0510359	0.718345	0.1525058	0.149829
522	2	2.3913831	0.8718719	0.1517889	0.2352665
523	0	2.3913831	0.8718719	0.1517889	0.0316499
524	0	2.8626282	1.0517402	0.1450956	0.0274703
525	2	2.0621829	0.7237651	0.1525058	0.2630723
526	0	2.0621829	0.7237651	0.1525058	0.0353905
527	0	2.8937437	1.0625511	0.1450956	0.0272323
528	0	2.0621829	0.7237651	0.1525058	0.0353905
529	0	2.0510359	0.718345	0.1525058	0.0355322
530	5	2.0956237	0.7398512	0.1525058	0.5974424
531	0	2.4043797	0.877292	0.1517889	0.031518
532	1	2.1067706	0.7451563	0.1525058	0.1468864
533	7	2.8626282	1.0517402	0.1450956	0.6460177
534	13	2.8315127	1.0408111	0.1450956	1.1865705
535	3	2.0510359	0.718345	0.1525058	0.3784225
536	7	2.3913831	0.8718719	0.1517889	0.7443082
537	1	2.4043797	0.877292	0.1517889	0.132902
538	0	2.4043797	0.877292	0.1517889	0.031518
539	0	2.0621829	0.7237651	0.1525058	0.0353905
540	0	2.430373	0.8880447	0.1517889	0.0312574
541	0	2.039889	0.7128954	0.1525058	0.0356751

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Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
542	0	2.4173764	0.8826828	0.1517889	0.0313871
543	0	2.3393965	0.849893	0.1517889	0.0321884
544	0	2.0956237	0.7398512	0.1525058	0.0349718
545	0	2.1067706	0.7451563	0.1525058	0.0348344
546	3	2.0510359	0.718345	0.1525058	0.3784225
547	0	2.0733298	0.7291559	0.1525058	0.0352499
548	35	2.878186	1.0571602	0.1450956	3.1066306
549	4	2.039889	0.7128954	0.1525058	0.4946999
550	6	2.3913831	0.8718719	0.1517889	0.6424998
551	15	2.3913831	0.8718719	0.1517889	1.5587748
552	10	2.0510359	0.718345	0.1525058	1.1784999
553	2	2.0621829	0.7237651	0.1525058	0.2630723
554	5	2.4173764	0.8826828	0.1517889	0.5362034
555	0	2.0510359	0.718345	0.1525058	0.0355322
556	0	2.1067706	0.7451563	0.1525058	0.0348344
557	4	2.4043797	0.877292	0.1517889	0.4370542
558	0	2.0621829	0.7237651	0.1525058	0.0353905
559	0	2.0510359	0.718345	0.1525058	0.0355322
560	0	2.430373	0.8880447	0.1517889	0.0312574
561	2	2.8626282	1.0517402	0.1450956	0.2041981
562	1	2.4043797	0.877292	0.1517889	0.132902
563	17	2.0850708	0.7348028	0.1523802	1.9546708
564	7	2.8937437	1.0625511	0.1450956	0.6404197
565	1	2.430373	0.8880447	0.1517889	0.1318032
566	0	2.0510359	0.718345	0.1525058	0.0355322

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567	8	2.1077347	0.7456137	0.1523802	0.9309341
568	2	2.8626282	1.0517402	0.1450956	0.2041981
569	2	2.3523931	0.8554332	0.1517889	0.2382565
570	0	2.878186	1.0571602	0.1450956	0.0273508
571	0	2.0621829	0.7237651	0.1525058	0.0353905
572	4	2.9559748	1.0838285	0.1450956	0.3711897
573	5	2.0956237	0.7398512	0.1525058	0.5974424
574	17	2.9093015	1.067913	0.1450956	1.5098589
575	23	2.8626282	1.0517402	0.1450956	2.0598404
576	2	2.0956237	0.7398512	0.1525058	0.25996
577	0	2.4043797	0.877292	0.1517889	0.031518
578	7	2.3783864	0.8664223	0.1517889	0.7474354
579	25	2.8626282	1.0517402	0.1450956	2.2365682
580	8	2.8626282	1.0517402	0.1450956	0.7343816
581	7	2.4043797	0.877292	0.1517889	0.7412064
582	4	2.3913831	0.8718719	0.1517889	0.4388832
583	1	2.0510359	0.718345	0.1525058	0.149829
584	0	2.4688243	0.903742	0.1489004	0.0308795
585	3	2.0964028	0.7402229	0.1523802	0.3723515
586	1	2.1530623	0.7668911	0.1523802	0.1445263
587	0	2.0850708	0.7348028	0.1523802	0.0351029
588	0	1.7883188	0.5812759	0.1570993	0.0392208
589	0	1.807757	0.5920869	0.1570993	0.0389229
590	0	2.4959542	0.9146711	0.1489004	0.0306183
591	8	2.0850708	0.7348028	0.1523802	0.938429

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
592	8	2.0850708	0.7348028	0.1523802	0.938429
593	2	2.4959542	0.9146711	0.1489004	0.2275984
594	12	1.7980379	0.586696	0.1570993	1.5472418
595	3	2.4959542	0.9146711	0.1489004	0.3260885
596	3	1.9243865	0.6546072	0.1570993	0.3964298
597	3	1.7883188	0.5812759	0.1570993	0.4177058
598	2	1.7883188	0.5812759	0.1570993	0.2915441
599	0	1.7591614	0.5648372	0.1570993	0.0396758
600	0	2.0737389	0.7293532	0.1523802	0.0352447
601	1	2.5230841	0.925482	0.1489004	0.1280249
602	0	1.7688805	0.5703469	0.1570993	0.039523
603	2	2.878186	1.0571602	0.1450956	0.2033096
604	3	1.7591614	0.5648372	0.1570993	0.4225522
605	1	2.0850708	0.7348028	0.1523802	0.1480187
606	0	2.0850708	0.7348028	0.1523802	0.0351029
607	1	2.4823892	0.9092215	0.1489004	0.1296569
608	0	2.9093015	1.067913	0.1450956	0.0271148
609	0	1.7883188	0.5812759	0.1570993	0.0392208
610	0	2.5230841	0.925482	0.1489004	0.0303613
611	4	2.1417304	0.7616141	0.1523802	0.4771587
612	21	2.4959542	0.9146711	0.1489004	2.0989099
613	1	2.0964028	0.7402229	0.1523802	0.1474253
614	0	1.7980379	0.586696	0.1570993	0.0390713
615	1	1.7785996	0.5758263	0.1570993	0.1660174
616	0	1.7883188	0.5812759	0.1570993	0.0392208

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Observation Statistics

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617	1	2.4552593	0.8982324	0.1489004	0.1307677
618	1	2.0964028	0.7402229	0.1523802	0.1474253
619	3	2.4959542	0.9146711	0.1489004	0.3260885
620	1	1.8271953	0.6027822	0.1570993	0.1628886
621	34	2.577344	0.9467594	0.1489004	3.2955796
622	0	1.7785996	0.5758263	0.1570993	0.0393713
623	1	2.4959542	0.9146711	0.1489004	0.1291084
624	0	2.0850708	0.7348028	0.1523802	0.0351029
625	0	2.062407	0.7238738	0.1523802	0.0353877
626	1	1.7883188	0.5812759	0.1570993	0.1653824
627	0	1.5057115	0.4092655	0.1489004	0.0440966
628	0	2.1643942	0.7721405	0.1523802	0.0341403
629	5	1.8174761	0.5974488	0.1570993	0.662424
630	0	2.0964028	0.7402229	0.1523802	0.0349622
631	2	2.4688243	0.903742	0.1489004	0.2295404
632	0	1.7980379	0.586696	0.1570993	0.0390713
633	3	2.0737389	0.7293532	0.1523802	0.3753606
634	0	2.5366491	0.930844	0.1489004	0.0302344
635	0	2.0850708	0.7348028	0.1523802	0.0351029
636	9	1.8174761	0.5974488	0.1570993	1.1613427
637	0	1.7785996	0.5758263	0.1570993	0.0393713
638	3	2.2890452	0.8281348	0.1523802	0.3485501
639	1	2.4823892	0.9092215	0.1489004	0.1296569
640	24	1.7688805	0.5703469	0.1570993	3.0907379
641	0	2.4959542	0.9146711	0.1489004	0.0306183

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Observation Statistics

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642	0	2.4043797	0.877292	0.1517889	0.031518
643	0	1.7980379	0.586696	0.1570993	0.0390713
644	0	2.3783864	0.8664223	0.1517889	0.0317828
645	1	1.7883188	0.5812759	0.1570993	0.1653824
646	1	2.8626282	1.0517402	0.1450956	0.1158342
647	1	1.7883188	0.5812759	0.1570993	0.1653824
648	1	2.8626282	1.0517402	0.1450956	0.1158342
649	7	2.469363	0.9039602	0.1517889	0.7260697
650	0	2.8937437	1.0625511	0.1450956	0.0272323
651	1	2.0850708	0.7348028	0.1523802	0.1480187
652	0	2.4959542	0.9146711	0.1489004	0.0306183
653	10	2.4959542	0.9146711	0.1489004	1.015519
654	5	2.9093015	1.067913	0.1450956	0.463216
655	5	2.3653898	0.8609428	0.1517889	0.5452537
656	0	2.8937437	1.0625511	0.1450956	0.0272323
657	1	2.4173764	0.8826828	0.1517889	0.1323504
658	0	2.3783864	0.8664223	0.1517889	0.0317828
659	6	3.1893412	1.1598144	0.1450956	0.5107271
660	0	2.0510359	0.718345	0.1525058	0.0355322
661	4	1.807757	0.5920869	0.1570993	0.5397371
662	0	2.286991	0.827237	0.1450956	0.0327497
663	0	3.3011484	1.1942704	0.1517889	0.0244535
664	0	2.4433697	0.8933781	0.1517889	0.0311287
665	2	2.5343462	0.9299357	0.1517889	0.2249047
666	6	2.1067706	0.7451563	0.1525058	0.7071465

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
667	0	2.0733298	0.7291559	0.1525058	0.0352499
668	0	1.4296312	0.3574165	0.1517889	0.0456088
669	1	2.1704401	0.7749299	0.1517889	0.1436593
670	0	1.8369144	0.6080872	0.1570993	0.0384841
671	0	2.4688243	0.903742	0.1489004	0.0308795
672	2	1.8271953	0.6027822	0.1570993	0.2871478
673	1	1.7883188	0.5812759	0.1570993	0.1653824
674	0	2.4959542	0.9146711	0.1489004	0.0306183
675	8	2.4959542	0.9146711	0.1489004	0.8185389
676	2	2.0850708	0.7348028	0.1523802	0.2609344
677	5	2.062407	0.7238738	0.1523802	0.6045464
678	2	1.9243865	0.6546072	0.1570993	0.2766942
679	2	2.4823892	0.9092215	0.1489004	0.2285654
680	10	2.0850708	0.7348028	0.1523802	1.1642605
681	5	2.5095192	0.9200912	0.1489004	0.5208648
682	5	2.4959542	0.9146711	0.1489004	0.5230687
683	0	2.1530623	0.7668911	0.1523802	0.0342747
684	3	2.0397432	0.7128239	0.1523802	0.3799637
685	1	1.7883188	0.5812759	0.1570993	0.1653824
686	0	2.5366491	0.930844	0.1489004	0.0302344
687	0	1.8660718	0.6238356	0.1570993	0.0380547
688	0	2.0510751	0.7183641	0.1523802	0.0355317
689	2	2.0850708	0.7348028	0.1523802	0.2609344
690	3	2.0850708	0.7348028	0.1523802	0.3738502
691	0	2.062407	0.7238738	0.1523802	0.0353877

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Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
692	2	2.5095192	0.9200912	0.1489004	0.2266395
693	1	1.7883188	0.5812759	0.1570993	0.1653824
694	1	1.0794113	0.0764158	0.1995988	0.2275766
695	5	1.1028767	0.097922	0.1995988	0.9110331
696	0	0.925787	-0.077111	0.1921581	0.0585039
697	3	1.0559458	0.0544369	0.1995988	0.5817665
698	0	0.9157241	-0.08804	0.1921581	0.0588213
699	1	1.0618122	0.059977	0.1995988	0.2296432
700	7	0.9610071	-0.039773	0.1921581	1.3501732
701	1	1.2921197	0.256284	0.1985305	0.2049217
702	0	1.0794113	0.0764158	0.1995988	0.0539702
703	9	1.0383467	0.0376297	0.1995988	1.6510246
704	15	1.2921197	0.256284	0.1985305	2.3934592
705	1	1.0735449	0.0709662	0.1995988	0.228262
706	0	1.0676785	0.0654867	0.1995988	0.0542961
707	0	1.2780749	0.245355	0.1985305	0.0489228
708	4	0.9358499	-0.0663	0.1921581	0.8068962
709	0	1.0794113	0.0764158	0.1995988	0.0539702
710	0	1.2921197	0.256284	0.1985305	0.0485976
711	0	0.9106926	-0.09355	0.1921581	0.058981
712	0	0.9106926	-0.09355	0.1921581	0.058981
713	0	1.0794113	0.0764158	0.1995988	0.0539702
714	0	1.0618122	0.059977	0.1995988	0.0544603
715	0	1.0148812	0.0147716	0.1995988	0.0558038
716	0	0.925787	-0.077111	0.1921581	0.0585039

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Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=H23HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 2-3 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
717	5	1.2850973	0.2508344	0.1985305	0.8329884
718	2	1.0735449	0.0709662	0.1995988	0.4023913
719	0	1.2921197	0.256284	0.1985305	0.0485976
720	0	1.0794113	0.0764158	0.1995988	0.0539702
721	0	1.0794113	0.0764158	0.1995988	0.0539702
722	8	1.2850973	0.2508344	0.1985305	1.3035256
723	0	1.2850973	0.2508344	0.1985305	0.0487597
724	5	1.2921197	0.256284	0.1985305	0.8302181
725	4	1.2644935	0.2346717	0.1523969	0.6828185
726	9	2.0029267	0.6946095	0.1694132	1.0829068
727	4	1.4958147	0.402671	0.170297	0.6141349
728	13	1.9711342	0.6786091	0.1694132	1.566303
729	0	1.5793374	0.4570054	0.170297	0.0427198
730	4	1.9181467	0.6513595	0.1694132	0.5173763
731	0	2.1089016	0.7461673	0.1694132	0.0348082
732	1	1.2644935	0.2346717	0.1523969	0.2076355
733	3	1.4125707	0.3454113	0.1479411	0.4894919
734	0	1.4125707	0.3454113	0.1479411	0.0459611
735	0	1.2181508	0.197334	0.1523969	0.0503555
736	1	1.6539712	0.5031792	0.1504029	0.1745904
737	0	0.9533354	-0.047788	0.1523969	0.0576478
738	1	1.3895132	0.3289534	0.170297	0.1958465
739	1	1.4125707	0.3454113	0.1479411	0.1938047
740	0	1.4434466	0.3670337	0.1479411	0.0453271
741	0	1.2512527	0.2241452	0.1523969	0.049555

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Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=H23HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 2-3 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
742	0	1.4046991	0.3398231	0.170297	0.0461254
743	4	1.4046991	0.3398231	0.170297	0.6396132
744	0	1.4202897	0.3508609	0.1479411	0.0458011
745	0	1.4125707	0.3454113	0.1479411	0.0459611
746	0	1.7278917	0.546902	0.1504029	0.0401751
747	0	1.3971061	0.334403	0.170297	0.0462849
748	3	1.4357276	0.3616718	0.1479411	0.4844114
749	1	1.9499392	0.6677982	0.1694132	0.155468
750	0	1.7556119	0.5628175	0.1504029	0.0397319
751	3	1.6289407	0.4879299	0.1700151	0.445569
752	0	1.3971061	0.334403	0.170297	0.0462849
753	2	1.7094116	0.5361492	0.1504029	0.3008743
754	3	1.3895132	0.3289534	0.170297	0.4946489
755	0	1.764852	0.5680668	0.1504029	0.0395862
756	4	1.7001715	0.5307291	0.1504029	0.5633804
757	3	1.6909315	0.5252795	0.1504029	0.4343226
758	1	1.4202897	0.3508609	0.1479411	0.1931299
759	0	1.2181508	0.197334	0.1523969	0.0503555
760	0	1.4202897	0.3508609	0.1479411	0.0458011
761	1	1.7094116	0.5361492	0.1504029	0.1706751
762	0	1.4125707	0.3454113	0.1479411	0.0459611
763	0	1.7001715	0.5307291	0.1504029	0.0406279
764	3	1.7278917	0.546902	0.1504029	0.4278703
765	0	1.4125707	0.3454113	0.1479411	0.0459611
766	0	1.6466466	0.4987408	0.1700151	0.0415301

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Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=H23HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 2-3 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
767	4	1.4202897	0.3508609	0.1479411	0.6351163
768	0	1.2115304	0.1918844	0.1523969	0.0505184
769	0	1.7094116	0.5361492	0.1504029	0.0404759
770	0	1.4743225	0.3881985	0.1479411	0.0447091
771	1	1.7094116	0.5361492	0.1504029	0.1706751
772	1	1.4280087	0.3562809	0.1479411	0.1924594
773	0	1.6724513	0.5142904	0.1504029	0.0410905
774	6	1.7186516	0.5415401	0.1504029	0.8186074
775	0	1.4202897	0.3508609	0.1479411	0.0458011
776	0	1.7001715	0.5307291	0.1504029	0.0406279
777	1	1.2181508	0.197334	0.1523969	0.2123346
778	7	1.7094116	0.5361492	0.1504029	0.9518703
779	0	0.3839823	-0.957159	0.1523969	0.0768589
780	0	1.2181508	0.197334	0.1523969	0.0503555
781	0	1.3971061	0.334403	0.170297	0.0462849
782	0	1.7186516	0.5415401	0.1504029	0.040325
783	3	1.4202897	0.3508609	0.1479411	0.4877875
784	0	1.2644935	0.2346717	0.1523969	0.0492411
785	2	1.6816914	0.5198001	0.1504029	0.3042882
786	1	1.3971061	0.334403	0.170297	0.1951698
787	0	1.3971061	0.334403	0.170297	0.0462849
788	0	1.7371318	0.5522353	0.1504029	0.0400264
789	0	1.3971061	0.334403	0.170297	0.0462849
790	0	1.4743225	0.3881985	0.1479411	0.0447091
791	1	1.9588933	0.6723797	0.1504029	0.1549521

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Parameter Code=H23HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 2-3 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
792	0	1.2578731	0.2294223	0.1523969	0.0493976
793	0	1.4202897	0.3508609	0.1479411	0.0458011
794	7	1.4280087	0.3562809	0.1479411	1.0733633
795	0	1.4357276	0.3616718	0.1479411	0.0454841
796	0	1.2181508	0.197334	0.1523969	0.0503555
797	0	1.7001715	0.5307291	0.1504029	0.0406279
798	0	1.2181508	0.197334	0.1523969	0.0503555
799	2	1.6820583	0.5200182	0.1700151	0.3042425
800	0	1.4730358	0.3873254	0.170297	0.0447345
801	0	1.4882217	0.3975819	0.170297	0.044436
802	6	1.3895132	0.3289534	0.170297	0.9428523
803	0	1.9499392	0.6677982	0.1694132	0.0368695
804	0	1.6289407	0.4879299	0.1700151	0.041837
805	0	1.6732054	0.5147412	0.1700151	0.0410778
806	0	2.0347192	0.7103578	0.1694132	0.0357417
807	0	1.6466466	0.4987408	0.1700151	0.0415301
808	0	1.7174701	0.5408523	0.1700151	0.0403442
809	2	1.9711342	0.6786091	0.1694132	0.271923
810	1	1.9923292	0.6893044	0.1694132	0.1530544
811	0	1.6909113	0.5252676	0.1700151	0.0407813
812	1	1.2711139	0.2398936	0.1523969	0.2069793
813	0	1.2446324	0.2188402	0.1523969	0.0497133
814	0	1.8387725	0.6090982	0.1504029	0.0384565
815	3	1.1718081	0.158548	0.1523969	0.5486434
816	3	1.2247712	0.2027541	0.1523969	0.5345681

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Parameter Code=H23HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 2-3 hours after meal

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
817	0	1.9499392	0.6677982	0.1694132	0.0368695
818	0	1.1982897	0.1808953	0.1523969	0.0508469
819	0	1.4125707	0.3454113	0.1479411	0.0459611
820	1	1.4820414	0.3934205	0.1479411	0.1878839
821	0	1.4743225	0.3881985	0.1479411	0.0447091
822	0	1.8110523	0.593908	0.1504029	0.0388728
823	0	1.6816914	0.5198001	0.1504029	0.0409352
824	0	1.2247712	0.2027541	0.1523969	0.0501936
825	1	1.2247712	0.2027541	0.1523969	0.2116518
826	0	1.3971328	0.3344221	0.1479411	0.0462843
827	0	1.3971061	0.334403	0.170297	0.0462849
828	0	1.3373177	0.2906659	0.1523969	0.0475767
829	5	1.6909315	0.5252795	0.1504029	0.6966837
830	0	1.764852	0.5680668	0.1504029	0.0395862
831	1	1.4897604	0.3986153	0.1479411	0.1872467
832	3	1.4202897	0.3508609	0.1479411	0.4877875
833	1	1.7001715	0.5307291	0.1504029	0.171316
834	0	1.7001715	0.5307291	0.1504029	0.0406279
835	2	1.2578731	0.2294223	0.1523969	0.3671932
836	0	1.6909113	0.5252676	0.1700151	0.0407813
837	1	1.6909113	0.5252676	0.1700151	0.171963
838	2	1.3971061	0.334403	0.170297	0.3440547
839	0	1.3819202	0.323474	0.170297	0.0466069
840	0	1.6289407	0.4879299	0.1700151	0.041837
841	0	1.9923292	0.6893044	0.1694132	0.0362971

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Parameter Code=H23HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 2-3 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
842	0	1.6997642	0.5304895	0.1700151	0.0406346
843	0	1.6200878	0.4824803	0.1700151	0.041992
844	0	1.3971061	0.334403	0.170297	0.0462849
845	1	1.7440289	0.5561979	0.1700151	0.168314
846	1	1.4046991	0.3398231	0.170297	0.1944974
847	0	1.6289407	0.4879299	0.1700151	0.041837
848	0	1.9499392	0.6677982	0.1694132	0.0368695
849	0	1.9711342	0.6786091	0.1694132	0.0365812
850	14	1.3971061	0.334403	0.170297	2.1306738
851	1	1.4122921	0.345214	0.170297	0.1938292
852	5	1.9499392	0.6677982	0.1694132	0.6298618
853	4	1.9499392	0.6677982	0.1694132	0.5112633
854	0	1.4202897	0.3508609	0.1479411	0.0458011
855	1	1.4202897	0.3508609	0.1479411	0.1931299
856	0	1.7001715	0.5307291	0.1504029	0.0406279
857	4	1.7001715	0.5307291	0.1504029	0.5633804
858	0	1.3306974	0.2857031	0.1523969	0.0477238
859	0	1.3108362	0.2706653	0.1523969	0.0481701
860	3	1.9499392	0.6677982	0.1694132	0.3926649
861	0	1.4122921	0.345214	0.170297	0.0459669
862	0	1.6200878	0.4824803	0.1700151	0.041992
863	3	1.6724513	0.5142904	0.1504029	0.4376186
864	1	1.9499392	0.6677982	0.1694132	0.155468
865	0	1.7278917	0.546902	0.1504029	0.0401751
866	0	1.7278917	0.546902	0.1504029	0.0401751

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Parameter Code=H23HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 2-3 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
867	1	1.4125707	0.3454113	0.1479411	0.1938047
868	0	1.2843547	0.2502564	0.1523969	0.0487769
869	8	1.7278917	0.546902	0.1504029	1.0740288
870	0	1.4048518	0.3399318	0.1479411	0.0461222
871	3	1.3971061	0.334403	0.170297	0.4929396
872	0	1.2313916	0.2081449	0.1523969	0.0500326
873	3	1.4357276	0.3616718	0.1479411	0.4844114
874	0	1.4280087	0.3562809	0.1479411	0.0456421
875	3	1.238012	0.2135068	0.1523969	0.5311483
876	3	1.2313916	0.2081449	0.1523969	0.5328533
877	2	1.4357276	0.3616718	0.1479411	0.3381023
878	7	1.6724513	0.5142904	0.1504029	0.9663227
879	0	1.2115304	0.1918844	0.1523969	0.0505184
880	10	1.7001715	0.5307291	0.1504029	1.3475091
881	0	1.2115304	0.1918844	0.1523969	0.0505184
882	1	0.3773619	-0.974551	0.1523969	0.324661
883	2	1.20491	0.1864049	0.1523969	0.3767416
884	2	1.4202897	0.3508609	0.1479411	0.3404587
885	0	1.4125707	0.3454113	0.1479411	0.0459611
886	4	1.7278917	0.546902	0.1504029	0.557102
887	0	1.4202897	0.3508609	0.1479411	0.0458011
888	3	1.2181508	0.197334	0.1523969	0.5362926
889	1	1.4202897	0.3508609	0.1479411	0.1931299
890	0	1.7556119	0.5628175	0.1504029	0.0397319
891	1	1.6909315	0.5252795	0.1504029	0.1719615

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The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
892	8	1.4048518	0.3399318	0.1479411	1.2330156
893	1	1.7094116	0.5361492	0.1504029	0.1706751
894	1	1.6909315	0.5252795	0.1504029	0.1719615
895	5	1.4820414	0.3934205	0.1479411	0.7611916
896	1	1.4202897	0.3508609	0.1479411	0.1931299
897	1	1.9393417	0.6623486	0.1694132	0.1560829
898	2	1.2313916	0.2081449	0.1523969	0.3719131
899	0	1.6447311	0.4975769	0.1504029	0.0415631
900	7	1.7001715	0.5307291	0.1504029	0.9554447
901	0	1.2115304	0.1918844	0.1523969	0.0505184
902	0	1.2115304	0.1918844	0.1523969	0.0505184
903	2	1.2313916	0.2081449	0.1523969	0.3719131
904	0	1.6909315	0.5252795	0.1504029	0.040781
905	0	1.6289407	0.4879299	0.1700151	0.041837
906	1	1.7086172	0.5356844	0.1700151	0.17073
907	0	1.7001715	0.5307291	0.1504029	0.0406279
908	1	1.3971061	0.334403	0.170297	0.1951698
909	0	1.9499392	0.6677982	0.1694132	0.0368695
910	0	1.6200878	0.4824803	0.1700151	0.041992
911	0	1.6724513	0.5142904	0.1504029	0.0410905
912	0	1.6820583	0.5200182	0.1700151	0.040929
913	0	1.9605367	0.6732183	0.1694132	0.0367248
914	0	1.9711342	0.6786091	0.1694132	0.0365812
915	0	1.419885	0.3505759	0.170297	0.0458095
916	17	1.6200878	0.4824803	0.1700151	2.3382847

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
917	0	1.6200878	0.4824803	0.1700151	0.041992
918	0	1.2247712	0.2027541	0.1523969	0.0501936
919	0	1.2313916	0.2081449	0.1523969	0.0500326
920	1	1.3895132	0.3289534	0.170297	0.1958465
921	6	1.4280087	0.3562809	0.1479411	0.926546
922	0	1.4426639	0.3664914	0.170297	0.045343
923	0	1.2247712	0.2027541	0.1523969	0.0501936
924	0	1.7186516	0.5415401	0.1504029	0.040325
925	0	1.3971061	0.334403	0.170297	0.0462849
926	2	1.7001715	0.5307291	0.1504029	0.3020041
927	0	1.4280087	0.3562809	0.1479411	0.0456421
928	0	1.9499392	0.6677982	0.1694132	0.0368695
929	0	1.2247712	0.2027541	0.1523969	0.0501936
930	2	1.3895132	0.3289534	0.170297	0.3452477
931	0	1.9287442	0.6568691	0.1694132	0.0371623
932	0	1.7094116	0.5361492	0.1504029	0.0404759
933	0	1.0357938	0.0351681	0.1700151	0.0551985
934	0	1.4122921	0.345214	0.170297	0.0459669
935	9	1.3971061	0.334403	0.170297	1.3862492
936	1	1.4202897	0.3508609	0.1479411	0.1931299
937	2	1.3971061	0.334403	0.170297	0.3440547
938	1	2.0771092	0.7309771	0.1694132	0.1484383
939	0	1.7094116	0.5361492	0.1504029	0.0404759
940	2	1.2181508	0.197334	0.1523969	0.3743136
941	0	1.6023819	0.4714912	0.1700151	0.0423054

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Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=H23HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 2-3 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
942	0	1.2711139	0.2398936	0.1523969	0.0490855
943	2	1.6816914	0.5198001	0.1504029	0.3042882
944	1	1.2181508	0.197334	0.1523969	0.2123346
945	1	1.20491	0.1864049	0.1523969	0.2137119
946	0	1.3971061	0.334403	0.170297	0.0462849
947	0	1.9311731	0.6581276	0.1504029	0.0371285
948	0	1.764852	0.5680668	0.1504029	0.0395862
949	3	1.7094116	0.5361492	0.1504029	0.4310735
950	1	1.6997642	0.5304895	0.1700151	0.1713444
951	0	1.2247712	0.2027541	0.1523969	0.0501936
952	0	1.6021163	0.4713254	0.170297	0.0423101
953	0	1.4202897	0.3508609	0.1479411	0.0458011
954	1	1.4666035	0.3829492	0.1479411	0.1891705
955	11	1.6909315	0.5252795	0.1504029	1.483767
956	0	1.2181508	0.197334	0.1523969	0.0503555
957	0	1.3971061	0.334403	0.170297	0.0462849
958	0	1.1982897	0.1808953	0.1523969	0.0508469
959	2	1.7001715	0.5307291	0.1504029	0.3020041
960	0	1.7001715	0.5307291	0.1504029	0.0406279
961	0	1.2181508	0.197334	0.1523969	0.0503555
962	0	1.3971061	0.334403	0.170297	0.0462849
963	1	1.2181508	0.197334	0.1523969	0.2123346
964	0	1.4743225	0.3881985	0.1479411	0.0447091
965	0	1.4046991	0.3398231	0.170297	0.0461254
966	1	1.4202897	0.3508609	0.1479411	0.1931299

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Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=H23HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 2-3 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
967	0	1.2247712	0.2027541	0.1523969	0.0501936
968	0	0.3243989	-1.125781	0.1523969	0.077684
969	0	1.1784285	0.1641818	0.1523969	0.0513467
970	1	1.4511656	0.3723671	0.1479411	0.1904735
971	0	1.6289407	0.4879299	0.1700151	0.041837
972	0	1.7001715	0.5307291	0.1504029	0.0406279
973	2	1.9817317	0.6839711	0.1694132	0.2708634
974	1	1.6289407	0.4879299	0.1700151	0.1764143
975	0	1.9393417	0.6623486	0.1694132	0.0370153
976	0	1.3971061	0.334403	0.170297	0.0462849
977	0	1.4434466	0.3670337	0.1479411	0.0453271
978	1	1.6200878	0.4824803	0.1700151	0.1770681
979	0	1.2644935	0.2346717	0.1523969	0.0492411
980	5	1.6732054	0.5147412	0.1700151	0.7017534
981	0	1.3819202	0.323474	0.170297	0.0466069
982	0	1.4958147	0.402671	0.170297	0.0442881
983	1	1.5051983	0.4089247	0.1479411	0.1859843
984	0	1.2115304	0.1918844	0.1523969	0.0505184
985	1	1.4125707	0.3454113	0.1479411	0.1938047
986	6	1.9605367	0.6732183	0.1694132	0.7455223
987	0	1.7001715	0.5307291	0.1504029	0.0406279
988	0	1.4048518	0.3399318	0.1479411	0.0461222
989	8	1.4048518	0.3399318	0.1479411	1.2330156
990	0	1.2313916	0.2081449	0.1523969	0.0500326
991	7	1.4202897	0.3508609	0.1479411	1.0771027

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Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=H23HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 2-3 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
992	6	1.358538	0.3064091	0.1479411	0.9563599
993	3	1.7001715	0.5307291	0.1504029	0.4326923
994	0	1.4357276	0.3616718	0.1479411	0.0454841
995	0	1.7001715	0.5307291	0.1504029	0.0406279
996	0	1.7094116	0.5361492	0.1504029	0.0404759
997	0	0.8722431	-0.136687	0.1479411	0.0602222
998	8	1.3667342	0.3124241	0.170297	1.2546909
999	0	1.4820414	0.3934205	0.1479411	0.044557
1000	2	1.2247712	0.2027541	0.1523969	0.3731099
1001	0	1.4654428	0.3821575	0.170297	0.0448852
1002	10	1.9393417	0.6623486	0.1694132	1.2276906
1003	0	1.2118776	0.1921709	0.1479411	0.0505098
1004	0	0.6468044	-0.435711	0.1504029	0.0681566
1005	2	1.4280087	0.3562809	0.1479411	0.3392767
1006	2	1.2181508	0.197334	0.1523969	0.3743136
1007	7	1.2247712	0.2027541	0.1523969	1.1804007
1008	10	1.4202897	0.3508609	0.1479411	1.519089
1009	3	1.4588845	0.3776721	0.1479411	0.4794275
1010	0	1.6816914	0.5198001	0.1504029	0.0409352
1011	0	1.3637993	0.3102744	0.1523969	0.0469965
1012	5	1.2115304	0.1918844	0.1523969	0.8630327
1013	5	1.2313916	0.2081449	0.1523969	0.8547338
1014	1	1.7186516	0.5415401	0.1504029	0.1700387
1015	0	1.2247712	0.2027541	0.1523969	0.0501936
1016	0	1.7463718	0.5575404	0.1504029	0.0398786

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Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=H23HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 2-3 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
1017	1	1.6909315	0.5252795	0.1504029	0.1719615
1018	19	1.4202897	0.3508609	0.1479411	2.8450482
1019	2	1.3971061	0.334403	0.170297	0.3440547
1020	0	1.238012	0.2135068	0.1523969	0.0498725
1021	1	1.7186516	0.5415401	0.1504029	0.1700387
1022	0	1.2181508	0.197334	0.1523969	0.0503555
1023	2	1.4202897	0.3508609	0.1479411	0.3404587
1024	5	1.4202897	0.3508609	0.1479411	0.7824451
1025	0	1.4202897	0.3508609	0.1479411	0.0458011

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Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=H34HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 3-4 hours after meal

The GENMOD Procedure

Model Information

Data Set	WORK.ENDPOINT	
Distribution	Negative Binomial	
Link Function	Log	
Dependent Variable	AVAL	Analysis Value
Offset Variable	log_offset	

Number of Observations Read	1025
Number of Observations Used	1025

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Parameter Information

Parameter	Effect	TRTPN	REGION1	BOLAD1
Prm1	Intercept			
Prm2	TRTPN	2		
Prm3	TRTPN	3		
Prm4	TRTPN	4		
Prm5	REGION1		ASIA (EXCLUDING JAPAN)	
Prm6	REGION1		EUROPE	

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Parameter Code=H34HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 3-4 hours after meal

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Parameter Information

Parameter	Effect	TRTPN	REGION1	BOLAD1
Prm7	REGION1		JAPAN	
Prm8	REGION1		NORTH AMERICA	
Prm9	BOLAD1			BOLUS INSULIN ALGORITHM (SLIDING SCALE)
Prm10	BOLAD1			CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Criteria For Assessing Goodness Of Fit

Criterion	DF	Value	Value/DF
Deviance	1018	904.8620	0.8889
Scaled Deviance	1018	904.8620	0.8889
Pearson Chi-Square	1018	1023.9104	1.0058
Scaled Pearson X2	1018	1023.9104	1.0058
Log Likelihood		362.7856	
Full Log Likelihood		-1737.2618	
AIC (smaller is better)		3490.5236	
AICC (smaller is better)		3490.6653	
BIC (smaller is better)		3529.9832	

Algorithm converged.

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Parameter Code=H34HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 3-4 hours after meal

The GENMOD Procedure

Analysis Of Maximum Likelihood Parameter Estimates

Parameter		DF	Estimate	Standard Error	Wald 95% Confidence Limits		Wald Chi-Square
Intercept		1	5.9878	0.1417	5.7102	6.2655	1786.76
TRTPN	2	1	-0.3255	0.1442	-0.6082	-0.0429	5.10
TRTPN	3	1	0.0025	0.1415	-0.2749	0.2799	0.00
TRTPN	4	0	0.0000	0.0000	0.0000	0.0000	.
REGION1	ASIA (EXCLUDING JAPAN)	1	-0.4979	0.2183	-0.9258	-0.0700	5.20
REGION1	EUROPE	1	-0.0428	0.1484	-0.3337	0.2480	0.08
REGION1	JAPAN	1	0.1283	0.1694	-0.2037	0.4602	0.57
REGION1	NORTH AMERICA	0	0.0000	0.0000	0.0000	0.0000	.
BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	1	0.0471	0.1325	-0.2126	0.3068	0.13
BOLAD1	CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY	0	0.0000	0.0000	0.0000	0.0000	.
Dispersion		1	2.8981	0.2016	2.5287	3.3213	

Analysis Of Maximum Likelihood Parameter Estimates

Parameter		Pr > ChiSq
Intercept		<.0001
TRTPN	2	0.0240
TRTPN	3	0.9858
TRTPN	4	.
REGION1	ASIA (EXCLUDING JAPAN)	0.0226
REGION1	EUROPE	0.7729
REGION1	JAPAN	0.4489
REGION1	NORTH AMERICA	.
BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.7222
BOLAD1	CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY	.
Dispersion		

NOTE: The negative binomial dispersion parameter was estimated by maximum likelihood.

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Parameter Code=H34HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 3-4 hours after meal

The GENMOD Procedure

Coefficients for TRTPN Least Squares Means Using WORK.ENDPOINT Margins

Parameter	Geographic Region Grouping Method 1
Intercept	
Planned Treatment (N) 2	
Planned Treatment (N) 3	
Planned Treatment (N) 4	
Geographic Region Grouping Method 1 ASIA (EXCLUDING JAPAN)	ASIA (EXCLUDING JAPAN)
Geographic Region Grouping Method 1 EUROPE	EUROPE
Geographic Region Grouping Method 1 JAPAN	JAPAN
Geographic Region Grouping Method 1 NORTH AMERICA	NORTH AMERICA
Bolus Adjustment Method at Timepoint 1 BOLUS INSULIN ALGORITHM (SLIDING SCALE)	
Bolus Adjustment Method at Timepoint 1 CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY	

Coefficients for TRTPN Least Squares Means Using WORK.ENDPOINT Margins

	Planned Treatment (N)	Row1	Row2	Row3
Bolus Adjustment Method at Timepoint 1				
	1	1	1	1
	2	1		
	3		1	
	4			1
		0.1307	0.1307	0.1307
		0.3366	0.3366	0.3366
		0.239	0.239	0.239
		0.2937	0.2937	0.2937
BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.5824	0.5824	0.5824
CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0.4176	0.4176	0.4176

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Parameter Code=H34HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 3-4 hours after meal

The GENMOD Procedure

TRTPN Least Squares Means

Planned Treatment (N)	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
2	WORK.ENDPOINT	5.6409	0.1034	54.55	<.0001	0.05	5.4382	5.8436
3	WORK.ENDPOINT	5.9689	0.1004	59.48	<.0001	0.05	5.7723	6.1656
4	WORK.ENDPOINT	5.9664	0.1001	59.59	<.0001	0.05	5.7702	6.1627

Differences of TRTPN Least Squares Means

Planned Treatment (N)	Planned Treatment (N)	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
2	4	WORK.ENDPOINT	-0.3255	0.1442	-2.26	0.0240	0.05	-0.6082	-0.04292
3	4	WORK.ENDPOINT	0.002516	0.1415	0.02	0.9858	0.05	-0.2749	0.2799

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) / NovoRapid (meal)	WORK.ENDPOINT	-0.3255	0.1442	-2.26	0.0240	0.05	-0.6082	-0.04292

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Parameter Code=H34HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 3-4 hours after meal

The GENMOD Procedure

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
TRTPN	Faster aspart (post) / NovoRapid (meal)	WORK.ENDPOINT	0.002516	0.1415	0.02	0.9858	0.05	-0.2749	0.2799

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
1	14	1.6483118	0.4997516	0.1778649	2.053332
2	0	1.6483118	0.4997516	0.1778649	0.0493913
3	0	1.6483118	0.4997516	0.1778649	0.0493913
4	0	1.6483118	0.4997516	0.1778649	0.0493913
5	3	1.6483118	0.4997516	0.1778649	0.4788072
6	9	1.7372041	0.552277	0.145022	1.2919787
7	3	2.288297	0.8278079	0.1771753	0.3808823
8	1	2.350479	0.8546191	0.1771753	0.1501414
9	0	1.7110193	0.5370893	0.1778649	0.0481907
10	0	0.4031078	-0.908551	0.1468492	0.0857455
11	2	1.6303953	0.4888225	0.1778649	0.3380698
12	0	2.350479	0.8546191	0.1771753	0.038517
13	0	2.288297	0.8278079	0.1771753	0.0392899
14	3	2.2577369	0.8143629	0.1747854	0.384672
15	3	1.6483118	0.4997516	0.1778649	0.4788072
16	0	2.2949523	0.8307121	0.1747854	0.0392057

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The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
17	3	1.7278138	0.5468569	0.145022	0.4641401
18	0	2.5029569	0.9174728	0.1496419	0.0367414
19	1	2.3926399	0.8723973	0.1468492	0.1481635
20	0	2.2577369	0.8143629	0.1747854	0.0396808
21	4	1.7278138	0.5468569	0.145022	0.602894
22	0	0.4093699	-0.893136	0.1747854	0.085638
23	0	2.288297	0.8278079	0.1771753	0.0392899
24	0	2.3986671	0.8749132	0.1496419	0.0379381
25	1	2.3753517	0.8651455	0.1771753	0.1489684
26	0	2.288297	0.8278079	0.1771753	0.0392899
27	3	2.5494613	0.9358821	0.1771753	0.3512309
28	3	2.3986671	0.8749132	0.1496419	0.3677782
29	1	1.65727	0.5051717	0.1778649	0.1918481
30	4	2.4706608	0.9044856	0.1468492	0.4672224
31	3	2.3986671	0.8749132	0.1496419	0.3677782
32	0	1.6483118	0.4997516	0.1778649	0.0493913
33	1	2.288297	0.8278079	0.1771753	0.153154
34	0	2.3796364	0.8669477	0.1468492	0.0381647
35	0	2.4499701	0.8960758	0.1771753	0.0373401
36	0	2.2825472	0.825292	0.1747854	0.0393629
37	0	2.2825472	0.825292	0.1747854	0.0393629
38	5	2.288297	0.8278079	0.1771753	0.6086105
39	1	2.288297	0.8278079	0.1771753	0.153154
40	1	2.2509878	0.8113691	0.1771753	0.1550184
41	0	2.288297	0.8278079	0.1771753	0.0392899

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The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
42	3	2.4247395	0.8857241	0.1496419	0.3648096
43	7	2.3986671	0.8749132	0.1496419	0.8075649
44	12	2.3926399	0.8723973	0.1468492	1.3598557
45	0	1.7278138	0.5468569	0.145022	0.0478783
46	0	1.8029362	0.5894165	0.145022	0.0465266
47	4	1.7278138	0.5468569	0.145022	0.602894
48	0	2.4377758	0.8910861	0.1496419	0.0374806
49	17	2.3796364	0.8669477	0.1468492	1.918422
50	2	1.7465944	0.5576678	0.145022	0.3230428
51	2	1.7465944	0.5576678	0.145022	0.3230428
52	1	2.3986671	0.8749132	0.1496419	0.1478848
53	0	2.4247395	0.8857241	0.1496419	0.0376319
54	0	2.4186469	0.8832082	0.1468492	0.037703
55	3	2.3725946	0.8639841	0.1496419	0.3707941
56	7	1.7465944	0.5576678	0.145022	1.0118161
57	7	2.672428	0.9829874	0.1496419	0.7438822
58	15	1.765375	0.5683631	0.145022	2.0987255
59	2	2.4056434	0.8778174	0.1468492	0.2572714
60	0	2.3986671	0.8749132	0.1496419	0.0379381
61	11	2.4316503	0.8885702	0.1468492	1.2346411
62	2	1.765375	0.5683631	0.145022	0.320731
63	4	2.3725946	0.8639841	0.1496419	0.4816424
64	1	2.3926399	0.8723973	0.1468492	0.1481635
65	15	2.4638482	0.9017244	0.1496419	1.6534894
66	2	2.4377758	0.8910861	0.1496419	0.254722

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Parameter Code=H34HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 3-4 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
67	4	2.3986671	0.8749132	0.1496419	0.4777249
68	4	2.3725946	0.8639841	0.1496419	0.4816424
69	8	1.6996429	0.5304182	0.145022	1.1706329
70	0	1.7278138	0.5468569	0.145022	0.0478783
71	7	1.8123265	0.5946114	0.145022	0.9868926
72	0	2.3926399	0.8723973	0.1468492	0.0380096
73	1	2.3986671	0.8749132	0.1496419	0.1478848
74	0	2.3926399	0.8723973	0.1468492	0.0380096
75	4	1.7372041	0.552277	0.145022	0.6007157
76	1	2.3926399	0.8723973	0.1468492	0.1481635
77	0	2.3986671	0.8749132	0.1496419	0.0379381
78	2	2.3926399	0.8723973	0.1468492	0.2583173
79	0	1.7278138	0.5468569	0.145022	0.0478783
80	13	1.7372041	0.552277	0.145022	1.844989
81	0	2.3926399	0.8723973	0.1468492	0.0380096
82	0	1.7278138	0.5468569	0.145022	0.0478783
83	0	2.3926399	0.8723973	0.1468492	0.0380096
84	0	2.3536295	0.8559586	0.1468492	0.0384787
85	0	1.7278138	0.5468569	0.145022	0.0478783
86	0	2.3856308	0.8694636	0.1496419	0.0380931
87	7	1.7278138	0.5468569	0.145022	1.0191558
88	0	2.3986671	0.8749132	0.1496419	0.0379381
89	0	2.4316503	0.8885702	0.1468492	0.0375515
90	0	2.3595584	0.8584745	0.1496419	0.0384067
91	1	2.3796364	0.8669477	0.1468492	0.1487681

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Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=H34HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 3-4 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
92	8	2.3926399	0.8723973	0.1468492	0.9192403
93	1	2.3536295	0.8559586	0.1468492	0.1499919
94	0	2.3796364	0.8669477	0.1468492	0.0381647
95	0	1.7278138	0.5468569	0.145022	0.0478783
96	0	2.3536295	0.8559586	0.1468492	0.0384787
97	1	2.3986671	0.8749132	0.1496419	0.1478848
98	5	2.2825472	0.825292	0.1747854	0.609741
99	1	1.7278138	0.5468569	0.145022	0.1866323
100	3	2.2509878	0.8113691	0.1771753	0.3855188
101	0	2.3926399	0.8723973	0.1468492	0.0380096
102	0	1.6393536	0.494302	0.1778649	0.0495674
103	2	2.3256062	0.8439807	0.1771753	0.2638425
104	10	2.3926399	0.8723973	0.1468492	1.139548
105	0	2.2577369	0.8143629	0.1747854	0.0396808
106	0	2.2453317	0.8088533	0.1747854	0.0398417
107	20	2.3926399	0.8723973	0.1468492	2.2410865
108	12	2.4117033	0.8803333	0.1496419	1.3517989
109	3	2.3725946	0.8639841	0.1496419	0.3707941
110	0	1.6483118	0.4997516	0.1778649	0.0493913
111	1	2.2577369	0.8143629	0.1747854	0.1546779
112	3	2.2825472	0.825292	0.1747854	0.3815898
113	0	2.2825472	0.825292	0.1747854	0.0393629
114	1	2.2825472	0.825292	0.1747854	0.1534385
115	2	1.6483118	0.4997516	0.1778649	0.3356686
116	4	2.288297	0.8278079	0.1771753	0.4947464

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Parameter Code=H34HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 3-4 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
117	0	2.2949523	0.8307121	0.1747854	0.0392057
118	0	1.6483118	0.4997516	0.1778649	0.0493913
119	5	2.2825472	0.825292	0.1747854	0.609741
120	3	1.6483118	0.4997516	0.1778649	0.4788072
121	0	2.2825472	0.825292	0.1747854	0.0393629
122	0	1.6483118	0.4997516	0.1778649	0.0493913
123	3	2.2509878	0.8113691	0.1771753	0.3855188
124	3	2.2825472	0.825292	0.1747854	0.3815898
125	2	1.6483118	0.4997516	0.1778649	0.3356686
126	3	2.2758606	0.8223583	0.1771753	0.3824157
127	2	2.288297	0.8278079	0.1771753	0.2670181
128	0	2.3256062	0.8439807	0.1771753	0.0388226
129	1	2.3986671	0.8749132	0.1496419	0.1478848
130	0	1.7110193	0.5370893	0.1778649	0.0481907
131	0	1.8217168	0.5997793	0.145022	0.0461998
132	1	2.288297	0.8278079	0.1771753	0.153154
133	0	2.7111345	0.9973672	0.1771753	0.0345602
134	1	2.4576573	0.8992086	0.1468492	0.1452105
135	0	2.2949523	0.8307121	0.1747854	0.0392057
136	0	2.5554604	0.9382324	0.1747854	0.0361664
137	0	1.4799312	0.3919956	0.1771753	0.0529064
138	1	2.6267025	0.9657293	0.1468492	0.1380442
139	1	1.6662282	0.5105625	0.1778649	0.1911707
140	4	2.2577369	0.8143629	0.1747854	0.4996691
141	0	2.3753517	0.8651455	0.1771753	0.0382161

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Parameter Code=H34HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 3-4 hours after meal

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
142	0	2.2634242	0.8168788	0.1771753	0.0396075
143	1	2.3926399	0.8723973	0.1468492	0.1481635
144	1	1.7278138	0.5468569	0.145022	0.1866323
145	0	1.7278138	0.5468569	0.145022	0.0478783
146	0	2.4576573	0.8992086	0.1468492	0.0372521
147	2	2.5811743	0.9482445	0.1496419	0.2439197
148	9	3.1286962	1.1406164	0.1496419	0.8360663
149	1	2.4056434	0.8778174	0.1468492	0.1475636
150	0	1.6996429	0.5304182	0.145022	0.0484044
151	2	2.3986671	0.8749132	0.1496419	0.2578315
152	1	2.3926399	0.8723973	0.1468492	0.1481635
153	0	2.3536295	0.8559586	0.1468492	0.0384787
154	0	2.3856308	0.8694636	0.1496419	0.0380931
155	1	2.366633	0.8614683	0.1468492	0.1493775
156	1	1.2301283	0.2071185	0.145022	0.2301023
157	0	1.9815076	0.683858	0.1496419	0.0435865
158	4	2.3986671	0.8749132	0.1496419	0.4777249
159	6	1.7465944	0.5576678	0.145022	0.8740614
160	2	1.7559847	0.5630298	0.145022	0.321883
161	6	1.7278138	0.5468569	0.145022	0.8804019
162	1	2.3986671	0.8749132	0.1496419	0.1478848
163	3	2.3986671	0.8749132	0.1496419	0.3677782
164	1	2.3986671	0.8749132	0.1496419	0.1478848
165	8	1.6254347	0.4857753	0.1468492	1.2054314
166	1	2.3725946	0.8639841	0.1496419	0.1490975

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
167	8	2.3926399	0.8723973	0.1468492	0.9192403
168	2	2.4186469	0.8832082	0.1468492	0.2562338
169	2	2.366633	0.8614683	0.1468492	0.260434
170	2	1.7184235	0.5414073	0.145022	0.3265699
171	1	2.3856308	0.8694636	0.1496419	0.1484888
172	0	1.7559847	0.5630298	0.145022	0.0473629
173	0	1.7372041	0.552277	0.145022	0.0477053
174	5	2.3536295	0.8559586	0.1468492	0.5960446
175	0	2.4186469	0.8832082	0.1468492	0.037703
176	0	2.3796364	0.8669477	0.1468492	0.0381647
177	0	2.4899207	0.9122509	0.1496419	0.036887
178	0	1.7559847	0.5630298	0.145022	0.0473629
179	0	2.3986671	0.8749132	0.1496419	0.0379381
180	6	2.3796364	0.8669477	0.1468492	0.7017849
181	2	1.6996429	0.5304182	0.145022	0.3289616
182	0	2.366633	0.8614683	0.1468492	0.0383211
183	0	2.3986671	0.8749132	0.1496419	0.0379381
184	0	2.3986671	0.8749132	0.1496419	0.0379381
185	2	2.4377758	0.8910861	0.1496419	0.254722
186	2	2.3796364	0.8669477	0.1468492	0.2593715
187	0	1.7278138	0.5468569	0.145022	0.0478783
188	1	1.7372041	0.552277	0.145022	0.1859579
189	1	1.3036234	0.2651476	0.1496419	0.2225939
190	3	1.6996429	0.5304182	0.145022	0.4692401
191	11	2.1957111	0.786506	0.1747854	1.3315114

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Parameter Code=H34HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 3-4 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
192	0	2.366633	0.8614683	0.1468492	0.0383211
193	2	1.7278138	0.5468569	0.145022	0.3253862
194	5	2.3926399	0.8723973	0.1468492	0.5887788
195	13	2.450812	0.8964194	0.1496419	1.4437431
196	7	2.3197626	0.8414649	0.1747854	0.827935
197	0	2.3926399	0.8723973	0.1468492	0.0380096
198	0	2.3536295	0.8559586	0.1468492	0.0384787
199	0	1.7278138	0.5468569	0.145022	0.0478783
200	0	2.4056434	0.8778174	0.1468492	0.0378557
201	0	1.7465944	0.5576678	0.145022	0.0475335
202	0	0.7542017	-0.282095	0.1468492	0.0743145
203	3	1.2514785	0.2243256	0.1496419	0.5667122
204	7	1.7278138	0.5468569	0.145022	1.0191558
205	1	2.4117033	0.8803333	0.1496419	0.1472856
206	0	1.7935459	0.5841946	0.145022	0.0466916
207	0	1.7278138	0.5468569	0.145022	0.0478783
208	0	2.4117033	0.8803333	0.1496419	0.0377844
209	4	1.6996429	0.5304182	0.145022	0.6095187
210	8	2.3926399	0.8723973	0.1468492	0.9192403
211	0	2.3753517	0.8651455	0.1771753	0.0382161
212	1	2.3725946	0.8639841	0.1496419	0.1490975
213	0	2.3986671	0.8749132	0.1496419	0.0379381
214	0	2.288297	0.8278079	0.1771753	0.0392899
215	0	0.0912536	-2.394112	0.1496419	0.0570744
216	0	1.6483118	0.4997516	0.1778649	0.0493913

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Parameter Code=H34HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 3-4 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
217	0	2.2577369	0.8143629	0.1747854	0.0396808
218	0	1.65727	0.5051717	0.1778649	0.0492164
219	0	2.2949523	0.8307121	0.1747854	0.0392057
220	0	2.2577369	0.8143629	0.1747854	0.0396808
221	1	2.3796364	0.8669477	0.1468492	0.1487681
222	2	1.7278138	0.5468569	0.145022	0.3253862
223	5	2.3986671	0.8749132	0.1496419	0.5876716
224	0	2.4899207	0.9122509	0.1496419	0.036887
225	0	1.7278138	0.5468569	0.145022	0.0478783
226	3	1.7278138	0.5468569	0.145022	0.4641401
227	2	2.3986671	0.8749132	0.1496419	0.2578315
228	0	2.3926399	0.8723973	0.1468492	0.0380096
229	0	2.4836643	0.909735	0.1468492	0.0369572
230	0	2.3986671	0.8749132	0.1496419	0.0379381
231	0	2.4117033	0.8803333	0.1496419	0.0377844
232	0	2.4446538	0.8939035	0.1468492	0.0374012
233	1	2.3986671	0.8749132	0.1496419	0.1478848
234	0	1.7559847	0.5630298	0.145022	0.0473629
235	1	2.3986671	0.8749132	0.1496419	0.1478848
236	2	2.4117033	0.8803333	0.1496419	0.2567868
237	0	2.3986671	0.8749132	0.1496419	0.0379381
238	0	2.3926399	0.8723973	0.1468492	0.0380096
239	1	2.3986671	0.8749132	0.1496419	0.1478848
240	0	1.7278138	0.5468569	0.145022	0.0478783
241	0	1.7278138	0.5468569	0.145022	0.0478783

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Parameter Code=H34HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 3-4 hours after meal

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
242	0	1.7278138	0.5468569	0.145022	0.0478783
243	0	2.3926399	0.8723973	0.1468492	0.0380096
244	1	2.3016156	0.8336113	0.1468492	0.1524989
245	0	2.4899207	0.9122509	0.1496419	0.036887
246	7	1.2792206	0.246251	0.189904	1.2288893
247	0	1.2792206	0.246251	0.189904	0.0577313
248	0	1.282443	0.2487669	0.1904177	0.0576478
249	0	1.4113141	0.3445212	0.189904	0.0544725
250	0	1.282443	0.2487669	0.1904177	0.0576478
251	0	1.2792206	0.246251	0.189904	0.0577313
252	0	0.9589161	-0.041952	0.1839963	0.0671474
253	0	1.3103222	0.2702731	0.1904177	0.0569337
254	0	1.2894128	0.254187	0.1904177	0.0574678
255	0	0.9237726	-0.079289	0.1839963	0.0683195
256	0	1.2963826	0.2595778	0.1904177	0.0572888
257	0	0.9237726	-0.079289	0.1839963	0.0683195
258	0	1.282443	0.2487669	0.1904177	0.0576478
259	1	1.3242618	0.2808552	0.1904177	0.2205613
260	0	1.2894128	0.254187	0.1904177	0.0574678
261	0	1.2792206	0.246251	0.189904	0.0577313
262	0	1.282443	0.2487669	0.1904177	0.0576478
263	0	0.9237726	-0.079289	0.1839963	0.0683195
264	1	1.2861729	0.2516711	0.189904	0.2243381
265	0	1.2861729	0.2516711	0.189904	0.0575513
266	0	1.2792206	0.246251	0.189904	0.0577313

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
267	0	1.2792206	0.246251	0.189904	0.0577313
268	2	1.3209344	0.2783393	0.189904	0.3851077
269	0	0.9438546	-0.057783	0.1839963	0.0676464
270	0	1.282443	0.2487669	0.1904177	0.0576478
271	0	0.9237726	-0.079289	0.1839963	0.0683195
272	1	1.2963826	0.2595778	0.1904177	0.2233147
273	0	1.2615336	0.2323282	0.1904177	0.0581935
274	0	0.9388341	-0.063117	0.1839963	0.0678139
275	0	1.3974095	0.3346202	0.189904	0.0548001
276	0	1.2894128	0.254187	0.1904177	0.0574678
277	0	1.2963826	0.2595778	0.1904177	0.0572888
278	0	1.282443	0.2487669	0.1904177	0.0576478
279	0	0.9388341	-0.063117	0.1839963	0.0678139
280	0	0.9287931	-0.073869	0.1839963	0.0681504
281	0	1.2894128	0.254187	0.1904177	0.0574678
282	2	0.9287931	-0.073869	0.1839963	0.4631571
283	0	0.9087111	-0.095728	0.1839963	0.0688299
284	3	0.9237726	-0.079289	0.1839963	0.6622996
285	0	1.2685034	0.2378378	0.1904177	0.0580106
286	0	1.2861729	0.2516711	0.189904	0.0575513
287	0	1.2861729	0.2516711	0.189904	0.0575513
288	0	1.2931252	0.2570619	0.189904	0.0573723
289	0	1.2861729	0.2516711	0.189904	0.0575513
290	0	1.2792206	0.246251	0.189904	0.0577313
291	0	1.3000775	0.2624239	0.189904	0.0571943

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Parameter Code=H34HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 3-4 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
292	0	1.282443	0.2487669	0.1904177	0.0576478
293	0	0.9237726	-0.079289	0.1839963	0.0683195
294	0	1.2792206	0.246251	0.189904	0.0577313
295	0	1.2894128	0.254187	0.1904177	0.0574678
296	0	1.2583638	0.2298123	0.189904	0.058277
297	0	1.2722683	0.2408014	0.189904	0.0579122
298	3	1.282443	0.2487669	0.1904177	0.05588464
299	0	0.6476449	-0.434413	0.1839963	0.0782501
300	0	0.9237726	-0.079289	0.1839963	0.0683195
301	0	1.2792206	0.246251	0.189904	0.0577313
302	0	1.282443	0.2487669	0.1904177	0.0576478
303	0	1.2963826	0.2595778	0.1904177	0.0572888
304	3	1.2931252	0.2570619	0.189904	0.05561764
305	12	0.9639366	-0.03673	0.1839963	2.3963974
306	0	0.9237726	-0.079289	0.1839963	0.0683195
307	0	1.2653161	0.2353219	0.189904	0.0580941
308	3	0.9237726	-0.079289	0.1839963	0.06622996
309	0	0.9287931	-0.073869	0.1839963	0.0681504
310	0	0.9287931	-0.073869	0.1839963	0.0681504
311	0	1.2963826	0.2595778	0.1904177	0.0572888
312	2	1.2931252	0.2570619	0.189904	0.03899084
313	0	1.2792206	0.246251	0.189904	0.0577313
314	0	1.3242618	0.2808552	0.1904177	0.0565824
315	0	0.9137316	-0.090218	0.1839963	0.0686592
316	0	1.2931252	0.2570619	0.189904	0.0573723

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Parameter Code=H34HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 3-4 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
317	6	1.2894128	0.254187	0.1904177	1.0567357
318	4	0.9187521	-0.084739	0.1839963	0.8624289
319	3	1.2754732	0.2433173	0.1904177	0.5606004
320	3	0.9338136	-0.068478	0.1839963	0.6590267
321	0	1.3000775	0.2624239	0.189904	0.0571943
322	0	1.3103222	0.2702731	0.1904177	0.0569337
323	0	0.9639366	-0.03673	0.1839963	0.0669822
324	2	1.3000775	0.2624239	0.189904	0.3886984
325	0	0.9237726	-0.079289	0.1839963	0.0683195
326	0	0.9338136	-0.068478	0.1839963	0.0679818
327	1	1.3000775	0.2624239	0.189904	0.2229464
328	0	1.2792206	0.246251	0.189904	0.0577313
329	0	1.2861729	0.2516711	0.189904	0.0575513
330	0	1.2894128	0.254187	0.1904177	0.0574678
331	0	1.2792206	0.246251	0.189904	0.0577313
332	0	0.9338136	-0.068478	0.1839963	0.0679818
333	0	1.3033524	0.2649397	0.1904177	0.0571108
334	0	0.9589161	-0.041952	0.1839963	0.0671474
335	0	0.9237726	-0.079289	0.1839963	0.0683195
336	0	0.1599026	-1.833191	0.189904	0.0746665
337	1	1.2792206	0.246251	0.189904	0.2250396
338	1	0.9287931	-0.073869	0.1839963	0.2656538
339	0	1.3278866	0.2835887	0.189904	0.0564917
340	0	1.3033524	0.2649397	0.1904177	0.0571108
341	0	0.9438546	-0.057783	0.1839963	0.0676464

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Parameter Code=H34HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 3-4 hours after meal

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
342	3	1.2792206	0.246251	0.189904	0.5596562
343	2	0.9237726	-0.079289	0.1839963	0.4643062
344	3	1.3000775	0.2624239	0.189904	0.5544505
345	5	0.9237726	-0.079289	0.1839963	1.0582863
346	0	1.282443	0.2487669	0.1904177	0.0576478
347	1	1.3000775	0.2624239	0.189904	0.2229464
348	7	0.9338136	-0.068478	0.1839963	1.4470865
349	0	2.0104709	0.698369	0.1434971	0.0431428
350	0	1.4481874	0.3703127	0.1495264	0.0536207
351	0	1.4323602	0.3593236	0.1495264	0.0539834
352	2	1.456101	0.3757623	0.1495264	0.3631904
353	0	1.456101	0.3757623	0.1495264	0.053441
354	0	1.4481874	0.3703127	0.1495264	0.0536207
355	0	2.0163778	0.7013027	0.1443608	0.0430533
356	0	2.0163778	0.7013027	0.1443608	0.0430533
357	6	1.3891013	0.328657	0.1535794	1.011311
358	8	1.9284436	0.6567133	0.1421751	1.0743335
359	0	1.9445067	0.6650083	0.1430008	0.0441663
360	1	1.3891013	0.328657	0.1535794	0.2143831
361	3	2.0018083	0.6940509	0.1421751	0.4195106
362	0	1.3891013	0.328657	0.1535794	0.0549975
363	2	1.9026893	0.6432683	0.1430008	0.3047334
364	0	1.4117497	0.3448299	0.1535794	0.0544623
365	0	1.3891013	0.328657	0.1535794	0.0549975
366	0	1.3740024	0.3177279	0.1535794	0.0553595

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Parameter Code=H34HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 3-4 hours after meal

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
367	3	1.3664529	0.3122183	0.1535794	0.5384337
368	2	1.923598	0.6541974	0.1430008	0.3024295
369	2	1.3664529	0.3122183	0.1535794	0.3774698
370	0	1.986324	0.6862857	0.1430008	0.0435121
371	0	1.3664529	0.3122183	0.1535794	0.0555421
372	0	1.9389243	0.6621333	0.1421751	0.044255
373	3	2.0332503	0.7096357	0.1421751	0.4149079
374	2	1.9389243	0.6621333	0.1421751	0.3007617
375	0	1.3891013	0.328657	0.1535794	0.0549975
376	3	1.9284436	0.6567133	0.1421751	0.4306391
377	0	1.9284436	0.6567133	0.1421751	0.0444225
378	0	1.9284436	0.6567133	0.1421751	0.0444225
379	3	1.923598	0.6541974	0.1430008	0.431394
380	0	1.949405	0.6675242	0.1421751	0.0440887
381	0	1.9284436	0.6567133	0.1421751	0.0444225
382	0	1.9284436	0.6567133	0.1421751	0.0444225
383	0	1.923598	0.6541974	0.1430008	0.0445004
384	0	1.456101	0.3757623	0.1495264	0.053441
385	0	1.923598	0.6541974	0.1430008	0.0445004
386	0	1.9179629	0.6512637	0.1421751	0.0445913
387	0	1.3891013	0.328657	0.1535794	0.0549975
388	3	1.9284436	0.6567133	0.1421751	0.4306391
389	0	1.9284436	0.6567133	0.1421751	0.0444225
390	0	1.949405	0.6675242	0.1421751	0.0440887
391	0	1.923598	0.6541974	0.1430008	0.0445004

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Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
392	0	2.0214571	0.7038186	0.1434971	0.0429767
393	1	2.0873742	0.7359069	0.1434971	0.1637395
394	0	1.4481874	0.3703127	0.1495264	0.0536207
395	1	1.5352369	0.4286847	0.1495264	0.2015385
396	0	2.0324433	0.7092387	0.1434971	0.0428118
397	0	1.3740024	0.3177279	0.1535794	0.0553595
398	2	1.4640146	0.3811824	0.1495264	0.3619765
399	1	1.456101	0.3757623	0.1495264	0.2083157
400	0	1.5035826	0.4078506	0.1495264	0.0523853
401	0	1.4719282	0.3865732	0.1495264	0.0530848
402	0	2.0214571	0.7038186	0.1434971	0.0429767
403	0	2.0273364	0.7067228	0.1443608	0.0428883
404	4	2.0544157	0.7199915	0.1434971	0.5349896
405	0	1.4640146	0.3811824	0.1495264	0.0532624
406	1	2.0434295	0.7146295	0.1434971	0.1662449
407	0	1.4640146	0.3811824	0.1495264	0.0532624
408	0	1.456101	0.3757623	0.1495264	0.053441
409	0	1.9074823	0.6457842	0.1421751	0.0447613
410	0	1.3664529	0.3122183	0.1535794	0.0555421
411	0	1.9179629	0.6512637	0.1421751	0.0445913
412	9	1.3966508	0.3340771	0.1535794	1.4846084
413	0	1.980847	0.6835245	0.1421751	0.0435967
414	0	1.9445067	0.6650083	0.1430008	0.0441663
415	0	1.9074823	0.6457842	0.1421751	0.0447613
416	0	1.9131437	0.6487478	0.1430008	0.0446693

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Parameter Code=H34HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 3-4 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
417	0	1.923598	0.6541974	0.1430008	0.0445004
418	1	1.9284436	0.6567133	0.1421751	0.1731614
419	0	1.9074823	0.6457842	0.1421751	0.0447613
420	25	2.0163778	0.7013027	0.1443608	3.162323
421	0	2.0214571	0.7038186	0.1434971	0.0429767
422	5	2.0273364	0.7067228	0.1443608	0.6643514
423	7	2.0273364	0.7067228	0.1443608	0.9129367
424	1	1.4640146	0.3811824	0.1495264	0.2076194
425	1	1.4402738	0.3648333	0.1495264	0.2097209
426	0	2.0434295	0.7146295	0.1434971	0.0426482
427	0	1.4640146	0.3811824	0.1495264	0.0532624
428	3	1.4640146	0.3811824	0.1495264	0.5163336
429	0	2.076388	0.7306299	0.1434971	0.0421644
430	0	2.1478807	0.7644816	0.1443608	0.0411504
431	0	2.076388	0.7306299	0.1434971	0.0421644
432	0	2.0163778	0.7013027	0.1443608	0.0430533
433	0	1.456101	0.3757623	0.1495264	0.053441
434	1	2.0382949	0.7121136	0.1443608	0.1665425
435	0	2.0163778	0.7013027	0.1443608	0.0430533
436	0	2.0054192	0.6958531	0.1443608	0.0432195
437	0	1.3891013	0.328657	0.1535794	0.0549975
438	0	2.0602121	0.7228089	0.1443608	0.0424005
439	1	1.3966508	0.3340771	0.1535794	0.2136837
440	0	1.9340523	0.6596175	0.1430008	0.0443327
441	0	1.4798418	0.3919352	0.1495264	0.0529083

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The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
442	0	1.3891013	0.328657	0.1535794	0.0549975
443	1	2.0163778	0.7013027	0.1443608	0.1678241
444	0	2.0492535	0.7174756	0.1443608	0.0425619
445	1	1.3891013	0.328657	0.1535794	0.2143831
446	0	1.3966508	0.3340771	0.1535794	0.0548181
447	0	2.0214571	0.7038186	0.1434971	0.0429767
448	0	1.8970016	0.6402745	0.1421751	0.0449325
449	0	1.923598	0.6541974	0.1430008	0.0445004
450	0	1.456101	0.3757623	0.1495264	0.053441
451	0	2.0163778	0.7013027	0.1443608	0.0430533
452	0	2.1369221	0.7593665	0.1443608	0.0413028
453	0	1.9389243	0.6621333	0.1421751	0.044255
454	2	1.449497	0.3712166	0.1535794	0.3642091
455	8	2.1590184	0.7696537	0.1421751	0.99148
456	2	2.1259635	0.7542251	0.1443608	0.2817409
457	0	1.3740024	0.3177279	0.1535794	0.0553595
458	0	1.9598856	0.6728861	0.1421751	0.0439235
459	0	2.0018083	0.6940509	0.1421751	0.0432746
460	1	2.0054192	0.6958531	0.1443608	0.168472
461	0	2.3122593	0.8382251	0.1443608	0.0389885
462	1	1.4117497	0.3448299	0.1535794	0.212297
463	1	1.923598	0.6541974	0.1430008	0.1734649
464	0	1.456101	0.3757623	0.1495264	0.053441
465	0	1.9131437	0.6487478	0.1430008	0.0446693
466	0	2.2411807	0.8070028	0.1434971	0.0398958

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
467	0	2.0821292	0.733391	0.1443608	0.0420812
468	2	2.0434295	0.7146295	0.1434971	0.2898417
469	0	2.0214571	0.7038186	0.1434971	0.0429767
470	0	1.9284436	0.6567133	0.1421751	0.0444225
471	0	1.5827185	0.4591439	0.1495264	0.0507081
472	0	2.0873742	0.7359069	0.1434971	0.0420055
473	0	1.4419476	0.3659947	0.1535794	0.0537631
474	0	2.0654018	0.7253248	0.1434971	0.0423245
475	1	2.0104709	0.698369	0.1434971	0.1681728
476	3	1.4719282	0.3865732	0.1495264	0.5146125
477	1	2.0602121	0.7228089	0.1443608	0.1652795
478	0	2.0434295	0.7146295	0.1434971	0.0426482
479	0	1.4402738	0.3648333	0.1495264	0.0538015
480	1	2.0544157	0.7199915	0.1434971	0.1656117
481	3	2.0492535	0.7174756	0.1443608	0.4126022
482	5	2.0324433	0.7092387	0.1434971	0.6631667
483	3	1.9994848	0.6928895	0.1434971	0.4198546
484	0	2.0104709	0.698369	0.1434971	0.0431428
485	0	1.9944606	0.6903737	0.1443608	0.043387
486	0	1.4323602	0.3593236	0.1495264	0.0539834
487	0	2.0104709	0.698369	0.1434971	0.0431428
488	2	1.456101	0.3757623	0.1495264	0.3631904
489	4	1.4640146	0.3811824	0.1495264	0.6706907
490	0	2.0544157	0.7199915	0.1434971	0.0424858
491	0	2.0324433	0.7092387	0.1434971	0.0428118

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
492	0	2.0054192	0.6958531	0.1443608	0.0432195
493	0	2.0382949	0.7121136	0.1443608	0.0427245
494	3	1.4086195	0.3426101	0.1495264	0.5286779
495	9	1.456101	0.3757623	0.1495264	1.4473134
496	10	2.0492535	0.7174756	0.1443608	1.2760293
497	1	2.0214571	0.7038186	0.1434971	0.1675254
498	0	2.0214571	0.7038186	0.1434971	0.0429767
499	1	2.0492535	0.7174756	0.1443608	0.1659087
500	0	2.0163778	0.7013027	0.1443608	0.0430533
501	11	1.9944606	0.6903737	0.1443608	1.4265024
502	3	2.0434295	0.7146295	0.1434971	0.4134384
503	0	1.456101	0.3757623	0.1495264	0.053441
504	0	1.9994848	0.6928895	0.1434971	0.0433101
505	0	2.0492535	0.7174756	0.1443608	0.0425619
506	0	2.0492535	0.7174756	0.1443608	0.0425619
507	0	1.9994848	0.6928895	0.1434971	0.0433101
508	0	0.3295854	-1.10992	0.1434971	0.0862195
509	3	1.9884986	0.6873799	0.1434971	0.4214885
510	1	2.0214571	0.7038186	0.1434971	0.1675254
511	1	2.0163778	0.7013027	0.1443608	0.1678241
512	2	2.0214571	0.7038186	0.1434971	0.2920741
513	6	2.0163778	0.7013027	0.1443608	0.791678
514	12	2.0324433	0.7092387	0.1434971	1.5316636
515	7	1.456101	0.3757623	0.1495264	1.137564
516	0	1.456101	0.3757623	0.1495264	0.053441

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Parameter Code=H34HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 3-4 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
517	2	2.0214571	0.7038186	0.1434971	0.2920741
518	0	2.0324433	0.7092387	0.1434971	0.0428118
519	5	2.0382949	0.7121136	0.1443608	0.6618143
520	0	2.0544157	0.7199915	0.1434971	0.0424858
521	1	1.456101	0.3757623	0.1495264	0.2083157
522	1	2.0163778	0.7013027	0.1443608	0.1678241
523	0	2.0163778	0.7013027	0.1443608	0.0430533
524	0	2.0214571	0.7038186	0.1434971	0.0429767
525	0	1.4640146	0.3811824	0.1495264	0.0532624
526	0	1.4640146	0.3811824	0.1495264	0.0532624
527	0	2.0434295	0.7146295	0.1434971	0.0426482
528	0	1.4640146	0.3811824	0.1495264	0.0532624
529	0	1.456101	0.3757623	0.1495264	0.053441
530	1	1.4877554	0.3972685	0.1495264	0.2055557
531	0	2.0273364	0.7067228	0.1443608	0.0428883
532	0	1.495669	0.4025736	0.1495264	0.0525586
533	0	2.0214571	0.7038186	0.1434971	0.0429767
534	16	1.9994848	0.6928895	0.1434971	2.0515475
535	2	1.456101	0.3757623	0.1495264	0.3631904
536	2	2.0163778	0.7013027	0.1443608	0.2925949
537	0	2.0273364	0.7067228	0.1443608	0.0428883
538	0	2.0273364	0.7067228	0.1443608	0.0428883
539	0	1.4640146	0.3811824	0.1495264	0.0532624
540	0	2.0492535	0.7174756	0.1443608	0.0425619
541	0	1.4481874	0.3703127	0.1495264	0.0536207

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Parameter Code=H34HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 3-4 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
542	0	2.0382949	0.7121136	0.1443608	0.0427245
543	0	1.9725435	0.6793238	0.1443608	0.0437256
544	0	1.4877554	0.3972685	0.1495264	0.0527329
545	0	1.495669	0.4025736	0.1495264	0.0525586
546	3	1.456101	0.3757623	0.1495264	0.5180651
547	1	1.4719282	0.3865732	0.1495264	0.2069274
548	11	2.0324433	0.7092387	0.1434971	1.4075926
549	1	1.4481874	0.3703127	0.1495264	0.2090162
550	6	2.0163778	0.7013027	0.1443608	0.791678
551	13	2.0163778	0.7013027	0.1443608	1.6650735
552	0	1.456101	0.3757623	0.1495264	0.053441
553	0	1.4640146	0.3811824	0.1495264	0.0532624
554	1	2.0382949	0.7121136	0.1443608	0.1665425
555	0	1.456101	0.3757623	0.1495264	0.053441
556	0	1.495669	0.4025736	0.1495264	0.0525586
557	1	2.0273364	0.7067228	0.1443608	0.1671809
558	0	1.4640146	0.3811824	0.1495264	0.0532624
559	0	1.456101	0.3757623	0.1495264	0.053441
560	0	2.0492535	0.7174756	0.1443608	0.0425619
561	2	2.0214571	0.7038186	0.1434971	0.2920741
562	0	2.0273364	0.7067228	0.1443608	0.0428883
563	20	1.923598	0.6541974	0.1430008	2.6237911
564	3	2.0434295	0.7146295	0.1434971	0.4134384
565	0	2.0492535	0.7174756	0.1443608	0.0425619
566	0	1.456101	0.3757623	0.1495264	0.053441

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
567	3	1.9445067	0.6650083	0.1430008	0.4281547
568	0	2.0214571	0.7038186	0.1434971	0.0429767
569	0	1.9835021	0.684864	0.1443608	0.0435557
570	1	2.0324433	0.7092387	0.1434971	0.1668828
571	2	1.4640146	0.3811824	0.1495264	0.3619765
572	2	2.0873742	0.7359069	0.1434971	0.2854736
573	3	1.4877554	0.3972685	0.1495264	0.5112014
574	3	2.0544157	0.7199915	0.1434971	0.4118637
575	2	2.0214571	0.7038186	0.1434971	0.2920741
576	3	1.4877554	0.3972685	0.1495264	0.5112014
577	2	2.0273364	0.7067228	0.1443608	0.2914736
578	18	2.0054192	0.6958531	0.1443608	2.2977644
579	19	2.0214571	0.7038186	0.1434971	2.4094023
580	2	2.0214571	0.7038186	0.1434971	0.2920741
581	2	2.0273364	0.7067228	0.1443608	0.2914736
582	0	2.0163778	0.7013027	0.1443608	0.0430533
583	2	1.456101	0.3757623	0.1495264	0.3631904
584	0	1.9074823	0.6457842	0.1421751	0.0447613
585	6	1.9340523	0.6596175	0.1430008	0.8152043
586	0	1.986324	0.6862857	0.1430008	0.0435121
587	0	1.923598	0.6541974	0.1430008	0.0445004
588	2	1.3891013	0.328657	0.1535794	0.3737687
589	1	1.4042002	0.3394679	0.1535794	0.2129883
590	0	1.9284436	0.6567133	0.1421751	0.0444225
591	10	1.923598	0.6541974	0.1430008	1.3341457

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592	17	1.923598	0.6541974	0.1430008	2.2368975
593	1	1.9284436	0.6567133	0.1421751	0.1731614
594	5	1.3966508	0.3340771	0.1535794	0.849146
595	0	1.9284436	0.6567133	0.1421751	0.0444225
596	4	1.4947938	0.4019883	0.1535794	0.6620708
597	1	1.3891013	0.328657	0.1535794	0.2143831
598	8	1.3891013	0.328657	0.1535794	1.3300822
599	2	1.3664529	0.3122183	0.1535794	0.3774698
600	1	1.9131437	0.6487478	0.1430008	0.1741233
601	7	1.949405	0.6675242	0.1421751	0.9384876
602	0	1.3740024	0.3177279	0.1535794	0.0553595
603	0	2.0324433	0.7092387	0.1434971	0.0428118
604	1	1.3664529	0.3122183	0.1535794	0.216506
605	4	1.923598	0.6541974	0.1430008	0.5603585
606	6	1.923598	0.6541974	0.1430008	0.8182876
607	2	1.9179629	0.6512637	0.1421751	0.3030471
608	0	2.0544157	0.7199915	0.1434971	0.0424858
609	0	1.3891013	0.328657	0.1535794	0.0549975
610	0	1.949405	0.6675242	0.1421751	0.0440887
611	2	1.9758697	0.6810087	0.1430008	0.2968125
612	41	1.9284436	0.6567133	0.1421751	5.3227161
613	2	1.9340523	0.6596175	0.1430008	0.3012899
614	0	1.3966508	0.3340771	0.1535794	0.0548181
615	1	1.3815518	0.3232074	0.1535794	0.2150866
616	0	1.3891013	0.328657	0.1535794	0.0549975

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Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
617	1	1.8970016	0.6402745	0.1421751	0.1751492
618	0	1.9340523	0.6596175	0.1430008	0.0443327
619	3	1.9284436	0.6567133	0.1421751	0.4306391
620	0	1.4192992	0.3501632	0.1535794	0.054286
621	21	1.9913277	0.6888016	0.1421751	2.6868555
622	1	1.3815518	0.3232074	0.1535794	0.2150866
623	2	1.9284436	0.6567133	0.1421751	0.3019003
624	3	1.923598	0.6541974	0.1430008	0.431394
625	0	1.9026893	0.6432683	0.1430008	0.0448394
626	1	1.3891013	0.328657	0.1535794	0.2143831
627	0	1.1633546	0.1513077	0.1421751	0.0608778
628	0	1.9967784	0.6915351	0.1430008	0.0433515
629	0	1.4117497	0.3448299	0.1535794	0.0544623
630	0	1.9340523	0.6596175	0.1430008	0.0443327
631	2	1.9074823	0.6457842	0.1421751	0.3042023
632	0	1.3966508	0.3340771	0.1535794	0.0548181
633	0	1.9131437	0.6487478	0.1430008	0.0446693
634	0	1.9598856	0.6728861	0.1421751	0.0439235
635	0	1.923598	0.6541974	0.1430008	0.0445004
636	2	1.4117497	0.3448299	0.1535794	0.3701316
637	0	1.3815518	0.3232074	0.1535794	0.055178
638	2	2.1117761	0.7475293	0.1430008	0.2831023
639	0	1.9179629	0.6512637	0.1421751	0.0445913
640	1	1.3740024	0.3177279	0.1535794	0.2157942
641	1	1.9284436	0.6567133	0.1421751	0.1731614

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642	0	2.0273364	0.7067228	0.1443608	0.0428883
643	0	1.3966508	0.3340771	0.1535794	0.0548181
644	0	2.0054192	0.6958531	0.1443608	0.0432195
645	1	1.3891013	0.328657	0.1535794	0.2143831
646	2	2.0214571	0.7038186	0.1434971	0.2920741
647	0	1.3891013	0.328657	0.1535794	0.0549975
648	1	2.0214571	0.7038186	0.1434971	0.1675254
649	12	2.0821292	0.733391	0.1443608	1.5055237
650	0	2.0434295	0.7146295	0.1434971	0.0426482
651	0	1.923598	0.6541974	0.1430008	0.0445004
652	1	1.9284436	0.6567133	0.1421751	0.1731614
653	7	1.9284436	0.6567133	0.1421751	0.9455946
654	6	2.0544157	0.7199915	0.1434971	0.7812415
655	1	1.9944606	0.6903737	0.1443608	0.1691248
656	0	2.0434295	0.7146295	0.1434971	0.0426482
657	0	2.0382949	0.7121136	0.1443608	0.0427245
658	0	2.0054192	0.6958531	0.1443608	0.0432195
659	2	2.2521669	0.8118928	0.1434971	0.2701647
660	0	1.456101	0.3757623	0.1495264	0.053441
661	0	1.4042002	0.3394679	0.1535794	0.0546397
662	0	1.6149685	0.4793154	0.1434971	0.0500527
663	0	2.783478	1.0237012	0.1443608	0.0338604
664	0	2.0602121	0.7228089	0.1443608	0.0424005
665	0	2.1369221	0.7593665	0.1443608	0.0413028
666	4	1.495669	0.4025736	0.1495264	0.6618287

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
667	0	1.4719282	0.3865732	0.1495264	0.0530848
668	0	1.2054432	0.1868473	0.1443608	0.0597021
669	1	1.830082	0.6043608	0.1443608	0.1795274
670	0	1.4268486	0.3554683	0.1535794	0.0541107
671	0	1.9074823	0.6457842	0.1421751	0.0447613
672	3	1.4192992	0.3501632	0.1535794	0.526257
673	4	1.3891013	0.328657	0.1535794	0.6925398
674	1	1.9284436	0.6567133	0.1421751	0.1731614
675	7	1.9284436	0.6567133	0.1421751	0.9455946
676	1	1.923598	0.6541974	0.1430008	0.1734649
677	6	1.9026893	0.6432683	0.1430008	0.8245212
678	2	1.4947938	0.4019883	0.1535794	0.3573243
679	1	1.9179629	0.6512637	0.1421751	0.1738192
680	6	1.923598	0.6541974	0.1430008	0.8182876
681	7	1.9389243	0.6621333	0.1421751	0.9420283
682	6	1.9284436	0.6567133	0.1421751	0.8168557
683	1	1.986324	0.6862857	0.1430008	0.1696125
684	8	1.8817807	0.6322185	0.1430008	1.0927333
685	0	1.3891013	0.328657	0.1535794	0.0549975
686	0	1.9598856	0.6728861	0.1421751	0.0439235
687	0	1.449497	0.3712166	0.1535794	0.0535909
688	0	1.892235	0.6377587	0.1430008	0.0450108
689	0	1.923598	0.6541974	0.1430008	0.0445004
690	1	1.923598	0.6541974	0.1430008	0.1734649
691	0	1.9026893	0.6432683	0.1430008	0.0448394

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Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
692	0	1.9389243	0.6621333	0.1421751	0.044255
693	0	1.3891013	0.328657	0.1535794	0.0549975
694	3	1.2792206	0.246251	0.189904	0.5596562
695	4	1.3070298	0.2677572	0.189904	0.7179729
696	0	0.9237726	-0.079289	0.1839963	0.0683195
697	3	1.2514115	0.2242721	0.189904	0.5667294
698	0	0.9137316	-0.090218	0.1839963	0.0686592
699	0	1.2583638	0.2298123	0.189904	0.058277
700	11	0.9589161	-0.041952	0.1839963	2.2077116
701	0	1.282443	0.2487669	0.1904177	0.0576478
702	0	1.2792206	0.246251	0.189904	0.0577313
703	6	1.2305546	0.207465	0.189904	1.0852523
704	5	1.282443	0.2487669	0.1904177	0.8929788
705	0	1.2722683	0.2408014	0.189904	0.0579122
706	0	1.2653161	0.2353219	0.189904	0.0580941
707	0	1.2685034	0.2378378	0.1904177	0.0580106
708	3	0.9338136	-0.068478	0.1839963	0.6590267
709	0	1.2792206	0.246251	0.189904	0.0577313
710	0	1.282443	0.2487669	0.1904177	0.0576478
711	0	0.9087111	-0.095728	0.1839963	0.0688299
712	0	0.9087111	-0.095728	0.1839963	0.0688299
713	0	1.2792206	0.246251	0.189904	0.0577313
714	2	1.2583638	0.2298123	0.189904	0.3960569
715	0	1.2027455	0.1846069	0.189904	0.0597763
716	4	0.9237726	-0.079289	0.1839963	0.860293

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
717	6	1.2754732	0.2433173	0.1904177	1.0633722
718	0	1.2722683	0.2408014	0.189904	0.0579122
719	0	1.282443	0.2487669	0.1904177	0.0576478
720	0	1.2792206	0.246251	0.189904	0.0577313
721	0	1.2792206	0.246251	0.189904	0.0577313
722	14	1.2754732	0.2433173	0.1904177	2.4040968
723	0	1.2754732	0.2433173	0.1904177	0.0578287
724	8	1.282443	0.2487669	0.1904177	1.3941774
725	5	1.5050499	0.408826	0.1460596	0.8109657
726	10	2.1672546	0.7734612	0.1609443	1.2257133
727	7	1.6272015	0.4868617	0.1609106	1.060234
728	16	2.1328537	0.7574609	0.1609443	1.9591569
729	0	1.7180604	0.541196	0.1609106	0.0480593
730	3	2.075519	0.7302112	0.1609443	0.4088707
731	2	2.2819242	0.825019	0.1609443	0.267568
732	0	1.5050499	0.408826	0.1460596	0.0523533
733	5	1.9968664	0.6915791	0.1416569	0.6715047
734	0	1.9968664	0.6915791	0.1416569	0.0433501
735	4	1.449891	0.3714884	0.1460596	0.6747144
736	0	1.9581393	0.6719947	0.1404924	0.043951
737	1	1.1346973	0.1263659	0.1460596	0.2405108
738	1	1.5115628	0.4131441	0.1609106	0.2035234
739	1	1.9968664	0.6915791	0.1416569	0.168981
740	0	2.0405137	0.7132016	0.1416569	0.0426915
741	0	1.4892902	0.3982996	0.1460596	0.052699

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Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=H34HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 3-4 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
742	0	1.5280826	0.4240138	0.1609106	0.0518553
743	2	1.5280826	0.4240138	0.1609106	0.3524139
744	4	2.0077782	0.6970287	0.1416569	0.5437776
745	0	1.9968664	0.6915791	0.1416569	0.0433501
746	0	2.0456539	0.7157175	0.1404924	0.0426152
747	5	1.5198227	0.4185937	0.1609106	0.8060027
748	0	2.0296019	0.7078397	0.1416569	0.0428544
749	3	2.1099198	0.7466499	0.1609443	0.4040805
750	5	2.0784718	0.7316329	0.1404924	0.6526694
751	3	2.1046182	0.7441341	0.1620023	0.4048117
752	0	1.5198227	0.4185937	0.1609106	0.0520329
753	6	2.0237752	0.7049647	0.1404924	0.7896275
754	4	1.5115628	0.4131441	0.1609106	0.6574589
755	0	2.0894112	0.7368823	0.1404924	0.0419761
756	0	2.0128359	0.6995446	0.1404924	0.0431069
757	3	2.0018966	0.694095	0.1404924	0.4194975
758	5	2.0077782	0.6970287	0.1416569	0.6689261
759	0	1.449891	0.3714884	0.1460596	0.0535819
760	0	2.0077782	0.6970287	0.1416569	0.0431837
761	0	2.0237752	0.7049647	0.1404924	0.0429418
762	0	1.9968664	0.6915791	0.1416569	0.0433501
763	1	2.0128359	0.6995446	0.1404924	0.168033
764	5	2.0456539	0.7157175	0.1404924	0.6601209
765	0	1.9968664	0.6915791	0.1416569	0.0433501
766	0	2.1274945	0.754945	0.1620023	0.0414347

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Parameter Code=H34HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 3-4 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
767	1	2.0077782	0.6970287	0.1416569	0.1683322
768	0	1.4420111	0.3660387	0.1460596	0.0537617
769	0	2.0237752	0.7049647	0.1404924	0.0429418
770	1	2.0841611	0.7343664	0.1416569	0.1639203
771	2	2.0237752	0.7049647	0.1404924	0.2918371
772	5	2.0186901	0.7024488	0.1416569	0.6663664
773	0	1.9800179	0.6831059	0.1404924	0.0436096
774	8	2.0347145	0.7103555	0.1404924	1.0345591
775	0	2.0077782	0.6970287	0.1416569	0.0431837
776	0	2.0128359	0.6995446	0.1404924	0.0431069
777	2	1.449891	0.3714884	0.1460596	0.3641481
778	10	2.0237752	0.7049647	0.1404924	1.287418
779	0	0.4570308	-0.783004	0.1460596	0.0845837
780	0	1.449891	0.3714884	0.1460596	0.0535819
781	0	1.5198227	0.4185937	0.1609106	0.0520329
782	0	2.0347145	0.7103555	0.1404924	0.0427779
783	3	2.0077782	0.6970287	0.1416569	0.4186291
784	0	1.5050499	0.408826	0.1460596	0.0523533
785	1	1.9909572	0.6886155	0.1404924	0.1693344
786	1	1.5198227	0.4185937	0.1609106	0.2028268
787	0	1.5198227	0.4185937	0.1609106	0.0520329
788	0	2.0565932	0.7210508	0.1404924	0.0424537
789	1	1.5198227	0.4185937	0.1609106	0.2028268
790	0	2.0841611	0.7343664	0.1416569	0.0420518
791	0	2.319137	0.8411951	0.1404924	0.0389029

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Parameter Code=H34HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 3-4 hours after meal

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
792	1	1.49717	0.4035767	0.1460596	0.2047477
793	0	2.0077782	0.6970287	0.1416569	0.0431837
794	7	2.0186901	0.7024488	0.1416569	0.9157056
795	0	2.0296019	0.7078397	0.1416569	0.0428544
796	0	1.449891	0.3714884	0.1460596	0.0535819
797	1	2.0128359	0.6995446	0.1404924	0.168033
798	0	1.449891	0.3714884	0.1460596	0.0535819
799	2	2.1732471	0.7762224	0.1620023	0.2772934
800	0	1.6024218	0.4715161	0.1609106	0.0503058
801	0	1.6189416	0.4817726	0.1609106	0.049973
802	1	1.5115628	0.4131441	0.1609106	0.2035234
803	0	2.1099198	0.7466499	0.1609443	0.0416829
804	0	2.1046182	0.7441341	0.1620023	0.0417583
805	0	2.1618089	0.7709453	0.1620023	0.0409583
806	0	2.2016555	0.7892096	0.1609443	0.0404181
807	5	2.1274945	0.754945	0.1620023	0.6418348
808	0	2.2189996	0.7970565	0.1620023	0.0401873
809	1	2.1328537	0.7574609	0.1609443	0.1612219
810	1	2.1557876	0.7681562	0.1609443	0.1599805
811	0	2.1846852	0.7814718	0.1620023	0.0406465
812	0	1.5129297	0.414048	0.1460596	0.0521819
813	0	1.4814103	0.3929946	0.1460596	0.0528735
814	0	2.1769258	0.7779137	0.1404924	0.0407517
815	9	1.3947321	0.3327023	0.1460596	1.4858408
816	2	1.4577708	0.3769084	0.1460596	0.3629337

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Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
817	0	2.1099198	0.7466499	0.1609443	0.0416829
818	0	1.4262514	0.3550496	0.1460596	0.0541245
819	1	1.9968664	0.6915791	0.1416569	0.168981
820	0	2.0950729	0.7395884	0.1416569	0.0418948
821	0	2.0841611	0.7343664	0.1416569	0.0420518
822	0	2.1441078	0.7627235	0.1404924	0.0412027
823	0	1.9909572	0.6886155	0.1404924	0.0434408
824	0	1.4577708	0.3769084	0.1460596	0.0534032
825	0	1.4577708	0.3769084	0.1460596	0.0534032
826	0	1.9750427	0.68059	0.1416569	0.0436868
827	0	1.5198227	0.4185937	0.1609106	0.0520329
828	2	1.5917281	0.4648203	0.1460596	0.3433623
829	1	2.0018966	0.694095	0.1404924	0.1686813
830	2	2.0894112	0.7368823	0.1404924	0.2852742
831	2	2.1059848	0.7447832	0.1416569	0.2836616
832	7	2.0077782	0.6970287	0.1416569	0.9192231
833	3	2.0128359	0.6995446	0.1404924	0.4178852
834	0	2.0128359	0.6995446	0.1404924	0.0431069
835	2	1.49717	0.4035767	0.1460596	0.3569697
836	0	2.1846852	0.7814718	0.1620023	0.0406465
837	2	2.1846852	0.7814718	0.1620023	0.2762378
838	0	1.5198227	0.4185937	0.1609106	0.0520329
839	0	1.5033029	0.4076646	0.1609106	0.0523914
840	0	2.1046182	0.7441341	0.1620023	0.0417583
841	0	2.1557876	0.7681562	0.1609443	0.0410411

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Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
842	0	2.1961234	0.7866937	0.1620023	0.0404923
843	0	2.0931801	0.7386845	0.1620023	0.0419219
844	0	1.5198227	0.4185937	0.1609106	0.0520329
845	5	2.2533141	0.8124021	0.1620023	0.6155522
846	0	1.5280826	0.4240138	0.1609106	0.0518553
847	0	2.1046182	0.7441341	0.1620023	0.0417583
848	0	2.1099198	0.7466499	0.1609443	0.0416829
849	0	2.1328537	0.7574609	0.1609443	0.0413596
850	14	1.5198227	0.4185937	0.1609106	2.1631485
851	1	1.5363425	0.4294046	0.1609106	0.2014467
852	6	2.1099198	0.7466499	0.1609443	0.7664782
853	8	2.1099198	0.7466499	0.1609443	1.0080766
854	0	2.0077782	0.6970287	0.1416569	0.0431837
855	0	2.0077782	0.6970287	0.1416569	0.0431837
856	0	2.0128359	0.6995446	0.1404924	0.0431069
857	1	2.0128359	0.6995446	0.1404924	0.168033
858	0	1.5838483	0.4598575	0.1460596	0.0506849
859	0	1.5602087	0.4448196	0.1460596	0.051175
860	2	2.1099198	0.7466499	0.1609443	0.2832813
861	1	1.5363425	0.4294046	0.1609106	0.2014467
862	0	2.0931801	0.7386845	0.1620023	0.0419219
863	7	1.9800179	0.6831059	0.1404924	0.9282895
864	2	2.1099198	0.7466499	0.1609443	0.2832813
865	1	2.0456539	0.7157175	0.1404924	0.1661164
866	0	2.0456539	0.7157175	0.1404924	0.0426152

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
867	0	1.9968664	0.6915791	0.1416569	0.0433501
868	0	1.5286894	0.4244108	0.1460596	0.0518423
869	4	2.0456539	0.7157175	0.1404924	0.5366198
870	3	1.9859545	0.6860997	0.1416569	0.4218686
871	4	1.5198227	0.4185937	0.1609106	0.6552087
872	0	1.4656506	0.3822993	0.1460596	0.0532256
873	14	2.0296019	0.7078397	0.1416569	1.7815732
874	0	2.0186901	0.7024488	0.1416569	0.0430184
875	4	1.4735305	0.3876612	0.1460596	0.6680041
876	2	1.4656506	0.3822993	0.1460596	0.3617265
877	6	2.0296019	0.7078397	0.1416569	0.7880196
878	11	1.9800179	0.6831059	0.1404924	1.4338209
879	0	1.4420111	0.3660387	0.1460596	0.0537617
880	6	2.0128359	0.6995446	0.1404924	0.7926634
881	0	1.4420111	0.3660387	0.1460596	0.0537617
882	2	0.449151	-0.800396	0.1460596	0.5761942
883	4	1.4341313	0.3605593	0.1460596	0.6792559
884	1	2.0077782	0.6970287	0.1416569	0.1683322
885	0	1.9968664	0.6915791	0.1416569	0.0433501
886	1	2.0456539	0.7157175	0.1404924	0.1661164
887	1	2.0077782	0.6970287	0.1416569	0.1683322
888	2	1.449891	0.3714884	0.1460596	0.3641481
889	9	2.0077782	0.6970287	0.1416569	1.1695201
890	0	2.0784718	0.7316329	0.1404924	0.0421342
891	3	2.0018966	0.694095	0.1404924	0.4194975

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The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
892	1	1.9859545	0.6860997	0.1416569	0.1696347
893	0	2.0237752	0.7049647	0.1404924	0.0429418
894	0	2.0018966	0.694095	0.1404924	0.0432732
895	9	2.0950729	0.7395884	0.1416569	1.1346143
896	1	2.0077782	0.6970287	0.1416569	0.1683322
897	2	2.0984529	0.7412003	0.1609443	0.2843923
898	2	1.4656506	0.3822993	0.1460596	0.3617265
899	0	1.9471999	0.6663924	0.1404924	0.0441236
900	6	2.0128359	0.6995446	0.1404924	0.7926634
901	1	1.4420111	0.3660387	0.1460596	0.2095658
902	0	1.4420111	0.3660387	0.1460596	0.0537617
903	3	1.4656506	0.3822993	0.1460596	0.5159769
904	0	2.0018966	0.694095	0.1404924	0.0432732
905	0	2.1046182	0.7441341	0.1620023	0.0417583
906	4	2.2075615	0.7918885	0.1620023	0.5079602
907	0	2.0128359	0.6995446	0.1404924	0.0431069
908	1	1.5198227	0.4185937	0.1609106	0.2028268
909	0	2.1099198	0.7466499	0.1609443	0.0416829
910	0	2.0931801	0.7386845	0.1620023	0.0419219
911	1	1.9800179	0.6831059	0.1404924	0.1699924
912	0	2.1732471	0.7762224	0.1620023	0.0408018
913	0	2.1213868	0.75207	0.1609443	0.0415207
914	0	2.1328537	0.7574609	0.1609443	0.0413596
915	1	1.5446024	0.4347665	0.1609106	0.2007631
916	11	2.0931801	0.7386845	0.1620023	1.3783339

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
917	0	2.0931801	0.7386845	0.1620023	0.0419219
918	0	1.4577708	0.3769084	0.1460596	0.0534032
919	0	1.4656506	0.3822993	0.1460596	0.0532256
920	0	1.5115628	0.4131441	0.1609106	0.0522116
921	2	2.0186901	0.7024488	0.1416569	0.2923576
922	0	1.5693821	0.450682	0.1609106	0.0509838
923	0	1.4577708	0.3769084	0.1460596	0.0534032
924	0	2.0347145	0.7103555	0.1404924	0.0427779
925	0	1.5198227	0.4185937	0.1609106	0.0520329
926	5	2.0128359	0.6995446	0.1404924	0.6677374
927	0	2.0186901	0.7024488	0.1416569	0.0430184
928	0	2.1099198	0.7466499	0.1609443	0.0416829
929	1	1.4577708	0.3769084	0.1460596	0.2081684
930	0	1.5115628	0.4131441	0.1609106	0.0522116
931	0	2.0869859	0.7357209	0.1609443	0.0420111
932	0	2.0237752	0.7049647	0.1404924	0.0429418
933	0	1.3382627	0.2913723	0.1620023	0.0562334
934	1	1.5363425	0.4294046	0.1609106	0.2014467
935	7	1.5198227	0.4185937	0.1609106	1.1075907
936	1	2.0077782	0.6970287	0.1416569	0.1683322
937	6	1.5198227	0.4185937	0.1609106	0.9567967
938	7	2.2475233	0.8098289	0.1609443	0.8474773
939	1	2.0237752	0.7049647	0.1404924	0.1673894
940	4	1.449891	0.3714884	0.1460596	0.6747144
941	1	2.0703038	0.7276954	0.1620023	0.1647041

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
942	0	1.5129297	0.414048	0.1460596	0.0521819
943	2	1.9909572	0.6886155	0.1404924	0.2952281
944	0	1.449891	0.3714884	0.1460596	0.0535819
945	0	1.4341313	0.3605593	0.1460596	0.0539426
946	0	1.5198227	0.4185937	0.1609106	0.0520329
947	0	2.286319	0.8269431	0.1404924	0.039315
948	0	2.0894112	0.7368823	0.1404924	0.0419761
949	4	2.0237752	0.7049647	0.1404924	0.5407323
950	5	2.1961234	0.7866937	0.1620023	0.6272364
951	0	1.4577708	0.3769084	0.1460596	0.0534032
952	0	1.7428402	0.5555161	0.1609106	0.0476021
953	1	2.0077782	0.6970287	0.1416569	0.1683322
954	3	2.0732493	0.7291171	0.1416569	0.4091906
955	15	2.0018966	0.694095	0.1404924	1.9243946
956	0	1.449891	0.3714884	0.1460596	0.0535819
957	0	1.5198227	0.4185937	0.1609106	0.0520329
958	2	1.4262514	0.3550496	0.1460596	0.367836
959	3	2.0128359	0.6995446	0.1404924	0.4178852
960	0	2.0128359	0.6995446	0.1404924	0.0431069
961	0	1.449891	0.3714884	0.1460596	0.0535819
962	0	1.5198227	0.4185937	0.1609106	0.0520329
963	3	1.449891	0.3714884	0.1460596	0.5194313
964	0	2.0841611	0.7343664	0.1416569	0.0420518
965	0	1.5280826	0.4240138	0.1609106	0.0518553
966	7	2.0077782	0.6970287	0.1416569	0.9192231

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Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=H34HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 3-4 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
967	0	1.4577708	0.3769084	0.1460596	0.0534032
968	0	0.3861123	-0.951627	0.1460596	0.0859929
969	0	1.4026119	0.3383361	0.1460596	0.0546771
970	0	2.0514256	0.718535	0.1416569	0.0425299
971	0	2.1046182	0.7441341	0.1620023	0.0417583
972	1	2.0128359	0.6995446	0.1404924	0.168033
973	0	2.1443207	0.7628228	0.1609443	0.0411998
974	2	2.1046182	0.7441341	0.1620023	0.2837939
975	0	2.0984529	0.7412003	0.1609443	0.0418464
976	0	1.5198227	0.4185937	0.1609106	0.0520329
977	0	2.0405137	0.7132016	0.1416569	0.0426915
978	1	2.0931801	0.7386845	0.1620023	0.1634139
979	1	1.5050499	0.408826	0.1460596	0.2040757
980	4	2.1618089	0.7709453	0.1620023	0.5157554
981	0	1.5033029	0.4076646	0.1609106	0.0523914
982	0	1.6272015	0.4868617	0.1609106	0.0498081
983	2	2.1278084	0.7550926	0.1416569	0.2815648
984	1	1.4420111	0.3660387	0.1460596	0.2095658
985	2	1.9968664	0.6915791	0.1416569	0.294612
986	10	2.1213868	0.75207	0.1609443	1.2448108
987	0	2.0128359	0.6995446	0.1404924	0.0431069
988	0	1.9859545	0.6860997	0.1416569	0.0435178
989	7	1.9859545	0.6860997	0.1416569	0.9263363
990	0	1.4656506	0.3822993	0.1460596	0.0532256
991	4	2.0077782	0.6970287	0.1416569	0.5437776

Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=H34HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 3-4 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
992	9	1.9204835	0.652577	0.1416569	1.2065404
993	4	2.0128359	0.6995446	0.1404924	0.5428113
994	0	2.0296019	0.7078397	0.1416569	0.0428544
995	0	2.0128359	0.6995446	0.1404924	0.0431069
996	0	2.0237752	0.7049647	0.1404924	0.0429418
997	0	1.2330377	0.2094808	0.1416569	0.0589517
998	6	1.4867831	0.3966148	0.1609106	0.970065
999	0	2.0950729	0.7395884	0.1416569	0.0418948
1000	1	1.4577708	0.3769084	0.1460596	0.2081684
1001	0	1.5941619	0.4663481	0.1609106	0.0504737
1002	8	2.0984529	0.7412003	0.1609443	1.01203
1003	2	1.7131586	0.5383388	0.1416569	0.3272371
1004	0	0.7657528	-0.266896	0.1404924	0.0738916
1005	8	2.0186901	0.7024488	0.1416569	1.0403752
1006	1	1.449891	0.3714884	0.1460596	0.208865
1007	3	1.4577708	0.3769084	0.1460596	0.5176989
1008	1	2.0077782	0.6970287	0.1416569	0.1683322
1009	1	2.0623374	0.72384	0.1416569	0.165158
1010	0	1.9909572	0.6886155	0.1404924	0.0434408
1011	0	1.6232475	0.4844288	0.1460596	0.0498869
1012	3	1.4420111	0.3660387	0.1460596	0.5211741
1013	3	1.4656506	0.3822993	0.1460596	0.5159769
1014	0	2.0347145	0.7103555	0.1404924	0.0427779
1015	0	1.4577708	0.3769084	0.1460596	0.0534032
1016	4	2.0675325	0.7263559	0.1404924	0.5325668

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Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=H34HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 3-4 hours after meal

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
1017	4	2.0018966	0.694095	0.1404924	0.5449056
1018	11	2.0077782	0.6970287	0.1416569	1.4198171
1019	1	1.5198227	0.4185937	0.1609106	0.2028268
1020	3	1.4735305	0.3876612	0.1460596	0.5142653
1021	3	2.0347145	0.7103555	0.1404924	0.4146959
1022	0	1.449891	0.3714884	0.1460596	0.0535819
1023	7	2.0077782	0.6970287	0.1416569	0.9192231
1024	2	2.0077782	0.6970287	0.1416569	0.2934806
1025	0	2.0077782	0.6970287	0.1416569	0.0431837

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Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=HY1HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 1 hour after meal

The GENMOD Procedure

Model Information

Data Set	WORK.ENDPOINT	
Distribution	Negative Binomial	
Link Function	Log	
Dependent Variable	AVAL	Analysis Value
Offset Variable	log_offset	

Number of Observations Read	1025
Number of Observations Used	1025

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Parameter Information

Parameter	Effect	TRTPN	REGION1	BOLAD1
Prm1	Intercept			
Prm2	TRTPN	2		
Prm3	TRTPN	3		
Prm4	TRTPN	4		
Prm5	REGION1		ASIA (EXCLUDING JAPAN)	
Prm6	REGION1		EUROPE	

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Parameter Code=HY1HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 1 hour after meal

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Parameter Information

Parameter	Effect	TRTPN	REGION1	BOLAD1
Prm7	REGION1		JAPAN	
Prm8	REGION1		NORTH AMERICA	
Prm9	BOLAD1			BOLUS INSULIN ALGORITHM (SLIDING SCALE)
Prm10	BOLAD1			CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Criteria For Assessing Goodness Of Fit

Criterion	DF	Value	Value/DF
Deviance	1018	593.2039	0.5827
Scaled Deviance	1018	593.2039	0.5827
Pearson Chi-Square	1018	1685.2548	1.6555
Scaled Pearson X2	1018	1685.2548	1.6555
Log Likelihood		-124.2355	
Full Log Likelihood		-1006.5615	
AIC (smaller is better)		2029.1229	
AICC (smaller is better)		2029.2646	
BIC (smaller is better)		2068.5825	

Algorithm converged.

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Parameter Code=HY1HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 1 hour after meal

The GENMOD Procedure

Analysis Of Maximum Likelihood Parameter Estimates

Parameter		DF	Estimate	Standard Error	Wald 95% Confidence Limits	Wald Chi-Square
Intercept		1	4.7944	0.1999	4.4026 5.1861	575.49
TRTPN	2	1	0.0845	0.2066	-0.3205 0.4895	0.17
TRTPN	3	1	0.2339	0.2054	-0.1686 0.6364	1.30
TRTPN	4	0	0.0000	0.0000	0.0000 0.0000	.
REGION1	ASIA (EXCLUDING JAPAN)	1	0.6416	0.3035	0.0467 1.2365	4.47
REGION1	EUROPE	1	0.0275	0.2190	-0.4018 0.4568	0.02
REGION1	JAPAN	1	-0.4612	0.2539	-0.9589 0.0365	3.30
REGION1	NORTH AMERICA	0	0.0000	0.0000	0.0000 0.0000	.
BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	1	0.0432	0.1962	-0.3413 0.4277	0.05
BOLAD1	CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY	0	0.0000	0.0000	0.0000 0.0000	.
Dispersion		1	5.5675	0.5104	4.6519 6.6634	

Analysis Of Maximum Likelihood Parameter Estimates

Parameter	Pr > ChiSq
Intercept	<.0001
TRTPN 2	0.6826
TRTPN 3	0.2547
TRTPN 4	.
REGION1 ASIA (EXCLUDING JAPAN)	0.0345
REGION1 EUROPE	0.9000
REGION1 JAPAN	0.0693
REGION1 NORTH AMERICA	.
BOLAD1 BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.8258
BOLAD1 CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY	.
Dispersion	

NOTE: The negative binomial dispersion parameter was estimated by maximum likelihood.

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Parameter Code=HY1HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 1 hour after meal

The GENMOD Procedure

Coefficients for TRTPN Least Squares Means Using WORK.ENDPOINT Margins

Parameter	Geographic Region Grouping Method 1
Intercept	
Planned Treatment (N) 2	
Planned Treatment (N) 3	
Planned Treatment (N) 4	
Geographic Region Grouping Method 1 ASIA (EXCLUDING JAPAN)	ASIA (EXCLUDING JAPAN)
Geographic Region Grouping Method 1 EUROPE	EUROPE
Geographic Region Grouping Method 1 JAPAN	JAPAN
Geographic Region Grouping Method 1 NORTH AMERICA	NORTH AMERICA
Bolus Adjustment Method at Timepoint 1 BOLUS INSULIN ALGORITHM (SLIDING SCALE)	
Bolus Adjustment Method at Timepoint 1 CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY	

Coefficients for TRTPN Least Squares Means Using WORK.ENDPOINT Margins

Bolus Adjustment Method at Timepoint 1	Planned Treatment (N)	Row1	Row2	Row3
	1	1	1	1
	2	1		
	3		1	
	4			1
		0.1307	0.1307	0.1307
		0.3366	0.3366	0.3366
		0.239	0.239	0.239
		0.2937	0.2937	0.2937
BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.5824	0.5824	0.5824
CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0.4176	0.4176	0.4176

Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=HY1HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 1 hour after meal

The GENMOD Procedure

TRTPN Least Squares Means

Planned Treatment (N)	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
2	WORK.ENDPOINT	4.8869	0.1452	33.65	<.0001	0.05	4.6022	5.1716
3	WORK.ENDPOINT	5.0363	0.1434	35.12	<.0001	0.05	4.7552	5.3174
4	WORK.ENDPOINT	4.8024	0.1467	32.74	<.0001	0.05	4.5149	5.0899

Differences of TRTPN Least Squares Means

Planned Treatment (N)	Planned Treatment (N)	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
2	4	WORK.ENDPOINT	0.08451	0.2066	0.41	0.6826	0.05	-0.3205	0.4895
3	4	WORK.ENDPOINT	0.2339	0.2054	1.14	0.2547	0.05	-0.1686	0.6364

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) / NovoRapid (meal)	WORK.ENDPOINT	0.08451	0.2066	0.41	0.6826	0.05	-0.3205	0.4895

Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=HY1HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 1 hour after meal

The GENMOD Procedure

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
TRTPN	Faster aspart (post) / NovoRapid (meal)	WORK.ENDPOINT	0.2339	0.2054	1.14	0.2547	0.05	-0.1686	0.6364

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
1	0	0.417641	-0.873133	0.2692003	0.0377713
2	0	0.417641	-0.873133	0.2692003	0.0377713
3	0	0.417641	-0.873133	0.2692003	0.0377713
4	0	0.417641	-0.873133	0.2692003	0.0377713
5	0	0.417641	-0.873133	0.2692003	0.0377713
6	5	0.4384399	-0.824533	0.2243688	1.0678104
7	0	0.4849389	-0.723732	0.2574099	0.0354247
8	0	0.4981166	-0.696921	0.2574099	0.034986
9	0	0.4335295	-0.835795	0.2692003	0.0372025
10	0	0.0675147	-2.695411	0.221855	0.0356641
11	0	0.4131014	-0.884062	0.2692003	0.0379352
12	0	0.4981166	-0.696921	0.2574099	0.034986
13	0	0.4849389	-0.723732	0.2574099	0.0354247
14	1	0.3796249	-0.968572	0.2516395	0.2571812
15	0	0.417641	-0.873133	0.2692003	0.0377713
16	0	0.3858825	-0.952222	0.2516395	0.038929

Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=HY1HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 1 hour after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
17	2	0.4360699	-0.829953	0.2243688	0.4503596
18	1	0.5283522	-0.637992	0.2189668	0.2233456
19	0	0.4007321	-0.914462	0.221855	0.0383847
20	1	0.3796249	-0.968572	0.2516395	0.2571812
21	0	0.4360699	-0.829953	0.2243688	0.0371123
22	0	0.0688331	-2.676071	0.2516395	0.0359757
23	0	0.4849389	-0.723732	0.2574099	0.0354247
24	0	0.5063375	-0.680552	0.2189668	0.0347161
25	0	0.5033877	-0.686395	0.2574099	0.0348126
26	0	0.4849389	-0.723732	0.2574099	0.0354247
27	0	0.5402852	-0.615658	0.2574099	0.0336324
28	2	0.5063375	-0.680552	0.2189668	0.4212812
29	0	0.4199108	-0.867713	0.2692003	0.0376895
30	1	0.4137995	-0.882374	0.221855	0.2489742
31	2	0.5063375	-0.680552	0.2189668	0.4212812
32	0	0.417641	-0.873133	0.2692003	0.0377713
33	0	0.4849389	-0.723732	0.2574099	0.0354247
34	0	0.3985542	-0.919912	0.221855	0.0384642
35	0	0.5192009	-0.655464	0.2574099	0.0342996
36	0	0.3837966	-0.957642	0.2516395	0.0390058
37	0	0.3837966	-0.957642	0.2516395	0.0390058
38	0	0.4849389	-0.723732	0.2574099	0.0354247
39	0	0.4849389	-0.723732	0.2574099	0.0354247
40	0	0.4770323	-0.740171	0.2574099	0.0356913
41	2	0.4849389	-0.723732	0.2574099	0.4298795

Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=HY1HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 1 hour after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
42	1	0.5118411	-0.669741	0.2189668	0.2268225
43	1	0.5063375	-0.680552	0.2189668	0.2279987
44	0	0.4007321	-0.914462	0.221855	0.0383847
45	0	0.4360699	-0.829953	0.2243688	0.0371123
46	0	0.4550295	-0.787393	0.2243688	0.0364467
47	0	0.4360699	-0.829953	0.2243688	0.0371123
48	0	0.514593	-0.664379	0.2189668	0.034448
49	1	0.3985542	-0.919912	0.221855	0.2526144
50	1	0.4408098	-0.819142	0.2243688	0.242635
51	0	0.4408098	-0.819142	0.2243688	0.0369447
52	0	0.5063375	-0.680552	0.2189668	0.0347161
53	0	0.5118411	-0.669741	0.2189668	0.034537
54	0	0.4050879	-0.903651	0.221855	0.0382259
55	0	0.5008338	-0.691481	0.2189668	0.0348965
56	0	0.4408098	-0.819142	0.2243688	0.0369447
57	0	0.564126	-0.572478	0.2189668	0.0329012
58	2	0.4455497	-0.808446	0.2243688	0.4463007
59	0	0.40291	-0.909042	0.221855	0.0383053
60	0	0.5063375	-0.680552	0.2189668	0.0347161
61	2	0.4072658	-0.898289	0.221855	0.4629121
62	0	0.4455497	-0.808446	0.2243688	0.0367779
63	0	0.5008338	-0.691481	0.2189668	0.0348965
64	0	0.4007321	-0.914462	0.221855	0.0383847
65	1	0.5200966	-0.653741	0.2189668	0.2250744
66	2	0.514593	-0.664379	0.2189668	0.4180273

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
67	1	0.5063375	-0.680552	0.2189668	0.2279987
68	1	0.5008338	-0.691481	0.2189668	0.2291833
69	0	0.4289601	-0.846391	0.2243688	0.0373652
70	0	0.4360699	-0.829953	0.2243688	0.0371123
71	0	0.4573995	-0.782198	0.2243688	0.0363644
72	0	0.4007321	-0.914462	0.221855	0.0383847
73	0	0.5063375	-0.680552	0.2189668	0.0347161
74	0	0.4007321	-0.914462	0.221855	0.0383847
75	0	0.4384399	-0.824533	0.2243688	0.0370284
76	0	0.4007321	-0.914462	0.221855	0.0383847
77	1	0.5063375	-0.680552	0.2189668	0.2279987
78	0	0.4007321	-0.914462	0.221855	0.0383847
79	0	0.4360699	-0.829953	0.2243688	0.0371123
80	0	0.4384399	-0.824533	0.2243688	0.0370284
81	0	0.4007321	-0.914462	0.221855	0.0383847
82	0	0.4360699	-0.829953	0.2243688	0.0371123
83	0	0.4007321	-0.914462	0.221855	0.0383847
84	0	0.3941985	-0.930901	0.221855	0.0386236
85	0	0.4360699	-0.829953	0.2243688	0.0371123
86	0	0.5035856	-0.686001	0.2189668	0.0348061
87	2	0.4360699	-0.829953	0.2243688	0.4503596
88	0	0.5063375	-0.680552	0.2189668	0.0347161
89	1	0.4072658	-0.898289	0.221855	0.2505294
90	0	0.498082	-0.696991	0.2189668	0.0349872
91	0	0.3985542	-0.919912	0.221855	0.0384642

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
92	2	0.4007321	-0.914462	0.221855	0.4657994
93	3	0.3941985	-0.930901	0.221855	0.6837366
94	0	0.3985542	-0.919912	0.221855	0.0384642
95	0	0.4360699	-0.829953	0.2243688	0.0371123
96	0	0.3941985	-0.930901	0.221855	0.0386236
97	0	0.5063375	-0.680552	0.2189668	0.0347161
98	0	0.3837966	-0.957642	0.2516395	0.0390058
99	0	0.4360699	-0.829953	0.2243688	0.0371123
100	0	0.4770323	-0.740171	0.2574099	0.0356913
101	1	0.4007321	-0.914462	0.221855	0.252092
102	0	0.4153712	-0.878583	0.2692003	0.0378531
103	0	0.4928455	-0.707559	0.2574099	0.0351606
104	2	0.4007321	-0.914462	0.221855	0.4657994
105	0	0.3796249	-0.968572	0.2516395	0.0391596
106	0	0.3775391	-0.974081	0.2516395	0.0392366
107	1	0.4007321	-0.914462	0.221855	0.252092
108	0	0.5090893	-0.675132	0.2189668	0.0346264
109	3	0.5008338	-0.691481	0.2189668	0.617757
110	0	0.417641	-0.873133	0.2692003	0.0377713
111	0	0.3796249	-0.968572	0.2516395	0.0391596
112	4	0.3837966	-0.957642	0.2516395	0.9076674
113	0	0.3837966	-0.957642	0.2516395	0.0390058
114	0	0.3837966	-0.957642	0.2516395	0.0390058
115	0	0.417641	-0.873133	0.2692003	0.0377713
116	0	0.4849389	-0.723732	0.2574099	0.0354247

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Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=HY1HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 1 hour after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
117	0	0.3858825	-0.952222	0.2516395	0.038929
118	0	0.417641	-0.873133	0.2692003	0.0377713
119	1	0.3837966	-0.957642	0.2516395	0.2561712
120	0	0.417641	-0.873133	0.2692003	0.0377713
121	0	0.3837966	-0.957642	0.2516395	0.0390058
122	0	0.417641	-0.873133	0.2692003	0.0377713
123	1	0.4770323	-0.740171	0.2574099	0.2344034
124	0	0.3837966	-0.957642	0.2516395	0.0390058
125	0	0.417641	-0.873133	0.2692003	0.0377713
126	0	0.4823034	-0.729182	0.2574099	0.0355133
127	1	0.4849389	-0.723732	0.2574099	0.2326521
128	0	0.4928455	-0.707559	0.2574099	0.0351606
129	0	0.5063375	-0.680552	0.2189668	0.0347161
130	0	0.4335295	-0.835795	0.2692003	0.0372025
131	0	0.4597694	-0.77703	0.2243688	0.0362823
132	1	0.4849389	-0.723732	0.2574099	0.2326521
133	0	0.5745472	-0.554173	0.2574099	0.0325893
134	0	0.4116216	-0.887651	0.221855	0.0379887
135	0	0.3858825	-0.952222	0.2516395	0.038929
136	0	0.4296854	-0.844702	0.2516395	0.0373394
137	0	0.313629	-1.159545	0.2574099	0.0415884
138	0	0.4399342	-0.82113	0.221855	0.0369756
139	0	0.4221806	-0.862322	0.2692003	0.0376079
140	1	0.3796249	-0.968572	0.2516395	0.2571812
141	10	0.5033877	-0.686395	0.2574099	1.9730117

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Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=HY1HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 1 hour after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
142	0	0.4796679	-0.734661	0.2574099	0.0356021
143	1	0.4007321	-0.914462	0.221855	0.252092
144	1	0.4360699	-0.829953	0.2243688	0.243736
145	0	0.4360699	-0.829953	0.2243688	0.0371123
146	1	0.4116216	-0.887651	0.221855	0.2494917
147	0	0.5448632	-0.607221	0.2189668	0.0334901
148	0	0.6604402	-0.414849	0.2189668	0.0301923
149	0	0.40291	-0.909042	0.221855	0.0383053
150	0	0.4289601	-0.846391	0.2243688	0.0373652
151	0	0.5063375	-0.680552	0.2189668	0.0347161
152	0	0.4007321	-0.914462	0.221855	0.0383847
153	0	0.3941985	-0.930901	0.221855	0.0386236
154	0	0.5035856	-0.686001	0.2189668	0.0348061
155	4	0.3963764	-0.925391	0.221855	0.8969184
156	0	0.3104628	-1.169691	0.2243688	0.0417022
157	0	0.4182788	-0.871607	0.2189668	0.0377483
158	0	0.5063375	-0.680552	0.2189668	0.0347161
159	3	0.4408098	-0.819142	0.2243688	0.6540156
160	0	0.4431798	-0.81378	0.2243688	0.0368612
161	0	0.4360699	-0.829953	0.2243688	0.0371123
162	0	0.5063375	-0.680552	0.2189668	0.0347161
163	0	0.5063375	-0.680552	0.2189668	0.0347161
164	0	0.5063375	-0.680552	0.2189668	0.0347161
165	0	0.2722365	-1.301084	0.221855	0.0430165
166	0	0.5008338	-0.691481	0.2189668	0.0348965

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Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=HY1HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 1 hour after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
167	0	0.4007321	-0.914462	0.221855	0.0383847
168	1	0.4050879	-0.903651	0.221855	0.2510495
169	0	0.3963764	-0.925391	0.221855	0.0385439
170	0	0.4337	-0.835402	0.2243688	0.0371965
171	2	0.5035856	-0.686001	0.2189668	0.4223737
172	0	0.4431798	-0.81378	0.2243688	0.0368612
173	0	0.4384399	-0.824533	0.2243688	0.0370284
174	0	0.3941985	-0.930901	0.221855	0.0386236
175	0	0.4050879	-0.903651	0.221855	0.0382259
176	1	0.3985542	-0.919912	0.221855	0.2526144
177	1	0.5256003	-0.643214	0.2189668	0.2239197
178	1	0.4431798	-0.81378	0.2243688	0.2420865
179	0	0.5063375	-0.680552	0.2189668	0.0347161
180	0	0.3985542	-0.919912	0.221855	0.0384642
181	0	0.4289601	-0.846391	0.2243688	0.0373652
182	0	0.3963764	-0.925391	0.221855	0.0385439
183	0	0.5063375	-0.680552	0.2189668	0.0347161
184	0	0.5063375	-0.680552	0.2189668	0.0347161
185	0	0.514593	-0.664379	0.2189668	0.034448
186	0	0.3985542	-0.919912	0.221855	0.0384642
187	0	0.4360699	-0.829953	0.2243688	0.0371123
188	0	0.4384399	-0.824533	0.2243688	0.0370284
189	0	0.2751834	-1.290317	0.2189668	0.0429205
190	0	0.4289601	-0.846391	0.2243688	0.0373652
191	1	0.3691957	-0.996429	0.2516395	0.2597122

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Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=HY1HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 1 hour after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
192	0	0.3963764	-0.925391	0.221855	0.0385439
193	0	0.4360699	-0.829953	0.2243688	0.0371123
194	0	0.4007321	-0.914462	0.221855	0.0383847
195	1	0.5173448	-0.659046	0.2189668	0.2256549
196	3	0.3900542	-0.94147	0.2516395	0.6864278
197	0	0.4007321	-0.914462	0.221855	0.0383847
198	0	0.3941985	-0.930901	0.221855	0.0386236
199	0	0.4360699	-0.829953	0.2243688	0.0371123
200	0	0.40291	-0.909042	0.221855	0.0383053
201	0	0.4408098	-0.819142	0.2243688	0.0369447
202	0	0.1263177	-2.068955	0.221855	0.0435406
203	1	0.2641761	-1.331139	0.2189668	0.2841959
204	3	0.4360699	-0.829953	0.2243688	0.6569832
205	1	0.5090893	-0.675132	0.2189668	0.2274095
206	1	0.4526596	-0.792615	0.2243688	0.2399058
207	1	0.4360699	-0.829953	0.2243688	0.243736
208	0	0.5090893	-0.675132	0.2189668	0.0346264
209	0	0.4289601	-0.846391	0.2243688	0.0373652
210	1	0.4007321	-0.914462	0.221855	0.252092
211	0	0.5033877	-0.686395	0.2574099	0.0348126
212	0	0.5008338	-0.691481	0.2189668	0.0348965
213	1	0.5063375	-0.680552	0.2189668	0.2279987
214	0	0.4849389	-0.723732	0.2574099	0.0354247
215	0	0.0192628	-3.949577	0.2189668	0.015712
216	0	0.417641	-0.873133	0.2692003	0.0377713

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Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=HY1HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 1 hour after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
217	0	0.3796249	-0.968572	0.2516395	0.0391596
218	0	0.4199108	-0.867713	0.2692003	0.0376895
219	0	0.3858825	-0.952222	0.2516395	0.038929
220	0	0.3796249	-0.968572	0.2516395	0.0391596
221	0	0.3985542	-0.919912	0.221855	0.0384642
222	0	0.4360699	-0.829953	0.2243688	0.0371123
223	3	0.5063375	-0.680552	0.2189668	0.6145637
224	0	0.5256003	-0.643214	0.2189668	0.034095
225	5	0.4360699	-0.829953	0.2243688	1.0702304
226	2	0.4360699	-0.829953	0.2243688	0.4503596
227	0	0.5063375	-0.680552	0.2189668	0.0347161
228	0	0.4007321	-0.914462	0.221855	0.0383847
229	0	0.4159774	-0.877124	0.221855	0.0378313
230	0	0.5063375	-0.680552	0.2189668	0.0347161
231	0	0.5090893	-0.675132	0.2189668	0.0346264
232	0	0.4094437	-0.892956	0.221855	0.0380677
233	0	0.5063375	-0.680552	0.2189668	0.0347161
234	0	0.4431798	-0.81378	0.2243688	0.0368612
235	0	0.5063375	-0.680552	0.2189668	0.0347161
236	0	0.5090893	-0.675132	0.2189668	0.0346264
237	0	0.5063375	-0.680552	0.2189668	0.0347161
238	2	0.4007321	-0.914462	0.221855	0.4657994
239	0	0.5063375	-0.680552	0.2189668	0.0347161
240	0	0.4360699	-0.829953	0.2243688	0.0371123
241	0	0.4360699	-0.829953	0.2243688	0.0371123

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Parameter Code=HY1HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 1 hour after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
242	0	0.4360699	-0.829953	0.2243688	0.0371123
243	0	0.4007321	-0.914462	0.221855	0.0383847
244	0	0.3854869	-0.953248	0.221855	0.0389436
245	0	0.5256003	-0.643214	0.2189668	0.034095
246	1	1.2071951	0.1882995	0.2497661	0.1329911
247	1	1.2071951	0.1882995	0.2497661	0.1329911
248	0	1.5253284	0.4222097	0.2584371	0.0169286
249	0	1.3318511	0.2865698	0.2497661	0.0188077
250	0	1.5253284	0.4222097	0.2584371	0.0169286
251	0	1.2071951	0.1882995	0.2497661	0.0202498
252	0	1.3636251	0.3101466	0.2383948	0.0184717
253	0	1.5584877	0.4437159	0.2584371	0.0166429
254	0	1.5336182	0.4276298	0.2584371	0.0168563
255	12	1.3136493	0.272809	0.2383948	1.2887807
256	0	1.541908	0.4330206	0.2584371	0.0167846
257	0	1.3136493	0.272809	0.2383948	0.0190057
258	0	1.5253284	0.4222097	0.2584371	0.0169286
259	0	1.5750674	0.454298	0.2584371	0.0165036
260	0	1.5336182	0.4276298	0.2584371	0.0168563
261	0	1.2071951	0.1882995	0.2497661	0.0202498
262	0	1.5253284	0.4222097	0.2584371	0.0169286
263	0	1.3136493	0.272809	0.2383948	0.0190057
264	15	1.2137559	0.1937196	0.2497661	1.7045043
265	0	1.2137559	0.1937196	0.2497661	0.0201686
266	0	1.2071951	0.1882995	0.2497661	0.0202498

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The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
267	0	1.2071951	0.1882995	0.2497661	0.0202498
268	2	1.2465601	0.2203879	0.2497661	0.239931
269	0	1.3422069	0.2943152	0.2383948	0.0186969
270	0	1.5253284	0.4222097	0.2584371	0.0169286
271	0	1.3136493	0.272809	0.2383948	0.0190057
272	0	1.541908	0.4330206	0.2584371	0.0167846
273	0	1.5004589	0.405771	0.2584371	0.0171492
274	0	1.3350675	0.2889818	0.2383948	0.0187732
275	0	1.3187294	0.2766687	0.2497661	0.01895
276	0	1.5336182	0.4276298	0.2584371	0.0168563
277	0	1.541908	0.4330206	0.2584371	0.0167846
278	0	1.5253284	0.4222097	0.2584371	0.0169286
279	0	1.3350675	0.2889818	0.2383948	0.0187732
280	0	1.3207887	0.278229	0.2383948	0.0189276
281	0	1.5336182	0.4276298	0.2584371	0.0168563
282	0	1.3207887	0.278229	0.2383948	0.0189276
283	0	1.2922311	0.2563702	0.2383948	0.0192439
284	1	1.3136493	0.272809	0.2383948	0.1248203
285	0	1.5087487	0.4112807	0.2584371	0.0170751
286	0	1.2137559	0.1937196	0.2497661	0.0201686
287	0	1.2137559	0.1937196	0.2497661	0.0201686
288	0	1.2203168	0.1991105	0.2497661	0.020088
289	0	1.2137559	0.1937196	0.2497661	0.0201686
290	0	1.2071951	0.1882995	0.2497661	0.0202498
291	0	1.2268776	0.2044724	0.2497661	0.020008

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Parameter Code=HY1HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 1 hour after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
292	0	1.5253284	0.4222097	0.2584371	0.0169286
293	1	1.3136493	0.272809	0.2383948	0.1248203
294	0	1.2071951	0.1882995	0.2497661	0.0202498
295	0	1.5336182	0.4276298	0.2584371	0.0168563
296	0	1.1875125	0.1718608	0.2497661	0.0204974
297	0	1.2006342	0.1828499	0.2497661	0.0203317
298	0	1.5253284	0.4222097	0.2584371	0.0169286
299	0	0.9209824	-0.082314	0.2383948	0.0245286
300	55	1.3136493	0.272809	0.2383948	5.8388077
301	0	1.2071951	0.1882995	0.2497661	0.0202498
302	0	1.5253284	0.4222097	0.2584371	0.0169286
303	0	1.541908	0.4330206	0.2584371	0.0167846
304	1	1.2203168	0.1991105	0.2497661	0.1319283
305	1	1.3707645	0.3153686	0.2383948	0.1208275
306	1	1.3136493	0.272809	0.2383948	0.1248203
307	0	1.1940734	0.1773705	0.2497661	0.0204142
308	0	1.3136493	0.272809	0.2383948	0.0190057
309	0	1.3207887	0.278229	0.2383948	0.0189276
310	0	1.3207887	0.278229	0.2383948	0.0189276
311	1	1.541908	0.4330206	0.2584371	0.110233
312	0	1.2203168	0.1991105	0.2497661	0.020088
313	14	1.2071951	0.1882995	0.2497661	1.5986279
314	0	1.5750674	0.454298	0.2584371	0.0165036
315	0	1.2993705	0.2618799	0.2383948	0.0191639
316	0	1.2203168	0.1991105	0.2497661	0.020088

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Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=HY1HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 1 hour after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
317	0	1.5336182	0.4276298	0.2584371	0.0168563
318	0	1.3065099	0.2673594	0.2383948	0.0190845
319	1	1.5170386	0.4167601	0.2584371	0.1116578
320	1	1.3279281	0.2836199	0.2383948	0.1237982
321	0	1.2268776	0.2044724	0.2497661	0.020008
322	0	1.5584877	0.4437159	0.2584371	0.0166429
323	0	1.3707645	0.3153686	0.2383948	0.0183977
324	0	1.2268776	0.2044724	0.2497661	0.020008
325	0	1.3136493	0.272809	0.2383948	0.0190057
326	0	1.3279281	0.2836199	0.2383948	0.0188501
327	0	1.2268776	0.2044724	0.2497661	0.020008
328	0	1.2071951	0.1882995	0.2497661	0.0202498
329	0	1.2137559	0.1937196	0.2497661	0.0201686
330	0	1.5336182	0.4276298	0.2584371	0.0168563
331	0	1.2071951	0.1882995	0.2497661	0.0202498
332	0	1.3279281	0.2836199	0.2383948	0.0188501
333	0	1.5501979	0.4383826	0.2584371	0.0167135
334	0	1.3636251	0.3101466	0.2383948	0.0184717
335	0	1.3136493	0.272809	0.2383948	0.0190057
336	0	0.1508994	-1.891142	0.2497661	0.0445644
337	1	1.2071951	0.1882995	0.2497661	0.1329911
338	0	1.3207887	0.278229	0.2383948	0.0189276
339	0	1.253121	0.2256372	0.2497661	0.0196942
340	0	1.5501979	0.4383826	0.2584371	0.0167135
341	0	1.3422069	0.2943152	0.2383948	0.0186969

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Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=HY1HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 1 hour after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
342	10	1.2071951	0.1882995	0.2497661	1.1476627
343	1	1.3136493	0.272809	0.2383948	0.1248203
344	0	1.2268776	0.2044724	0.2497661	0.020008
345	1	1.3136493	0.272809	0.2383948	0.1248203
346	1	1.5253284	0.4222097	0.2584371	0.1111789
347	1	1.2268776	0.2044724	0.2497661	0.1314031
348	1	1.3279281	0.2836199	0.2383948	0.1237982
349	0	0.8209455	-0.197299	0.1979501	0.0264549
350	0	0.7070179	-0.346699	0.1973883	0.0290149
351	0	0.6992909	-0.357688	0.1973883	0.0292046
352	1	0.7108814	-0.34125	0.1973883	0.1899383
353	0	0.7108814	-0.34125	0.1973883	0.0289209
354	0	0.7070179	-0.346699	0.1973883	0.0290149
355	0	0.6532737	-0.425759	0.2088288	0.0303809
356	0	0.6532737	-0.425759	0.2088288	0.0303809
357	0	0.6808385	-0.38443	0.2243447	0.0296666
358	2	0.7905476	-0.235029	0.2161913	0.3288201
359	0	0.6324661	-0.458129	0.2166871	0.0309398
360	0	0.6808385	-0.38443	0.2243447	0.0296666
361	1	0.8206228	-0.197692	0.2161913	0.1737867
362	0	0.6808385	-0.38443	0.2243447	0.0296666
363	0	0.6188647	-0.479869	0.2166871	0.0313146
364	0	0.6919391	-0.368257	0.2243447	0.0293872
365	0	0.6808385	-0.38443	0.2243447	0.0296666
366	0	0.6734381	-0.395359	0.2243447	0.0298555

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Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=HY1HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 1 hour after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
367	1	0.6697379	-0.400869	0.2243447	0.1967018
368	0	0.6256654	-0.46894	0.2166871	0.0311262
369	1	0.6697379	-0.400869	0.2243447	0.1967018
370	2	0.6460675	-0.436851	0.2166871	0.3709979
371	0	0.6697379	-0.400869	0.2243447	0.0299507
372	0	0.7948441	-0.229609	0.2161913	0.0270043
373	1	0.8335121	-0.182107	0.2161913	0.1720535
374	1	0.7948441	-0.229609	0.2161913	0.1773513
375	0	0.6808385	-0.38443	0.2243447	0.0296666
376	0	0.7905476	-0.235029	0.2161913	0.0270968
377	3	0.7905476	-0.235029	0.2161913	0.4796818
378	0	0.7905476	-0.235029	0.2161913	0.0270968
379	0	0.6256654	-0.46894	0.2166871	0.0311262
380	0	0.7991405	-0.224218	0.2161913	0.0269124
381	0	0.7905476	-0.235029	0.2161913	0.0270968
382	2	0.7905476	-0.235029	0.2161913	0.3288201
383	0	0.6256654	-0.46894	0.2166871	0.0311262
384	0	0.7108814	-0.34125	0.1973883	0.0289209
385	0	0.6256654	-0.46894	0.2166871	0.0311262
386	0	0.7862511	-0.240479	0.2161913	0.0271898
387	0	0.6808385	-0.38443	0.2243447	0.0296666
388	0	0.7905476	-0.235029	0.2161913	0.0270968
389	0	0.7905476	-0.235029	0.2161913	0.0270968
390	0	0.7991405	-0.224218	0.2161913	0.0269124
391	0	0.6256654	-0.46894	0.2166871	0.0311262

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Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=HY1HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 1 hour after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
392	0	0.8254315	-0.191849	0.1979501	0.0263625
393	0	0.8523478	-0.159761	0.1979501	0.0258206
394	0	0.7070179	-0.346699	0.1973883	0.0290149
395	0	0.7495162	-0.288327	0.1973883	0.0280095
396	0	0.8299176	-0.186429	0.1979501	0.0262708
397	0	0.6734381	-0.395359	0.2243447	0.0298555
398	0	0.7147449	-0.33583	0.1973883	0.0288274
399	0	0.7108814	-0.34125	0.1973883	0.0289209
400	0	0.7340623	-0.309161	0.1973883	0.0283678
401	0	0.7186083	-0.330439	0.1973883	0.0287344
402	0	0.8254315	-0.191849	0.1979501	0.0263625
403	0	0.6568241	-0.420339	0.2088288	0.0302872
404	1	0.8388896	-0.175676	0.1979501	0.1713398
405	0	0.7147449	-0.33583	0.1973883	0.0288274
406	0	0.8344036	-0.181038	0.1979501	0.0261796
407	0	0.7147449	-0.33583	0.1973883	0.0288274
408	0	0.7108814	-0.34125	0.1973883	0.0289209
409	0	0.7819547	-0.245958	0.2161913	0.0272834
410	0	0.6697379	-0.400869	0.2243447	0.0299507
411	0	0.7862511	-0.240479	0.2161913	0.0271898
412	2	0.6845387	-0.37901	0.2243447	0.3588687
413	0	0.8120299	-0.208218	0.2161913	0.0266402
414	0	0.6324661	-0.458129	0.2166871	0.0309398
415	0	0.7819547	-0.245958	0.2161913	0.0272834
416	0	0.622265	-0.474389	0.2166871	0.0312202

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Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=HY1HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 1 hour after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
417	0	0.6256654	-0.46894	0.2166871	0.0311262
418	0	0.7905476	-0.235029	0.2161913	0.0270968
419	0	0.7819547	-0.245958	0.2161913	0.0272834
420	7	0.6532737	-0.425759	0.2088288	1.2144022
421	0	0.8254315	-0.191849	0.1979501	0.0263625
422	2	0.6568241	-0.420339	0.2088288	0.3675362
423	1	0.6568241	-0.420339	0.2088288	0.1989117
424	0	0.7147449	-0.33583	0.1973883	0.0288274
425	0	0.7031544	-0.352179	0.1973883	0.0291095
426	0	0.8344036	-0.181038	0.1979501	0.0261796
427	0	0.7147449	-0.33583	0.1973883	0.0288274
428	0	0.7147449	-0.33583	0.1973883	0.0288274
429	0	0.8478617	-0.165038	0.1979501	0.0259095
430	0	0.6958785	-0.36258	0.2088288	0.0292891
431	0	0.8478617	-0.165038	0.1979501	0.0259095
432	0	0.6532737	-0.425759	0.2088288	0.0303809
433	0	0.7108814	-0.34125	0.1973883	0.0289209
434	0	0.6603745	-0.414948	0.2088288	0.030194
435	0	0.6532737	-0.425759	0.2088288	0.0303809
436	0	0.6497233	-0.431209	0.2088288	0.030475
437	5	0.6808385	-0.38443	0.2243447	0.8555134
438	0	0.6674753	-0.404253	0.2088288	0.0300092
439	0	0.6845387	-0.37901	0.2243447	0.0295729
440	0	0.6290657	-0.46352	0.2166871	0.0310328
441	0	0.7224718	-0.325077	0.1973883	0.028642

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Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=HY1HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 1 hour after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
442	0	0.6808385	-0.38443	0.2243447	0.0296666
443	0	0.6532737	-0.425759	0.2088288	0.0303809
444	0	0.6639249	-0.409586	0.2088288	0.0301014
445	0	0.6808385	-0.38443	0.2243447	0.0296666
446	0	0.6845387	-0.37901	0.2243447	0.0295729
447	0	0.8254315	-0.191849	0.1979501	0.0263625
448	1	0.7776582	-0.251468	0.2161913	0.1798029
449	0	0.6256654	-0.46894	0.2166871	0.0311262
450	0	0.7108814	-0.34125	0.1973883	0.0289209
451	0	0.6532737	-0.425759	0.2088288	0.0303809
452	0	0.6923281	-0.367695	0.2088288	0.0293775
453	8	0.7948441	-0.229609	0.2161913	1.2297802
454	1	0.7104402	-0.341871	0.2243447	0.1900087
455	0	0.8850696	-0.122089	0.2161913	0.0251892
456	0	0.6887777	-0.372837	0.2088288	0.0294663
457	0	0.6734381	-0.395359	0.2243447	0.0298555
458	0	0.803437	-0.218857	0.2161913	0.0268211
459	0	0.8206228	-0.197692	0.2161913	0.0264616
460	1	0.6497233	-0.431209	0.2088288	0.2001451
461	0	0.7491345	-0.288837	0.2088288	0.0280183
462	1	0.6919391	-0.368257	0.2243447	0.1930007
463	17	0.6256654	-0.46894	0.2166871	2.9771558
464	0	0.7108814	-0.34125	0.1973883	0.0289209
465	0	0.622265	-0.474389	0.2166871	0.0312202
466	0	0.9151523	-0.088665	0.1979501	0.0246336

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Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=HY1HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 1 hour after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
467	0	0.6745761	-0.393671	0.2088288	0.0298263
468	0	0.8344036	-0.181038	0.1979501	0.0261796
469	0	0.8254315	-0.191849	0.1979501	0.0263625
470	0	0.7905476	-0.235029	0.2161913	0.0270968
471	0	0.7726971	-0.257868	0.1973883	0.0274871
472	0	0.8523478	-0.159761	0.1979501	0.0258206
473	0	0.70674	-0.347092	0.2243447	0.0290217
474	0	0.8433757	-0.170343	0.1979501	0.025999
475	0	0.8209455	-0.197299	0.1979501	0.0264549
476	11	0.7186083	-0.330439	0.1973883	1.7885063
477	0	0.6674753	-0.404253	0.2088288	0.0300092
478	0	0.8344036	-0.181038	0.1979501	0.0261796
479	0	0.7031544	-0.352179	0.1973883	0.0291095
480	0	0.8388896	-0.175676	0.1979501	0.026089
481	2	0.6639249	-0.409586	0.2088288	0.3652812
482	2	0.8299176	-0.186429	0.1979501	0.3187966
483	0	0.8164594	-0.202778	0.1979501	0.0265479
484	0	0.8209455	-0.197299	0.1979501	0.0264549
485	0	0.6461729	-0.436688	0.2088288	0.0305696
486	0	0.6992909	-0.357688	0.1973883	0.0292046
487	0	0.8209455	-0.197299	0.1979501	0.0264549
488	0	0.7108814	-0.34125	0.1973883	0.0289209
489	7	0.7147449	-0.33583	0.1973883	1.1523054
490	0	0.8388896	-0.175676	0.1979501	0.026089
491	0	0.8299176	-0.186429	0.1979501	0.0262708

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Parameter Code=HY1HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 1 hour after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
492	0	0.6497233	-0.431209	0.2088288	0.030475
493	0	0.6603745	-0.414948	0.2088288	0.030194
494	1	0.6877005	-0.374402	0.1973883	0.1936979
495	0	0.7108814	-0.34125	0.1973883	0.0289209
496	0	0.6639249	-0.409586	0.2088288	0.0301014
497	0	0.8254315	-0.191849	0.1979501	0.0263625
498	0	0.8254315	-0.191849	0.1979501	0.0263625
499	0	0.6639249	-0.409586	0.2088288	0.0301014
500	0	0.6532737	-0.425759	0.2088288	0.0303809
501	5	0.6461729	-0.436688	0.2088288	0.8815548
502	0	0.8344036	-0.181038	0.1979501	0.0261796
503	0	0.7108814	-0.34125	0.1973883	0.0289209
504	0	0.8164594	-0.202778	0.1979501	0.0265479
505	0	0.6639249	-0.409586	0.2088288	0.0301014
506	0	0.6639249	-0.409586	0.2088288	0.0301014
507	0	0.8164594	-0.202778	0.1979501	0.0265479
508	0	0.1345812	-2.005587	0.1979501	0.0439809
509	2	0.8119734	-0.208288	0.1979501	0.3232945
510	0	0.8254315	-0.191849	0.1979501	0.0263625
511	0	0.6532737	-0.425759	0.2088288	0.0303809
512	0	0.8254315	-0.191849	0.1979501	0.0263625
513	3	0.6532737	-0.425759	0.2088288	0.5378186
514	0	0.8299176	-0.186429	0.1979501	0.0262708
515	1	0.7108814	-0.34125	0.1973883	0.1899383
516	0	0.7108814	-0.34125	0.1973883	0.0289209

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Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=HY1HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 1 hour after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
517	2	0.8254315	-0.191849	0.1979501	0.3199102
518	1	0.8299176	-0.186429	0.1979501	0.1725337
519	0	0.6603745	-0.414948	0.2088288	0.030194
520	0	0.8388896	-0.175676	0.1979501	0.026089
521	0	0.7108814	-0.34125	0.1973883	0.0289209
522	0	0.6532737	-0.425759	0.2088288	0.0303809
523	0	0.6532737	-0.425759	0.2088288	0.0303809
524	6	0.8254315	-0.191849	0.1979501	0.9070056
525	6	0.7147449	-0.33583	0.1973883	0.9918086
526	0	0.7147449	-0.33583	0.1973883	0.0288274
527	0	0.8344036	-0.181038	0.1979501	0.0261796
528	0	0.7147449	-0.33583	0.1973883	0.0288274
529	0	0.7108814	-0.34125	0.1973883	0.0289209
530	1	0.7263353	-0.319744	0.1973883	0.187503
531	0	0.6568241	-0.420339	0.2088288	0.0302872
532	1	0.7301988	-0.314438	0.1973883	0.1869028
533	2	0.8254315	-0.191849	0.1979501	0.3199102
534	3	0.8164594	-0.202778	0.1979501	0.4699647
535	0	0.7108814	-0.34125	0.1973883	0.0289209
536	0	0.6532737	-0.425759	0.2088288	0.0303809
537	0	0.6568241	-0.420339	0.2088288	0.0302872
538	0	0.6568241	-0.420339	0.2088288	0.0302872
539	0	0.7147449	-0.33583	0.1973883	0.0288274
540	0	0.6639249	-0.409586	0.2088288	0.0301014
541	0	0.7070179	-0.346699	0.1973883	0.0290149

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Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=HY1HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 1 hour after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
542	0	0.6603745	-0.414948	0.2088288	0.030194
543	0	0.6390721	-0.447738	0.2088288	0.0307605
544	1	0.7263353	-0.319744	0.1973883	0.187503
545	0	0.7301988	-0.314438	0.1973883	0.0284587
546	0	0.7108814	-0.34125	0.1973883	0.0289209
547	0	0.7186083	-0.330439	0.1973883	0.0287344
548	3	0.8299176	-0.186429	0.1979501	0.4650595
549	0	0.7070179	-0.346699	0.1973883	0.0290149
550	5	0.6532737	-0.425759	0.2088288	0.8761104
551	0	0.6532737	-0.425759	0.2088288	0.0303809
552	2	0.7108814	-0.34125	0.1973883	0.3509558
553	1	0.7147449	-0.33583	0.1973883	0.1893242
554	0	0.6603745	-0.414948	0.2088288	0.030194
555	1	0.7108814	-0.34125	0.1973883	0.1899383
556	0	0.7301988	-0.314438	0.1973883	0.0284587
557	0	0.6568241	-0.420339	0.2088288	0.0302872
558	0	0.7147449	-0.33583	0.1973883	0.0288274
559	0	0.7108814	-0.34125	0.1973883	0.0289209
560	0	0.6639249	-0.409586	0.2088288	0.0301014
561	0	0.8254315	-0.191849	0.1979501	0.0263625
562	0	0.6568241	-0.420339	0.2088288	0.0302872
563	3	0.6256654	-0.46894	0.2166871	0.5510138
564	0	0.8344036	-0.181038	0.1979501	0.0261796
565	0	0.6639249	-0.409586	0.2088288	0.0301014
566	0	0.7108814	-0.34125	0.1973883	0.0289209

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Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=HY1HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 1 hour after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
567	0	0.6324661	-0.458129	0.2166871	0.0309398
568	0	0.8254315	-0.191849	0.1979501	0.0263625
569	1	0.6426225	-0.442198	0.2088288	0.2013916
570	0	0.8299176	-0.186429	0.1979501	0.0262708
571	0	0.7147449	-0.33583	0.1973883	0.0288274
572	1	0.8523478	-0.159761	0.1979501	0.1695775
573	2	0.7263353	-0.319744	0.1973883	0.3464559
574	0	0.8388896	-0.175676	0.1979501	0.026089
575	3	0.8254315	-0.191849	0.1979501	0.466684
576	1	0.7263353	-0.319744	0.1973883	0.187503
577	0	0.6568241	-0.420339	0.2088288	0.0302872
578	5	0.6497233	-0.431209	0.2088288	0.8788254
579	2	0.8254315	-0.191849	0.1979501	0.3199102
580	2	0.8254315	-0.191849	0.1979501	0.3199102
581	0	0.6568241	-0.420339	0.2088288	0.0302872
582	0	0.6532737	-0.425759	0.2088288	0.0303809
583	18	0.7108814	-0.34125	0.1973883	2.927235
584	0	0.7819547	-0.245958	0.2161913	0.0272834
585	0	0.6290657	-0.46352	0.2166871	0.0310328
586	0	0.6460675	-0.436851	0.2166871	0.0305725
587	3	0.6256654	-0.46894	0.2166871	0.5510138
588	0	0.6808385	-0.38443	0.2243447	0.0296666
589	0	0.6882389	-0.373619	0.2243447	0.0294798
590	2	0.7905476	-0.235029	0.2161913	0.3288201
591	0	0.6256654	-0.46894	0.2166871	0.0311262

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Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=HY1HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 1 hour after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
592	0	0.6256654	-0.46894	0.2166871	0.0311262
593	4	0.7905476	-0.235029	0.2161913	0.6305435
594	2	0.6845387	-0.37901	0.2243447	0.3588687
595	1	0.7905476	-0.235029	0.2161913	0.1779584
596	0	0.7326414	-0.311099	0.2243447	0.0284012
597	1	0.6808385	-0.38443	0.2243447	0.194836
598	0	0.6808385	-0.38443	0.2243447	0.0296666
599	0	0.6697379	-0.400869	0.2243447	0.0299507
600	1	0.622265	-0.474389	0.2166871	0.205039
601	0	0.7991405	-0.224218	0.2161913	0.0269124
602	0	0.6734381	-0.395359	0.2243447	0.0298555
603	0	0.8299176	-0.186429	0.1979501	0.0262708
604	0	0.6697379	-0.400869	0.2243447	0.0299507
605	0	0.6256654	-0.46894	0.2166871	0.0311262
606	1	0.6256654	-0.46894	0.2166871	0.2044221
607	0	0.7862511	-0.240479	0.2161913	0.0271898
608	0	0.8388896	-0.175676	0.1979501	0.026089
609	0	0.6808385	-0.38443	0.2243447	0.0296666
610	0	0.7991405	-0.224218	0.2161913	0.0269124
611	0	0.6426672	-0.442128	0.2166871	0.0306636
612	0	0.7905476	-0.235029	0.2161913	0.0270968
613	0	0.6290657	-0.46352	0.2166871	0.0310328
614	0	0.6845387	-0.37901	0.2243447	0.0295729
615	2	0.6771383	-0.38988	0.2243447	0.3611482
616	0	0.6808385	-0.38443	0.2243447	0.0296666

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Parameter Code=HY1HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 1 hour after meal

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
617	0	0.7776582	-0.251468	0.2161913	0.0273776
618	0	0.6290657	-0.46352	0.2166871	0.0310328
619	0	0.7905476	-0.235029	0.2161913	0.0270968
620	0	0.6956393	-0.362924	0.2243447	0.029295
621	1	0.8163263	-0.202941	0.2161913	0.1743717
622	3	0.6771383	-0.38988	0.2243447	0.5268419
623	0	0.7905476	-0.235029	0.2161913	0.0270968
624	1	0.6256654	-0.46894	0.2166871	0.2044221
625	0	0.6188647	-0.479869	0.2166871	0.0313146
626	2	0.6808385	-0.38443	0.2243447	0.3600053
627	0	0.4769064	-0.740435	0.2161913	0.0356956
628	0	0.6494679	-0.431602	0.2166871	0.0304818
629	1	0.6919391	-0.368257	0.2243447	0.1930007
630	0	0.6290657	-0.46352	0.2166871	0.0310328
631	1	0.7819547	-0.245958	0.2161913	0.1791842
632	0	0.6845387	-0.37901	0.2243447	0.0295729
633	0	0.622265	-0.474389	0.2166871	0.0312202
634	0	0.803437	-0.218857	0.2161913	0.0268211
635	0	0.6256654	-0.46894	0.2166871	0.0311262
636	1	0.6919391	-0.368257	0.2243447	0.1930007
637	0	0.6771383	-0.38988	0.2243447	0.0297608
638	0	0.6868718	-0.375608	0.2166871	0.0295142
639	1	0.7862511	-0.240479	0.2161913	0.1785694
640	0	0.6734381	-0.395359	0.2243447	0.0298555
641	1	0.7905476	-0.235029	0.2161913	0.1779584

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Parameter Code=HY1HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 1 hour after meal

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
642	0	0.6568241	-0.420339	0.2088288	0.0302872
643	1	0.6845387	-0.37901	0.2243447	0.1942208
644	1	0.6497233	-0.431209	0.2088288	0.2001451
645	0	0.6808385	-0.38443	0.2243447	0.0296666
646	1	0.8254315	-0.191849	0.1979501	0.1731364
647	0	0.6808385	-0.38443	0.2243447	0.0296666
648	0	0.8254315	-0.191849	0.1979501	0.0263625
649	0	0.6745761	-0.393671	0.2088288	0.0298263
650	30	0.8344036	-0.181038	0.1979501	4.3988374
651	0	0.6256654	-0.46894	0.2166871	0.0311262
652	0	0.7905476	-0.235029	0.2161913	0.0270968
653	0	0.7905476	-0.235029	0.2161913	0.0270968
654	1	0.8388896	-0.175676	0.1979501	0.1713398
655	1	0.6461729	-0.436688	0.2088288	0.2007667
656	0	0.8344036	-0.181038	0.1979501	0.0261796
657	1	0.6603745	-0.414948	0.2088288	0.1982999
658	0	0.6497233	-0.431209	0.2088288	0.030475
659	0	0.9196384	-0.083775	0.1979501	0.0245527
660	1	0.7108814	-0.34125	0.1973883	0.1899383
661	1	0.6882389	-0.373619	0.2243447	0.1936091
662	1	0.659448	-0.416352	0.1979501	0.1984592
663	0	0.9018017	-0.103361	0.2088288	0.0248773
664	0	0.6674753	-0.404253	0.2088288	0.0300092
665	0	0.6923281	-0.367695	0.2088288	0.0293775
666	0	0.7301988	-0.314438	0.1973883	0.0284587

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
667	0	0.7186083	-0.330439	0.1973883	0.0287344
668	0	0.390544	-0.940215	0.2088288	0.0387577
669	0	0.5929169	-0.522701	0.2088288	0.0320509
670	0	0.6993395	-0.357619	0.2243447	0.0292034
671	0	0.7819547	-0.245958	0.2161913	0.0272834
672	0	0.6956393	-0.362924	0.2243447	0.029295
673	0	0.6808385	-0.38443	0.2243447	0.0296666
674	0	0.7905476	-0.235029	0.2161913	0.0270968
675	3	0.7905476	-0.235029	0.2161913	0.4796818
676	1	0.6256654	-0.46894	0.2166871	0.2044221
677	0	0.6188647	-0.479869	0.2166871	0.0313146
678	0	0.7326414	-0.311099	0.2243447	0.0284012
679	0	0.7862511	-0.240479	0.2161913	0.0271898
680	2	0.6256654	-0.46894	0.2166871	0.377718
681	0	0.7948441	-0.229609	0.2161913	0.0270043
682	0	0.7905476	-0.235029	0.2161913	0.0270968
683	0	0.6460675	-0.436851	0.2166871	0.0305725
684	2	0.612064	-0.490918	0.2166871	0.3823124
685	0	0.6808385	-0.38443	0.2243447	0.0296666
686	0	0.803437	-0.218857	0.2161913	0.0268211
687	0	0.7104402	-0.341871	0.2243447	0.0289316
688	0	0.6154643	-0.485378	0.2166871	0.0314095
689	0	0.6256654	-0.46894	0.2166871	0.0311262
690	0	0.6256654	-0.46894	0.2166871	0.0311262
691	0	0.6188647	-0.479869	0.2166871	0.0313146

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Parameter Code=HY1HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 1 hour after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
692	4	0.7948441	-0.229609	0.2161913	0.6283922
693	0	0.6808385	-0.38443	0.2243447	0.0296666
694	0	1.2071951	0.1882995	0.2497661	0.0202498
695	2	1.2334384	0.2098057	0.2497661	0.2418351
696	0	1.3136493	0.272809	0.2383948	0.0190057
697	1	1.1809517	0.1663206	0.2497661	0.1351673
698	0	1.2993705	0.2618799	0.2383948	0.0191639
699	0	1.1875125	0.1718608	0.2497661	0.0204974
700	0	1.3636251	0.3101466	0.2383948	0.0184717
701	34	1.5253284	0.4222097	0.2584371	3.2214388
702	1	1.2071951	0.1882995	0.2497661	0.1329911
703	0	1.1612692	0.1495135	0.2497661	0.0208367
704	0	1.5253284	0.4222097	0.2584371	0.0169286
705	1	1.2006342	0.1828499	0.2497661	0.1335288
706	0	1.1940734	0.1773705	0.2497661	0.0204142
707	0	1.5087487	0.4112807	0.2584371	0.0170751
708	9	1.3279281	0.2836199	0.2383948	0.9633829
709	0	1.2071951	0.1882995	0.2497661	0.0202498
710	0	1.5253284	0.4222097	0.2584371	0.0169286
711	0	1.2922311	0.2563702	0.2383948	0.0192439
712	0	1.2922311	0.2563702	0.2383948	0.0192439
713	0	1.2071951	0.1882995	0.2497661	0.0202498
714	1	1.1875125	0.1718608	0.2497661	0.1346168
715	0	1.1350258	0.1266554	0.2497661	0.021187
716	0	1.3136493	0.272809	0.2383948	0.0190057

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Parameter Code=HY1HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 1 hour after meal

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
717	1	1.5170386	0.4167601	0.2584371	0.1116578
718	0	1.2006342	0.1828499	0.2497661	0.0203317
719	0	1.5253284	0.4222097	0.2584371	0.0169286
720	0	1.2071951	0.1882995	0.2497661	0.0202498
721	0	1.2071951	0.1882995	0.2497661	0.0202498
722	1	1.5170386	0.4167601	0.2584371	0.1116578
723	2	1.5170386	0.4167601	0.2584371	0.2063142
724	0	1.5253284	0.4222097	0.2584371	0.0169286
725	1	0.6875531	-0.374616	0.2049863	0.1937222
726	0	0.8248436	-0.192561	0.2388451	0.0263746
727	1	0.7404438	-0.300506	0.2370015	0.1853278
728	2	0.8117509	-0.208562	0.2388451	0.323351
729	0	0.7817884	-0.246171	0.2370015	0.027287
730	2	0.7899296	-0.235811	0.2388451	0.3289821
731	1	0.8684861	-0.141004	0.2388451	0.1675082
732	0	0.6875531	-0.374616	0.2049863	0.029497
733	0	0.6053715	-0.501913	0.1998523	0.031694
734	0	0.6053715	-0.501913	0.1998523	0.031694
735	0	0.6623548	-0.411954	0.2049863	0.0301423
736	0	0.7481864	-0.290103	0.1976934	0.02804
737	0	0.5183646	-0.657076	0.2049863	0.0343264
738	0	0.6878235	-0.374223	0.2370015	0.0294902
739	0	0.6053715	-0.501913	0.1998523	0.031694
740	0	0.6186037	-0.48029	0.1998523	0.0313219
741	0	0.6803536	-0.385143	0.2049863	0.0296789

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
742	0	0.6953406	-0.363353	0.2370015	0.0293025
743	0	0.6953406	-0.363353	0.2370015	0.0293025
744	0	0.6086795	-0.496463	0.1998523	0.0316002
745	0	0.6053715	-0.501913	0.1998523	0.031694
746	0	0.7816249	-0.24638	0.1976934	0.0272906
747	0	0.6915821	-0.368773	0.2370015	0.0293961
748	0	0.6152956	-0.485652	0.1998523	0.0314142
749	0	0.8030224	-0.219373	0.2388451	0.0268299
750	0	0.7941643	-0.230465	0.1976934	0.0270189
751	2	0.6355383	-0.453283	0.2492306	0.3744405
752	0	0.6915821	-0.368773	0.2370015	0.0293961
753	1	0.7732653	-0.257133	0.1976934	0.1804394
754	0	0.6878235	-0.374223	0.2370015	0.0294902
755	0	0.7983442	-0.225215	0.1976934	0.0269294
756	0	0.7690855	-0.262553	0.1976934	0.0275673
757	0	0.7649057	-0.268003	0.1976934	0.0276607
758	0	0.6086795	-0.496463	0.1998523	0.0316002
759	0	0.6623548	-0.411954	0.2049863	0.0301423
760	0	0.6086795	-0.496463	0.1998523	0.0316002
761	0	0.7732653	-0.257133	0.1976934	0.0274745
762	0	0.6053715	-0.501913	0.1998523	0.031694
763	0	0.7690855	-0.262553	0.1976934	0.0275673
764	0	0.7816249	-0.24638	0.1976934	0.0272906
765	0	0.6053715	-0.501913	0.1998523	0.031694
766	0	0.6424463	-0.442472	0.2492306	0.0306695

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Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=HY1HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 1 hour after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
767	1	0.6086795	-0.496463	0.1998523	0.2075351
768	3	0.658755	-0.417404	0.2049863	0.5352627
769	1	0.7732653	-0.257133	0.1976934	0.1804394
770	0	0.6318358	-0.459126	0.1998523	0.030957
771	1	0.7732653	-0.257133	0.1976934	0.1804394
772	1	0.6119876	-0.491043	0.1998523	0.2069227
773	0	0.756546	-0.278992	0.1976934	0.0278492
774	0	0.7774451	-0.251742	0.1976934	0.0273823
775	9	0.6086795	-0.496463	0.1998523	1.6150144
776	0	0.7690855	-0.262553	0.1976934	0.0275673
777	0	0.6623548	-0.411954	0.2049863	0.0301423
778	0	0.7732653	-0.257133	0.1976934	0.0274745
779	1	0.2087858	-1.566447	0.2049863	0.2932396
780	4	0.6623548	-0.411954	0.2049863	0.7014133
781	1	0.6915821	-0.368773	0.2370015	0.1930593
782	0	0.7774451	-0.251742	0.1976934	0.0273823
783	8	0.6086795	-0.496463	0.1998523	1.4390795
784	1	0.6875531	-0.374616	0.2049863	0.1937222
785	0	0.7607258	-0.273482	0.1976934	0.0277547
786	0	0.6915821	-0.368773	0.2370015	0.0293961
787	0	0.6915821	-0.368773	0.2370015	0.0293961
788	0	0.7858047	-0.241047	0.1976934	0.0271995
789	0	0.6915821	-0.368773	0.2370015	0.0293961
790	0	0.6318358	-0.459126	0.1998523	0.030957
791	0	0.8861202	-0.120903	0.1976934	0.0251694

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Parameter Code=HY1HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 1 hour after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
792	1	0.6839533	-0.379866	0.2049863	0.1943179
793	0	0.6086795	-0.496463	0.1998523	0.0316002
794	1	0.6119876	-0.491043	0.1998523	0.2069227
795	0	0.6152956	-0.485652	0.1998523	0.0314142
796	0	0.6623548	-0.411954	0.2049863	0.0301423
797	0	0.7690855	-0.262553	0.1976934	0.0275673
798	0	0.6623548	-0.411954	0.2049863	0.0301423
799	3	0.6562624	-0.421195	0.2492306	0.5364224
800	0	0.729168	-0.315851	0.2370015	0.028483
801	0	0.7366852	-0.305595	0.2370015	0.0283064
802	2	0.6878235	-0.374223	0.2370015	0.357865
803	0	0.8030224	-0.219373	0.2388451	0.0268299
804	0	0.6355383	-0.453283	0.2492306	0.0308562
805	0	0.6528084	-0.426472	0.2492306	0.0303932
806	0	0.8379364	-0.176813	0.2388451	0.0261082
807	0	0.6424463	-0.442472	0.2492306	0.0306695
808	0	0.6700784	-0.400361	0.2492306	0.0299419
809	1	0.8117509	-0.208562	0.2388451	0.1749985
810	0	0.8204794	-0.197867	0.2388451	0.0264645
811	0	0.6597164	-0.415945	0.2492306	0.0302113
812	0	0.6911528	-0.369394	0.2049863	0.0294068
813	0	0.6767538	-0.390448	0.2049863	0.0297706
814	0	0.8317827	-0.184184	0.1976934	0.0262328
815	2	0.6371565	-0.45074	0.2049863	0.3739079
816	0	0.6659546	-0.406534	0.2049863	0.0300486

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
817	0	0.8030224	-0.219373	0.2388451	0.0268299
818	0	0.6515555	-0.428393	0.2049863	0.0304263
819	0	0.6053715	-0.501913	0.1998523	0.031694
820	0	0.6351439	-0.453904	0.1998523	0.0308669
821	0	0.6318358	-0.459126	0.1998523	0.030957
822	0	0.8192432	-0.199374	0.1976934	0.0264901
823	0	0.7607258	-0.273482	0.1976934	0.0277547
824	0	0.6659546	-0.406534	0.2049863	0.0300486
825	0	0.6659546	-0.406534	0.2049863	0.0300486
826	2	0.5987554	-0.512902	0.1998523	0.3868981
827	0	0.6915821	-0.368773	0.2370015	0.0293961
828	0	0.7271504	-0.318622	0.2049863	0.0285307
829	0	0.7649057	-0.268003	0.1976934	0.0276607
830	2	0.7983442	-0.225215	0.1976934	0.3267895
831	0	0.6384519	-0.448709	0.1998523	0.0307772
832	0	0.6086795	-0.496463	0.1998523	0.0316002
833	0	0.7690855	-0.262553	0.1976934	0.0275673
834	0	0.7690855	-0.262553	0.1976934	0.0275673
835	0	0.6839533	-0.379866	0.2049863	0.0295877
836	0	0.6597164	-0.415945	0.2492306	0.0302113
837	0	0.6597164	-0.415945	0.2492306	0.0302113
838	0	0.6915821	-0.368773	0.2370015	0.0293961
839	0	0.6840649	-0.379703	0.2370015	0.0295849
840	0	0.6355383	-0.453283	0.2492306	0.0308562
841	0	0.8204794	-0.197867	0.2388451	0.0264645

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842	0	0.6631704	-0.410723	0.2492306	0.030121
843	0	0.6320843	-0.458733	0.2492306	0.0309502
844	0	0.6915821	-0.368773	0.2370015	0.0293961
845	0	0.6804405	-0.385015	0.2492306	0.0296767
846	0	0.6953406	-0.363353	0.2370015	0.0293025
847	0	0.6355383	-0.453283	0.2492306	0.0308562
848	0	0.8030224	-0.219373	0.2388451	0.0268299
849	0	0.8117509	-0.208562	0.2388451	0.0266461
850	0	0.6915821	-0.368773	0.2370015	0.0293961
851	0	0.6990992	-0.357963	0.2370015	0.0292094
852	0	0.8030224	-0.219373	0.2388451	0.0268299
853	6	0.8030224	-0.219373	0.2388451	0.9230864
854	0	0.6086795	-0.496463	0.1998523	0.0316002
855	1	0.6086795	-0.496463	0.1998523	0.2075351
856	0	0.7690855	-0.262553	0.1976934	0.0275673
857	1	0.7690855	-0.262553	0.1976934	0.181049
858	0	0.7235506	-0.323585	0.2049863	0.0286162
859	1	0.7127514	-0.338623	0.2049863	0.1896407
860	1	0.8030224	-0.219373	0.2388451	0.176206
861	1	0.6990992	-0.357963	0.2370015	0.191833
862	0	0.6320843	-0.458733	0.2492306	0.0309502
863	1	0.756546	-0.278992	0.1976934	0.1829001
864	0	0.8030224	-0.219373	0.2388451	0.0268299
865	0	0.7816249	-0.24638	0.1976934	0.0272906
866	0	0.7816249	-0.24638	0.1976934	0.0272906

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
867	0	0.6053715	-0.501913	0.1998523	0.031694
868	0	0.6983523	-0.359032	0.2049863	0.0292278
869	1	0.7816249	-0.24638	0.1976934	0.1792315
870	3	0.6020635	-0.507392	0.1998523	0.5627307
871	0	0.6915821	-0.368773	0.2370015	0.0293961
872	4	0.6695543	-0.401143	0.2049863	0.6970654
873	0	0.6152956	-0.485652	0.1998523	0.0314142
874	0	0.6119876	-0.491043	0.1998523	0.031507
875	0	0.6731541	-0.395781	0.2049863	0.0298628
876	9	0.6695543	-0.401143	0.2049863	1.5309529
877	0	0.6152956	-0.485652	0.1998523	0.0314142
878	1	0.756546	-0.278992	0.1976934	0.1829001
879	0	0.658755	-0.417404	0.2049863	0.0302365
880	2	0.7690855	-0.262553	0.1976934	0.3345306
881	0	0.658755	-0.417404	0.2049863	0.0302365
882	0	0.205186	-1.583838	0.2049863	0.044705
883	1	0.6551553	-0.422883	0.2049863	0.1992004
884	0	0.6086795	-0.496463	0.1998523	0.0316002
885	0	0.6053715	-0.501913	0.1998523	0.031694
886	0	0.7816249	-0.24638	0.1976934	0.0272906
887	0	0.6086795	-0.496463	0.1998523	0.0316002
888	1	0.6623548	-0.411954	0.2049863	0.19796
889	1	0.6086795	-0.496463	0.1998523	0.2075351
890	0	0.7941643	-0.230465	0.1976934	0.0270189
891	0	0.7649057	-0.268003	0.1976934	0.0276607

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
892	1	0.6020635	-0.507392	0.1998523	0.208769
893	0	0.7732653	-0.257133	0.1976934	0.0274745
894	0	0.7649057	-0.268003	0.1976934	0.0276607
895	3	0.6351439	-0.453904	0.1998523	0.5464224
896	0	0.6086795	-0.496463	0.1998523	0.0316002
897	0	0.7986581	-0.224822	0.2388451	0.0269227
898	0	0.6695543	-0.401143	0.2049863	0.0299555
899	0	0.7440066	-0.295705	0.1976934	0.0281363
900	1	0.7690855	-0.262553	0.1976934	0.181049
901	2	0.658755	-0.417404	0.2049863	0.3669206
902	0	0.658755	-0.417404	0.2049863	0.0302365
903	2	0.6695543	-0.401143	0.2049863	0.3635104
904	40	0.7649057	-0.268003	0.1976934	6.187721
905	0	0.6355383	-0.453283	0.2492306	0.0308562
906	0	0.6666244	-0.405528	0.2492306	0.0300312
907	0	0.7690855	-0.262553	0.1976934	0.0275673
908	0	0.6915821	-0.368773	0.2370015	0.0293961
909	0	0.8030224	-0.219373	0.2388451	0.0268299
910	0	0.6320843	-0.458733	0.2492306	0.0309502
911	0	0.756546	-0.278992	0.1976934	0.0278492
912	0	0.6562624	-0.421195	0.2492306	0.030302
913	0	0.8073866	-0.213953	0.2388451	0.0267377
914	0	0.8117509	-0.208562	0.2388451	0.0266461
915	1	0.7028578	-0.352601	0.2370015	0.191225
916	2	0.6320843	-0.458733	0.2492306	0.3755817

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
917	0	0.6320843	-0.458733	0.2492306	0.0309502
918	0	0.6659546	-0.406534	0.2049863	0.0300486
919	0	0.6695543	-0.401143	0.2049863	0.0299555
920	0	0.6878235	-0.374223	0.2370015	0.0294902
921	0	0.6119876	-0.491043	0.1998523	0.031507
922	0	0.7141336	-0.336685	0.2370015	0.0288421
923	0	0.6659546	-0.406534	0.2049863	0.0300486
924	0	0.7774451	-0.251742	0.1976934	0.0273823
925	0	0.6915821	-0.368773	0.2370015	0.0293961
926	0	0.7690855	-0.262553	0.1976934	0.0275673
927	0	0.6119876	-0.491043	0.1998523	0.031507
928	10	0.8030224	-0.219373	0.2388451	1.5205907
929	0	0.6659546	-0.406534	0.2049863	0.0300486
930	0	0.6878235	-0.374223	0.2370015	0.0294902
931	0	0.7942938	-0.230302	0.2388451	0.0270161
932	0	0.7732653	-0.257133	0.1976934	0.0274745
933	0	0.4041195	-0.906045	0.2492306	0.0382612
934	2	0.6990992	-0.357963	0.2370015	0.3544566
935	1	0.6915821	-0.368773	0.2370015	0.1930593
936	1	0.6086795	-0.496463	0.1998523	0.2075351
937	0	0.6915821	-0.368773	0.2370015	0.0293961
938	2	0.8553934	-0.156194	0.2388451	0.3126061
939	0	0.7732653	-0.257133	0.1976934	0.0274745
940	0	0.6623548	-0.411954	0.2049863	0.0301423
941	0	0.6251763	-0.469722	0.2492306	0.0311397

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
942	0	0.6911528	-0.369394	0.2049863	0.0294068
943	0	0.7607258	-0.273482	0.1976934	0.0277547
944	0	0.6623548	-0.411954	0.2049863	0.0301423
945	0	0.6551553	-0.422883	0.2049863	0.0303312
946	0	0.6915821	-0.368773	0.2370015	0.0293961
947	0	0.8735808	-0.135155	0.1976934	0.0254076
948	0	0.7983442	-0.225215	0.1976934	0.0269294
949	0	0.7732653	-0.257133	0.1976934	0.0274745
950	1	0.6631704	-0.410723	0.2492306	0.1978204
951	1	0.6659546	-0.406534	0.2049863	0.1973448
952	0	0.7930642	-0.231851	0.2370015	0.0270425
953	0	0.6086795	-0.496463	0.1998523	0.0316002
954	1	0.6285278	-0.464375	0.1998523	0.2039052
955	0	0.7649057	-0.268003	0.1976934	0.0276607
956	0	0.6623548	-0.411954	0.2049863	0.0301423
957	0	0.6915821	-0.368773	0.2370015	0.0293961
958	0	0.6515555	-0.428393	0.2049863	0.0304263
959	1	0.7690855	-0.262553	0.1976934	0.181049
960	0	0.7690855	-0.262553	0.1976934	0.0275673
961	0	0.6623548	-0.411954	0.2049863	0.0301423
962	0	0.6915821	-0.368773	0.2370015	0.0293961
963	0	0.6623548	-0.411954	0.2049863	0.0301423
964	0	0.6318358	-0.459126	0.1998523	0.030957
965	0	0.6953406	-0.363353	0.2370015	0.0293025
966	0	0.6086795	-0.496463	0.1998523	0.0316002

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
967	0	0.6659546	-0.406534	0.2049863	0.0300486
968	0	0.176388	-1.735069	0.2049863	0.0448996
969	1	0.6407563	-0.445106	0.2049863	0.2017214
970	0	0.6219117	-0.474957	0.1998523	0.03123
971	0	0.6355383	-0.453283	0.2492306	0.0308562
972	0	0.7690855	-0.262553	0.1976934	0.0275673
973	0	0.8161151	-0.2032	0.2388451	0.026555
974	0	0.6355383	-0.453283	0.2492306	0.0308562
975	0	0.7986581	-0.224822	0.2388451	0.0269227
976	0	0.6915821	-0.368773	0.2370015	0.0293961
977	0	0.6186037	-0.48029	0.1998523	0.0313219
978	1	0.6320843	-0.458733	0.2492306	0.2032659
979	0	0.6875531	-0.374616	0.2049863	0.029497
980	2	0.6528084	-0.426472	0.2492306	0.368822
981	0	0.6840649	-0.379703	0.2370015	0.0295849
982	0	0.7404438	-0.300506	0.2370015	0.0282189
983	0	0.645068	-0.4384	0.1998523	0.0305992
984	1	0.658755	-0.417404	0.2049863	0.1985785
985	1	0.6053715	-0.501913	0.1998523	0.2081506
986	1	0.8073866	-0.213953	0.2388451	0.1756004
987	0	0.7690855	-0.262553	0.1976934	0.0275673
988	2	0.6020635	-0.507392	0.1998523	0.3857499
989	0	0.6020635	-0.507392	0.1998523	0.0317881
990	0	0.6695543	-0.401143	0.2049863	0.0299555
991	2	0.6086795	-0.496463	0.1998523	0.38347

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Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=HY1HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 1 hour after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
992	1	0.5822152	-0.540915	0.1998523	0.2125432
993	0	0.7690855	-0.262553	0.1976934	0.0275673
994	1	0.6152956	-0.485652	0.1998523	0.2063133
995	0	0.7690855	-0.262553	0.1976934	0.0275673
996	0	0.7732653	-0.257133	0.1976934	0.0274745
997	3	0.3738086	-0.984011	0.1998523	0.6970266
998	5	0.6765477	-0.390752	0.2370015	0.8586642
999	0	0.6351439	-0.453904	0.1998523	0.0308669
1000	1	0.6659546	-0.406534	0.2049863	0.1973448
1001	0	0.7254094	-0.321019	0.2370015	0.028572
1002	2	0.7986581	-0.224822	0.2388451	0.3267082
1003	1	0.5193624	-0.655153	0.1998523	0.2252291
1004	1	0.2925869	-1.228994	0.1976934	0.278023
1005	0	0.6119876	-0.491043	0.1998523	0.031507
1006	0	0.6623548	-0.411954	0.2049863	0.0301423
1007	8	0.6659546	-0.406534	0.2049863	1.3684184
1008	0	0.6086795	-0.496463	0.1998523	0.0316002
1009	3	0.6252198	-0.469652	0.1998523	0.5512313
1010	0	0.7607258	-0.273482	0.1976934	0.0277547
1011	0	0.7415494	-0.299014	0.2049863	0.0281932
1012	0	0.658755	-0.417404	0.2049863	0.0302365
1013	1	0.6695543	-0.401143	0.2049863	0.1967329
1014	0	0.7774451	-0.251742	0.1976934	0.0273823
1015	0	0.6659546	-0.406534	0.2049863	0.0300486
1016	0	0.7899845	-0.235742	0.1976934	0.0271089

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Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=HY1HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 1 hour after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
1017	1	0.7649057	-0.268003	0.1976934	0.1816622
1018	0	0.6086795	-0.496463	0.1998523	0.0316002
1019	0	0.6915821	-0.368773	0.2370015	0.0293961
1020	1	0.6731541	-0.395781	0.2049863	0.1961243
1021	0	0.7774451	-0.251742	0.1976934	0.0273823
1022	0	0.6623548	-0.411954	0.2049863	0.0301423
1023	0	0.6086795	-0.496463	0.1998523	0.0316002
1024	2	0.6086795	-0.496463	0.1998523	0.38347
1025	0	0.6086795	-0.496463	0.1998523	0.0316002

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Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=HY24SEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 2-4 hours after meal

The GENMOD Procedure

Model Information

Data Set	WORK.ENDPOINT	
Distribution	Negative Binomial	
Link Function	Log	
Dependent Variable	AVAL	Analysis Value
Offset Variable	log_offset	

Number of Observations Read	1025
Number of Observations Used	1025

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Parameter Information

Parameter	Effect	TRTPN	REGION1	BOLAD1
Prm1	Intercept			
Prm2	TRTPN	2		
Prm3	TRTPN	3		
Prm4	TRTPN	4		
Prm5	REGION1		ASIA (EXCLUDING JAPAN)	
Prm6	REGION1		EUROPE	

Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=HY24SEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 2-4 hours after meal

The GENMOD Procedure

Parameter Information

Parameter	Effect	TRTPN	REGION1	BOLAD1
Prm7	REGION1		JAPAN	
Prm8	REGION1		NORTH AMERICA	
Prm9	BOLAD1			BOLUS INSULIN ALGORITHM (SLIDING SCALE)
Prm10	BOLAD1			CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Criteria For Assessing Goodness Of Fit

Criterion	DF	Value	Value/DF
Deviance	1018	993.1693	0.9756
Scaled Deviance	1018	993.1693	0.9756
Pearson Chi-Square	1018	944.2952	0.9276
Scaled Pearson X2	1018	944.2952	0.9276
Log Likelihood		3722.4623	
Full Log Likelihood		-2256.8726	
AIC (smaller is better)		4529.7453	
AICC (smaller is better)		4529.8870	
BIC (smaller is better)		4569.2049	

Algorithm converged.

Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=HY24SEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 2-4 hours after meal

The GENMOD Procedure

Analysis Of Maximum Likelihood Parameter Estimates

Parameter		DF	Estimate	Standard Error	Wald 95% Confidence Limits	Wald Chi-Square
Intercept		1	6.5064	0.1371	6.2377 6.7751	2251.94
TRTPN	2	1	-0.2310	0.1399	-0.5052 0.0431	2.73
TRTPN	3	1	0.0967	0.1384	-0.1745 0.3678	0.49
TRTPN	4	0	0.0000	0.0000	0.0000 0.0000	.
REGION1	ASIA (EXCLUDING JAPAN)	1	-0.4580	0.2106	-0.8708 -0.0452	4.73
REGION1	EUROPE	1	0.1747	0.1447	-0.1089 0.4583	1.46
REGION1	JAPAN	1	0.1482	0.1657	-0.1767 0.4730	0.80
REGION1	NORTH AMERICA	0	0.0000	0.0000	0.0000 0.0000	.
BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	1	0.0954	0.1290	-0.1575 0.3482	0.55
BOLAD1	CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY	0	0.0000	0.0000	0.0000 0.0000	.
Dispersion		1	2.9974	0.1757	2.6720 3.3624	

Analysis Of Maximum Likelihood Parameter Estimates

Parameter		Pr > ChiSq
Intercept		<.0001
TRTPN	2	0.0986
TRTPN	3	0.4848
TRTPN	4	.
REGION1	ASIA (EXCLUDING JAPAN)	0.0297
REGION1	EUROPE	0.2272
REGION1	JAPAN	0.3713
REGION1	NORTH AMERICA	.
BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.4598
BOLAD1	CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY	.
Dispersion		

NOTE: The negative binomial dispersion parameter was estimated by maximum likelihood.

Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=HY24SEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 2-4 hours after meal

The GENMOD Procedure

Coefficients for TRTPN Least Squares Means Using WORK.ENDPOINT Margins

Parameter	Geographic Region Grouping Method 1
Intercept	
Planned Treatment (N) 2	
Planned Treatment (N) 3	
Planned Treatment (N) 4	
Geographic Region Grouping Method 1 ASIA (EXCLUDING JAPAN)	ASIA (EXCLUDING JAPAN)
Geographic Region Grouping Method 1 EUROPE	EUROPE
Geographic Region Grouping Method 1 JAPAN	JAPAN
Geographic Region Grouping Method 1 NORTH AMERICA	NORTH AMERICA
Bolus Adjustment Method at Timepoint 1 BOLUS INSULIN ALGORITHM (SLIDING SCALE)	
Bolus Adjustment Method at Timepoint 1 CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY	

Coefficients for TRTPN Least Squares Means Using WORK.ENDPOINT Margins

Bolus Adjustment Method at Timepoint 1	Planned Treatment (N)	Row1	Row2	Row3
	1	1	1	1
	2	1		
	3		1	
	4			1
		0.1307	0.1307	0.1307
		0.3366	0.3366	0.3366
		0.239	0.239	0.239
		0.2937	0.2937	0.2937
BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.5824	0.5824	0.5824
CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0.4176	0.4176	0.4176

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Parameter Code=HY24SEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 2-4 hours after meal

The GENMOD Procedure

TRTPN Least Squares Means

Planned Treatment (N)	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
2	WORK.ENDPOINT	6.3652	0.09943	64.02	<.0001	0.05	6.1704	6.5601
3	WORK.ENDPOINT	6.6929	0.09786	68.39	<.0001	0.05	6.5011	6.8847
4	WORK.ENDPOINT	6.5963	0.09801	67.30	<.0001	0.05	6.4042	6.7884

Differences of TRTPN Least Squares Means

Planned Treatment (N)	Planned Treatment (N)	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
2	4	WORK.ENDPOINT	-0.2310	0.1399	-1.65	0.0986	0.05	-0.5052	0.04309
3	4	WORK.ENDPOINT	0.09666	0.1384	0.70	0.4848	0.05	-0.1745	0.3678

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) / NovoRapid (meal)	WORK.ENDPOINT	-0.2310	0.1399	-1.65	0.0986	0.05	-0.5052	0.04309

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Parameter Code=HY24SEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 2-4 hours after meal

The GENMOD Procedure

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
TRTPN	Faster aspart (post) / NovoRapid (meal)	WORK.ENDPOINT	0.09666	0.1384	0.70	0.4848	0.05	-0.1745	0.3678

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
1	14	3.1040603	1.132711	0.1728105	1.2560527
2	0	3.1040603	1.132711	0.1728105	0.0292351
3	0	3.1040603	1.132711	0.1728105	0.0292351
4	0	3.1040603	1.132711	0.1728105	0.0292351
5	9	3.1040603	1.132711	0.1728105	0.8179035
6	25	3.43318	1.2334869	0.1422229	2.0450385
7	7	4.3077256	1.4604101	0.173919	0.4892507
8	3	4.4247834	1.4872213	0.173919	0.2173394
9	0	3.2221496	1.1700487	0.1728105	0.0283651
10	0	0.7248098	-0.321846	0.1432654	0.0720121
11	5	3.0703206	1.121782	0.1728105	0.4715141
12	0	4.4247834	1.4872213	0.173919	0.0217508
13	0	4.3077256	1.4604101	0.173919	0.022257
14	14	3.8683097	1.3528176	0.1697595	1.047689
15	3	3.1040603	1.132711	0.1728105	0.2921246
16	0	3.9320731	1.3691668	0.1697595	0.0240518

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Parameter Code=HY24SEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 2-4 hours after meal

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
17	4	3.4146222	1.2280669	0.1422229	0.3513913
18	0	4.9447455	1.5983255	0.1459802	0.0197538
19	4	4.3020968	1.4591025	0.1432654	0.2894344
20	0	3.8683097	1.3528176	0.1697595	0.0243854
21	10	3.4146222	1.2280669	0.1422229	0.8379009
22	0	0.7013968	-0.354681	0.1697595	0.0728743
23	0	4.3077256	1.4604101	0.173919	0.022257
24	0	4.7387145	1.5557659	0.1459802	0.0204998
25	1	4.4716065	1.4977477	0.173919	0.086163
26	1	4.3077256	1.4604101	0.173919	0.0889704
27	6	4.7993682	1.5684843	0.173919	0.3849004
28	8	4.7387145	1.5557659	0.1459802	0.5120723
29	2	3.1209302	1.1381311	0.1728105	0.2036029
30	15	4.4423826	1.4911909	0.1432654	0.9962868
31	9	4.7387145	1.5557659	0.1459802	0.5735189
32	1	3.1040603	1.132711	0.1728105	0.1168649
33	2	4.3077256	1.4604101	0.173919	0.1556837
34	0	4.2787159	1.4536529	0.1432654	0.022386
35	0	4.6120758	1.528678	0.173919	0.0209869
36	0	3.9108186	1.3637467	0.1697595	0.024162
37	1	3.9108186	1.3637467	0.1697595	0.0965856
38	8	4.3077256	1.4604101	0.173919	0.5559641
39	1	4.3077256	1.4604101	0.173919	0.0889704
40	1	4.237491	1.4439713	0.173919	0.0902299
41	2	4.3077256	1.4604101	0.173919	0.1556837

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Parameter Code=HY24SEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 2-4 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
42	11	4.7902222	1.5665768	0.1459802	0.6898992
43	15	4.7387145	1.5557659	0.1459802	0.9421983
44	18	4.3020968	1.4591025	0.1432654	1.224468
45	0	3.4146222	1.2280669	0.1422229	0.0270516
46	0	3.5630841	1.2706265	0.1422229	0.0261178
47	7	3.4146222	1.2280669	0.1422229	0.5946461
48	1	4.8159761	1.5719387	0.1459802	0.0808022
49	23	4.2787159	1.4536529	0.1432654	1.5656927
50	2	3.4517377	1.2388778	0.1422229	0.1875456
51	8	3.4517377	1.2388778	0.1422229	0.6697465
52	3	4.7387145	1.5557659	0.1459802	0.2048395
53	0	4.7902222	1.5665768	0.1459802	0.0203081
54	0	4.3488588	1.4699135	0.1432654	0.0220765
55	4	4.6872067	1.5448368	0.1459802	0.2688236
56	8	3.4517377	1.2388778	0.1422229	0.6697465
57	8	5.279546	1.6638401	0.1459802	0.4658728
58	20	3.4888532	1.2495731	0.1422229	1.6197996
59	8	4.3254778	1.4645226	0.1432654	0.5540092
60	0	4.7387145	1.5557659	0.1459802	0.0204998
61	16	4.3722397	1.4752754	0.1432654	1.0758737
62	8	3.4888532	1.2495731	0.1422229	0.6638658
63	4	4.6872067	1.5448368	0.1459802	0.2688236
64	2	4.3020968	1.4591025	0.1432654	0.1558581
65	22	4.8674839	1.5825771	0.1459802	1.3406809
66	10	4.8159761	1.5719387	0.1459802	0.6260994

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The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
67	4	4.7387145	1.5557659	0.1459802	0.2662861
68	8	4.6872067	1.5448368	0.1459802	0.516952
69	8	3.358949	1.2116281	0.1422229	0.6849087
70	0	3.4146222	1.2280669	0.1422229	0.0270516
71	12	3.5816418	1.2758213	0.1422229	0.9613995
72	0	4.3020968	1.4591025	0.1432654	0.0222819
73	3	4.7387145	1.5557659	0.1459802	0.2048395
74	0	4.3020968	1.4591025	0.1432654	0.0222819
75	7	3.43318	1.2334869	0.1422229	0.5920013
76	1	4.3020968	1.4591025	0.1432654	0.08907
77	1	4.7387145	1.5557659	0.1459802	0.0819464
78	3	4.3020968	1.4591025	0.1432654	0.2226462
79	0	3.4146222	1.2280669	0.1422229	0.0270516
80	22	3.43318	1.2334869	0.1422229	1.8028657
81	0	4.3020968	1.4591025	0.1432654	0.0222819
82	0	3.4146222	1.2280669	0.1422229	0.0270516
83	0	4.3020968	1.4591025	0.1432654	0.0222819
84	1	4.231954	1.4426638	0.1432654	0.0903307
85	0	3.4146222	1.2280669	0.1422229	0.0270516
86	0	4.7129606	1.5503163	0.1459802	0.0205971
87	17	3.4146222	1.2280669	0.1422229	1.4054954
88	0	4.7387145	1.5557659	0.1459802	0.0204998
89	0	4.3722397	1.4752754	0.1432654	0.0219751
90	0	4.6614528	1.5393272	0.1459802	0.0207943
91	1	4.2787159	1.4536529	0.1432654	0.0894863

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
92	14	4.3020968	1.4591025	0.1432654	0.9573155
93	4	4.231954	1.4426638	0.1432654	0.2935309
94	0	4.2787159	1.4536529	0.1432654	0.022386
95	0	3.4146222	1.2280669	0.1422229	0.0270516
96	4	4.231954	1.4426638	0.1432654	0.2935309
97	1	4.7387145	1.5557659	0.1459802	0.0819464
98	5	3.9108186	1.3637467	0.1697595	0.3862799
99	3	3.4146222	1.2280669	0.1422229	0.2703064
100	5	4.237491	1.4439713	0.173919	0.3608612
101	1	4.3020968	1.4591025	0.1432654	0.08907
102	0	3.0871904	1.1272614	0.1728105	0.0293637
103	4	4.3779603	1.4765829	0.173919	0.2851296
104	14	4.3020968	1.4591025	0.1432654	0.9573155
105	1	3.8683097	1.3528176	0.1697595	0.0974785
106	1	3.8470553	1.347308	0.1697595	0.0979311
107	49	4.3020968	1.4591025	0.1432654	3.2948995
108	32	4.7644684	1.561186	0.1459802	1.9774563
109	7	4.6872067	1.5448368	0.1459802	0.4549199
110	1	3.1040603	1.132711	0.1728105	0.1168649
111	3	3.8683097	1.3528176	0.1697595	0.2436647
112	11	3.9108186	1.3637467	0.1697595	0.8208213
113	2	3.9108186	1.3637467	0.1697595	0.1690091
114	1	3.9108186	1.3637467	0.1697595	0.0965856
115	2	3.1040603	1.132711	0.1728105	0.2044948
116	10	4.3077256	1.4604101	0.173919	0.6893909

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Parameter Code=HY24SEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 2-4 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
117	0	3.9320731	1.3691668	0.1697595	0.0240518
118	0	3.1040603	1.132711	0.1728105	0.0292351
119	5	3.9108186	1.3637467	0.1697595	0.3862799
120	5	3.1040603	1.132711	0.1728105	0.4673842
121	0	3.9108186	1.3637467	0.1697595	0.024162
122	0	3.1040603	1.132711	0.1728105	0.0292351
123	6	4.237491	1.4439713	0.173919	0.428519
124	5	3.9108186	1.3637467	0.1697595	0.3862799
125	9	3.1040603	1.132711	0.1728105	0.8179035
126	6	4.2843141	1.4549605	0.173919	0.4245127
127	3	4.3077256	1.4604101	0.173919	0.2223971
128	0	4.3779603	1.4765829	0.173919	0.0219505
129	6	4.7387145	1.5557659	0.1459802	0.3891792
130	0	3.2221496	1.1700487	0.1728105	0.0283651
131	0	3.6001995	1.2809893	0.1422229	0.0258943
132	1	4.3077256	1.4604101	0.173919	0.0889704
133	0	5.1037184	1.6299694	0.173919	0.0192141
134	1	4.4190017	1.4859138	0.1432654	0.0870448
135	0	3.9320731	1.3691668	0.1697595	0.0240518
136	0	4.3784165	1.4766871	0.1697595	0.0219485
137	0	2.7859747	1.0245978	0.173919	0.031863
138	1	4.7229541	1.5524345	0.1432654	0.0821838
139	5	3.1378001	1.143522	0.1728105	0.4633251
140	5	3.8683097	1.3528176	0.1697595	0.3898509
141	0	4.4716065	1.4977477	0.173919	0.0215547

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Parameter Code=HY24SEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 2-4 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
142	0	4.2609025	1.449481	0.173919	0.022466
143	2	4.3020968	1.4591025	0.1432654	0.1558581
144	2	3.4146222	1.2280669	0.1422229	0.1892215
145	4	3.4146222	1.2280669	0.1422229	0.3513913
146	0	4.4190017	1.4859138	0.1432654	0.0217753
147	3	5.0992688	1.6290972	0.1459802	0.1921389
148	9	6.1809319	1.8214691	0.1459802	0.453511
149	2	4.3254778	1.4645226	0.1432654	0.1551363
150	0	3.358949	1.2116281	0.1422229	0.027419
151	14	4.7387145	1.5557659	0.1459802	0.8807517
152	5	4.3020968	1.4591025	0.1432654	0.3562225
153	0	4.231954	1.4426638	0.1432654	0.0225973
154	0	4.7129606	1.5503163	0.1459802	0.0205971
155	4	4.2553349	1.4481735	0.1432654	0.2921527
156	1	2.4310626	0.8883284	0.1422229	0.1415111
157	0	3.9145902	1.3647107	0.1459802	0.0241424
158	4	4.7387145	1.5557659	0.1459802	0.2662861
159	15	3.4517377	1.2388778	0.1422229	1.2323141
160	2	3.4702954	1.2442397	0.1422229	0.1867187
161	10	3.4146222	1.2280669	0.1422229	0.8379009
162	2	4.7387145	1.5557659	0.1459802	0.143393
163	3	4.7387145	1.5557659	0.1459802	0.2048395
164	7	4.7387145	1.5557659	0.1459802	0.4506258
165	9	2.9226201	1.0724805	0.1432654	0.8583065
166	2	4.6872067	1.5448368	0.1459802	0.1447594

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Parameter Code=HY24SEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 2-4 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
167	12	4.3020968	1.4591025	0.1432654	0.8237393
168	3	4.3488588	1.4699135	0.1432654	0.2205935
169	3	4.2553349	1.4481735	0.1432654	0.2247373
170	4	3.3960645	1.2226173	0.1422229	0.3529681
171	1	4.7129606	1.5503163	0.1459802	0.082335
172	0	3.4702954	1.2442397	0.1422229	0.0266938
173	0	3.43318	1.2334869	0.1422229	0.0269313
174	6	4.231954	1.4426638	0.1432654	0.4289978
175	0	4.3488588	1.4699135	0.1432654	0.0220765
176	0	4.2787159	1.4536529	0.1432654	0.022386
177	0	4.9189917	1.5931036	0.1459802	0.0198441
178	0	3.4702954	1.2442397	0.1422229	0.0266938
179	0	4.7387145	1.5557659	0.1459802	0.0204998
180	8	4.2787159	1.4536529	0.1432654	0.5591884
181	2	3.358949	1.2116281	0.1422229	0.1917914
182	0	4.2553349	1.4481735	0.1432654	0.0224912
183	1	4.7387145	1.5557659	0.1459802	0.0819464
184	0	4.7387145	1.5557659	0.1459802	0.0204998
185	9	4.8159761	1.5719387	0.1459802	0.5655109
186	2	4.2787159	1.4536529	0.1432654	0.1565866
187	0	3.4146222	1.2280669	0.1422229	0.0270516
188	1	3.43318	1.2334869	0.1422229	0.1076556
189	1	2.5753883	0.9460003	0.1459802	0.135406
190	9	3.358949	1.2116281	0.1422229	0.7670949
191	17	3.7620375	1.3249607	0.1697595	1.2969342

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Parameter Code=HY24SEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 2-4 hours after meal

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Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
192	0	4.2553349	1.4481735	0.1432654	0.0224912
193	2	3.4146222	1.2280669	0.1422229	0.1892215
194	5	4.3020968	1.4591025	0.1432654	0.3562225
195	18	4.84173	1.5772721	0.1459802	1.1056615
196	11	3.974582	1.3799196	0.1697595	0.8096938
197	0	4.3020968	1.4591025	0.1432654	0.0222819
198	0	4.231954	1.4426638	0.1432654	0.0225973
199	0	3.4146222	1.2280669	0.1422229	0.0270516
200	0	4.3254778	1.4645226	0.1432654	0.0221787
201	0	3.4517377	1.2388778	0.1422229	0.026812
202	0	1.3560957	0.3046098	0.1432654	0.052865
203	4	2.4723728	0.9051783	0.1459802	0.4539881
204	19	3.4146222	1.2280669	0.1422229	1.5676653
205	2	4.7644684	1.561186	0.1459802	0.1427193
206	0	3.5445263	1.2654045	0.1422229	0.026231
207	0	3.4146222	1.2280669	0.1422229	0.0270516
208	0	4.7644684	1.561186	0.1459802	0.0204035
209	5	3.358949	1.2116281	0.1422229	0.4383501
210	19	4.3020968	1.4591025	0.1432654	1.2912561
211	2	4.4716065	1.4977477	0.173919	0.1507714
212	1	4.6872067	1.5448368	0.1459802	0.0827273
213	3	4.7387145	1.5557659	0.1459802	0.2048395
214	0	4.3077256	1.4604101	0.173919	0.022257
215	0	0.1802772	-1.71326	0.1459802	0.0759789
216	0	3.1040603	1.132711	0.1728105	0.0292351

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Parameter Code=HY24SEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 2-4 hours after meal

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
217	0	3.8683097	1.3528176	0.1697595	0.0243854
218	0	3.1209302	1.1381311	0.1728105	0.0291076
219	0	3.9320731	1.3691668	0.1697595	0.0240518
220	0	3.8683097	1.3528176	0.1697595	0.0243854
221	2	4.2787159	1.4536529	0.1432654	0.1565866
222	3	3.4146222	1.2280669	0.1422229	0.2703064
223	11	4.7387145	1.5557659	0.1459802	0.696412
224	0	4.9189917	1.5931036	0.1459802	0.0198441
225	0	3.4146222	1.2280669	0.1422229	0.0270516
226	3	3.4146222	1.2280669	0.1422229	0.2703064
227	3	4.7387145	1.5557659	0.1459802	0.2048395
228	0	4.3020968	1.4591025	0.1432654	0.0222819
229	0	4.4657636	1.4964402	0.1432654	0.021579
230	0	4.7387145	1.5557659	0.1459802	0.0204998
231	0	4.7644684	1.561186	0.1459802	0.0204035
232	0	4.3956207	1.4806087	0.1432654	0.0218748
233	1	4.7387145	1.5557659	0.1459802	0.0819464
234	0	3.4702954	1.2442397	0.1422229	0.0266938
235	1	4.7387145	1.5557659	0.1459802	0.0819464
236	2	4.7644684	1.561186	0.1459802	0.1427193
237	0	4.7387145	1.5557659	0.1459802	0.0204998
238	5	4.3020968	1.4591025	0.1432654	0.3562225
239	1	4.7387145	1.5557659	0.1459802	0.0819464
240	0	3.4146222	1.2280669	0.1422229	0.0270516
241	0	3.4146222	1.2280669	0.1422229	0.0270516

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Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
242	0	3.4146222	1.2280669	0.1422229	0.0270516
243	0	4.3020968	1.4591025	0.1432654	0.0222819
244	1	4.1384301	1.4203165	0.1432654	0.0920677
245	0	4.9189917	1.5931036	0.1459802	0.0198441
246	7	2.3465509	0.8529465	0.1831773	0.7992381
247	0	2.3465509	0.8529465	0.1831773	0.0363589
248	0	2.5847012	0.9496099	0.1826842	0.0337792
249	0	2.5888578	0.9512168	0.1831773	0.0337374
250	0	2.5847012	0.9496099	0.1826842	0.0337792
251	0	2.3465509	0.8529465	0.1831773	0.0363589
252	1	1.9333339	0.6592485	0.1747289	0.1673808
253	0	2.6408903	0.9711161	0.1826842	0.0332219
254	0	2.5987484	0.95503	0.1826842	0.0336382
255	0	1.8624836	0.6219109	0.1747289	0.0429826
256	0	2.6127957	0.9604208	0.1826842	0.0334983
257	0	1.8624836	0.6219109	0.1747289	0.0429826
258	0	2.5847012	0.9496099	0.1826842	0.0337792
259	4	2.6689849	0.9816982	0.1826842	0.4280095
260	0	2.5987484	0.95503	0.1826842	0.0336382
261	0	2.3465509	0.8529465	0.1831773	0.0363589
262	0	2.5847012	0.9496099	0.1826842	0.0337792
263	0	1.8624836	0.6219109	0.1747289	0.0429826
264	2	2.3593039	0.8583666	0.1831773	0.2532904
265	0	2.3593039	0.8583666	0.1831773	0.0362111
266	1	2.3465509	0.8529465	0.1831773	0.1453416

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
267	0	2.3465509	0.8529465	0.1831773	0.0363589
268	3	2.4230689	0.8850349	0.1831773	0.3546167
269	0	1.9029724	0.6434171	0.1747289	0.0423413
270	0	2.5847012	0.9496099	0.1826842	0.0337792
271	0	1.8624836	0.6219109	0.1747289	0.0429826
272	1	2.6127957	0.9604208	0.1826842	0.1339067
273	0	2.5425593	0.9331712	0.1826842	0.0342094
274	0	1.8928502	0.6380837	0.1747289	0.0424999
275	0	2.5633518	0.9413157	0.1831773	0.0339958
276	0	2.5987484	0.95503	0.1826842	0.0336382
277	0	2.6127957	0.9604208	0.1826842	0.0334983
278	0	2.5847012	0.9496099	0.1826842	0.0337792
279	0	1.8928502	0.6380837	0.1747289	0.0424999
280	0	1.8726058	0.6273309	0.1747289	0.0428205
281	0	2.5987484	0.95503	0.1826842	0.0336382
282	7	1.8726058	0.6273309	0.1747289	0.9412772
283	0	1.832117	0.6054721	0.1747289	0.0434758
284	4	1.8624836	0.6219109	0.1747289	0.5583292
285	0	2.5566066	0.9386808	0.1826842	0.0340648
286	0	2.3593039	0.8583666	0.1831773	0.0362111
287	0	2.3593039	0.8583666	0.1831773	0.0362111
288	0	2.3720569	0.8637575	0.1831773	0.0360644
289	0	2.3593039	0.8583666	0.1831773	0.0362111
290	0	2.3465509	0.8529465	0.1831773	0.0363589
291	0	2.3848099	0.8691194	0.1831773	0.0359189

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
292	0	2.5847012	0.9496099	0.1826842	0.0337792
293	0	1.8624836	0.6219109	0.1747289	0.0429826
294	0	2.3465509	0.8529465	0.1831773	0.0363589
295	0	2.5987484	0.95503	0.1826842	0.0336382
296	0	2.3082919	0.8365078	0.1831773	0.0368095
297	0	2.3337979	0.8474969	0.1831773	0.0365079
298	10	2.5847012	0.9496099	0.1826842	1.0462836
299	0	1.305763	0.2667875	0.1747289	0.0540766
300	0	1.8624836	0.6219109	0.1747289	0.0429826
301	0	2.3465509	0.8529465	0.1831773	0.0363589
302	0	2.5847012	0.9496099	0.1826842	0.0337792
303	0	2.6127957	0.9604208	0.1826842	0.0334983
304	3	2.3720569	0.8637575	0.1831773	0.3603646
305	21	1.9434612	0.6644705	0.1747289	2.6676945
306	0	1.8624836	0.6219109	0.1747289	0.0429826
307	0	2.3210449	0.8420175	0.1831773	0.0366581
308	4	1.8624836	0.6219109	0.1747289	0.5583292
309	0	1.8726058	0.6273309	0.1747289	0.0428205
310	0	1.8726058	0.6273309	0.1747289	0.0428205
311	0	2.6127957	0.9604208	0.1826842	0.0334983
312	2	2.3720569	0.8637575	0.1831773	0.2522645
313	0	2.3465509	0.8529465	0.1831773	0.0363589
314	0	2.6689849	0.9816982	0.1826842	0.03295
315	0	1.8422392	0.6109818	0.1747289	0.0433102
316	0	2.3720569	0.8637575	0.1831773	0.0360644

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
317	9	2.5987484	0.95503	0.1826842	0.9410876
318	5	1.8523614	0.6164613	0.1747289	0.6897752
319	5	2.5706539	0.9441603	0.1826842	0.5423046
320	5	1.882728	0.6327218	0.1747289	0.6820033
321	0	2.3848099	0.8691194	0.1831773	0.0359189
322	0	2.6408903	0.9711161	0.1826842	0.0332219
323	0	1.9434612	0.6644705	0.1747289	0.0417181
324	6	2.3848099	0.8691194	0.1831773	0.6819025
325	0	1.8624836	0.6219109	0.1747289	0.0429826
326	0	1.882728	0.6327218	0.1747289	0.0426596
327	1	2.3848099	0.8691194	0.1831773	0.1435828
328	0	2.3465509	0.8529465	0.1831773	0.0363589
329	0	2.3593039	0.8583666	0.1831773	0.0362111
330	0	2.5987484	0.95503	0.1826842	0.0336382
331	0	2.3465509	0.8529465	0.1831773	0.0363589
332	0	1.882728	0.6327218	0.1747289	0.0426596
333	0	2.626843	0.9657828	0.1826842	0.0333596
334	0	1.933339	0.6592485	0.1747289	0.0418722
335	0	1.8624836	0.6219109	0.1747289	0.0429826
336	0	0.2933189	-1.226495	0.1831773	0.0830605
337	1	2.3465509	0.8529465	0.1831773	0.1453416
338	1	1.8726058	0.6273309	0.1747289	0.1711715
339	0	2.4358219	0.8902842	0.1831773	0.0353481
340	0	2.626843	0.9657828	0.1826842	0.0333596
341	0	1.9029724	0.6434171	0.1747289	0.0423413

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Parameter Code=HY24SEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 2-4 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
342	3	2.3465509	0.8529465	0.1831773	0.3633071
343	6	1.8624836	0.6219109	0.1747289	0.8160026
344	7	2.3848099	0.8691194	0.1831773	0.7895664
345	12	1.8624836	0.6219109	0.1747289	1.5890226
346	0	2.5847012	0.9496099	0.1826842	0.0337792
347	4	2.3848099	0.8691194	0.1831773	0.4665746
348	24	1.882728	0.6327218	0.1747289	3.1115092
349	2	4.8397766	1.5768686	0.1375725	0.1407852
350	0	3.4874456	1.2491695	0.14407	0.0265855
351	0	3.4493314	1.2381804	0.14407	0.0268274
352	2	3.5065026	1.2546191	0.14407	0.1851258
353	0	3.5065026	1.2546191	0.14407	0.0264661
354	0	3.4874456	1.2491695	0.14407	0.0265855
355	0	4.4178574	1.4856548	0.1416554	0.0217801
356	0	4.4178574	1.4856548	0.1416554	0.0217801
357	16	3.1875842	1.1592633	0.1476059	1.4009237
358	27	4.4236376	1.4869623	0.1387769	1.7824452
359	0	4.0597034	1.4011099	0.1405517	0.0234107
360	1	3.1875842	1.1592633	0.1476059	0.1143837
361	10	4.5919282	1.5243	0.1387769	0.6525162
362	0	3.1875842	1.1592633	0.1476059	0.0286144
363	4	3.9723979	1.3793699	0.1405517	0.3097453
364	0	3.2395557	1.1754362	0.1476059	0.0282412
365	0	3.1875842	1.1592633	0.1476059	0.0286144
366	0	3.1529365	1.1483342	0.1476059	0.0288687

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Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=HY24SEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 2-4 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
367	3	3.1356127	1.1428246	0.1476059	0.2897507
368	3	4.0160507	1.390299	0.1405517	0.2360779
369	5	3.1356127	1.1428246	0.1476059	0.4635861
370	0	4.1470088	1.4223873	0.1405517	0.0229913
371	0	3.1356127	1.1428246	0.1476059	0.0289975
372	1	4.4476791	1.4923824	0.1387769	0.0865619
373	6	4.6640527	1.5398847	0.1387769	0.3945778
374	8	4.4476791	1.4923824	0.1387769	0.5409139
375	0	3.1875842	1.1592633	0.1476059	0.0286144
376	14	4.4236376	1.4869623	0.1387769	0.9347058
377	0	4.4236376	1.4869623	0.1387769	0.0217556
378	0	4.4236376	1.4869623	0.1387769	0.0217556
379	5	4.0160507	1.390299	0.1405517	0.3777125
380	0	4.4717206	1.4977733	0.1387769	0.0215542
381	0	4.4236376	1.4869623	0.1387769	0.0217556
382	0	4.4236376	1.4869623	0.1387769	0.0217556
383	0	4.0160507	1.390299	0.1405517	0.0236261
384	0	3.5065026	1.2546191	0.14407	0.0264661
385	0	4.0160507	1.390299	0.1405517	0.0236261
386	0	4.3995961	1.4815127	0.1387769	0.0218578
387	0	3.1875842	1.1592633	0.1476059	0.0286144
388	4	4.4236376	1.4869623	0.1387769	0.2825985
389	0	4.4236376	1.4869623	0.1387769	0.0217556
390	1	4.4717206	1.4977733	0.1387769	0.0861611
391	0	4.0160507	1.390299	0.1405517	0.0236261

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The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
392	0	4.8662235	1.5823182	0.1375725	0.0200317
393	4	5.0249047	1.6144065	0.1375725	0.253012
394	0	3.4874456	1.2491695	0.14407	0.0265855
395	1	3.6970734	1.3075415	0.14407	0.1012473
396	1	4.8926703	1.5877382	0.1375725	0.0796974
397	0	3.1529365	1.1483342	0.1476059	0.0288687
398	5	3.5255597	1.2600392	0.14407	0.4212239
399	1	3.5065026	1.2546191	0.14407	0.105796
400	0	3.6208451	1.2867075	0.14407	0.0257715
401	0	3.5446168	1.2654301	0.14407	0.0262305
402	0	4.8662235	1.5823182	0.1375725	0.0200317
403	0	4.4418675	1.4910749	0.1416554	0.0216788
404	5	4.9455641	1.598491	0.1375725	0.31576
405	0	3.5255597	1.2600392	0.14407	0.0263478
406	3	4.9191172	1.5931291	0.1375725	0.1982827
407	1	3.5255597	1.2600392	0.14407	0.105323
408	0	3.5065026	1.2546191	0.14407	0.0264661
409	0	4.3755546	1.4760333	0.1387769	0.0219609
410	0	3.1356127	1.1428246	0.1476059	0.0289975
411	0	4.3995961	1.4815127	0.1387769	0.0218578
412	15	3.204908	1.1646834	0.1476059	1.3093863
413	0	4.5438451	1.5137736	0.1387769	0.0212589
414	0	4.0597034	1.4011099	0.1405517	0.0234107
415	0	4.3755546	1.4760333	0.1387769	0.0219609
416	2	3.9942243	1.3848494	0.1405517	0.1660245

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Parameter Code=HY24SEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 2-4 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
417	0	4.0160507	1.390299	0.1405517	0.0236261
418	1	4.4236376	1.4869623	0.1387769	0.0869664
419	0	4.3755546	1.4760333	0.1387769	0.0219609
420	41	4.4178574	1.4856548	0.1416554	2.6984267
421	0	4.8662235	1.5823182	0.1375725	0.0200317
422	12	4.4418675	1.4910749	0.1416554	0.8014447
423	16	4.4418675	1.4910749	0.1416554	1.0613667
424	2	3.5255597	1.2600392	0.14407	0.1842982
425	1	3.4683885	1.2436901	0.14407	0.1067546
426	3	4.9191172	1.5931291	0.1375725	0.1982827
427	0	3.5255597	1.2600392	0.14407	0.0263478
428	9	3.5255597	1.2600392	0.14407	0.7371248
429	0	4.9984578	1.6091294	0.1375725	0.0195681
430	0	4.7059785	1.5488337	0.1416554	0.0206236
431	0	4.9984578	1.6091294	0.1375725	0.0195681
432	0	4.4178574	1.4856548	0.1416554	0.0217801
433	0	3.5065026	1.2546191	0.14407	0.0264661
434	2	4.4658776	1.4964657	0.1416554	0.1509379
435	0	4.4178574	1.4856548	0.1416554	0.0217801
436	0	4.3938473	1.4802052	0.1416554	0.0218823
437	0	3.1875842	1.1592633	0.1476059	0.0286144
438	0	4.5138977	1.507161	0.1416554	0.0213805
439	3	3.204908	1.1646834	0.1476059	0.2846684
440	0	4.037877	1.3957191	0.1405517	0.0235179
441	0	3.5636739	1.270792	0.14407	0.0261142

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Parameter Code=HY24SEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 2-4 hours after meal

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
442	0	3.1875842	1.1592633	0.1476059	0.0286144
443	1	4.4178574	1.4856548	0.1416554	0.0870642
444	0	4.4898876	1.5018277	0.1416554	0.0214791
445	3	3.1875842	1.1592633	0.1476059	0.2859224
446	3	3.204908	1.1646834	0.1476059	0.2846684
447	0	4.8662235	1.5823182	0.1375725	0.0200317
448	0	4.3515131	1.4705236	0.1387769	0.0220649
449	1	4.0160507	1.390299	0.1405517	0.0944434
450	0	3.5065026	1.2546191	0.14407	0.0264661
451	1	4.4178574	1.4856548	0.1416554	0.0870642
452	0	4.6819684	1.5437186	0.1416554	0.0207153
453	0	4.4476791	1.4923824	0.1387769	0.0216545
454	3	3.3261748	1.2018229	0.1476059	0.2761853
455	12	4.9525508	1.5999028	0.1387769	0.7292727
456	5	4.6579583	1.5385772	0.1416554	0.3326555
457	4	3.1529365	1.1483342	0.1476059	0.374995
458	0	4.4957621	1.5031352	0.1387769	0.0214549
459	0	4.5919282	1.5243	0.1387769	0.0210665
460	3	4.3938473	1.4802052	0.1416554	0.2186537
461	0	5.0661299	1.6225772	0.1416554	0.019339
462	2	3.2395557	1.1754362	0.1476059	0.1975421
463	2	4.0160507	1.390299	0.1405517	0.1652607
464	0	3.5065026	1.2546191	0.14407	0.0264661
465	0	3.9942243	1.3848494	0.1405517	0.0237353
466	0	5.3951608	1.6855024	0.1375725	0.0182972

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
467	0	4.5619179	1.5177431	0.1416554	0.0211862
468	4	4.9191172	1.5931291	0.1375725	0.2577624
469	0	4.8662235	1.5823182	0.1375725	0.0200317
470	0	4.4236376	1.4869623	0.1387769	0.0217556
471	0	3.8114159	1.3380008	0.14407	0.0246908
472	0	5.0249047	1.6144065	0.1375725	0.0194779
473	2	3.308851	1.196601	0.1476059	0.1941637
474	1	4.9720109	1.6038244	0.1375725	0.0785856
475	3	4.8397766	1.5768686	0.1375725	0.2011142
476	7	3.5446168	1.2654301	0.14407	0.5765963
477	2	4.5138977	1.507161	0.1416554	0.1495533
478	0	4.9191172	1.5931291	0.1375725	0.0198437
479	0	3.4683885	1.2436901	0.14407	0.0267059
480	2	4.9455641	1.598491	0.1375725	0.1381546
481	9	4.4898876	1.5018277	0.1416554	0.6009142
482	12	4.8926703	1.5877382	0.1375725	0.7370591
483	6	4.8133297	1.5713891	0.1375725	0.3839287
484	0	4.8397766	1.5768686	0.1375725	0.020127
485	0	4.3698372	1.4747257	0.1416554	0.0219855
486	0	3.4493314	1.2381804	0.14407	0.0268274
487	0	4.8397766	1.5768686	0.1375725	0.020127
488	2	3.5065026	1.2546191	0.14407	0.1851258
489	13	3.5255597	1.2600392	0.14407	1.0530256
490	0	4.9455641	1.598491	0.1375725	0.0197509
491	0	4.8926703	1.5877382	0.1375725	0.0199372

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
492	0	4.3938473	1.4802052	0.1416554	0.0218823
493	1	4.4658776	1.4964657	0.1416554	0.0862582
494	8	3.3921602	1.2214669	0.14407	0.6794045
495	10	3.5065026	1.2546191	0.14407	0.8197648
496	16	4.4898876	1.5018277	0.1416554	1.051586
497	1	4.8662235	1.5823182	0.1375725	0.0800749
498	0	4.8662235	1.5823182	0.1375725	0.0200317
499	1	4.4898876	1.5018277	0.1416554	0.0858607
500	0	4.4178574	1.4856548	0.1416554	0.0217801
501	21	4.3698372	1.4747257	0.1416554	1.40588
502	6	4.9191172	1.5931291	0.1375725	0.3767217
503	0	3.5065026	1.2546191	0.14407	0.0264661
504	0	4.8133297	1.5713891	0.1375725	0.0202233
505	0	4.4898876	1.5018277	0.1416554	0.0214791
506	0	4.4898876	1.5018277	0.1416554	0.0214791
507	0	4.8133297	1.5713891	0.1375725	0.0202233
508	0	0.793406	-0.23142	0.1375725	0.0695237
509	5	4.7868829	1.5658794	0.1375725	0.3248647
510	2	4.8662235	1.5823182	0.1375725	0.1401182
511	2	4.4178574	1.4856548	0.1416554	0.1523482
512	6	4.8662235	1.5823182	0.1375725	0.3802913
513	18	4.4178574	1.4856548	0.1416554	1.1968932
514	13	4.8926703	1.5877382	0.1375725	0.7968192
515	13	3.5065026	1.2546191	0.14407	1.0577544
516	0	3.5065026	1.2546191	0.14407	0.0264661

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
517	9	4.8662235	1.5823182	0.1375725	0.5604211
518	1	4.8926703	1.5877382	0.1375725	0.0796974
519	10	4.4658776	1.4964657	0.1416554	0.6683756
520	0	4.9455641	1.598491	0.1375725	0.0197509
521	2	3.5065026	1.2546191	0.14407	0.1851258
522	3	4.4178574	1.4856548	0.1416554	0.2176323
523	0	4.4178574	1.4856548	0.1416554	0.0217801
524	0	4.8662235	1.5823182	0.1375725	0.0200317
525	2	3.5255597	1.2600392	0.14407	0.1842982
526	0	3.5255597	1.2600392	0.14407	0.0263478
527	0	4.9191172	1.5931291	0.1375725	0.0198437
528	0	3.5255597	1.2600392	0.14407	0.0263478
529	0	3.5065026	1.2546191	0.14407	0.0264661
530	6	3.582731	1.2761253	0.14407	0.493578
531	0	4.4418675	1.4910749	0.1416554	0.0216788
532	1	3.601788	1.2814304	0.14407	0.1034722
533	7	4.8662235	1.5823182	0.1375725	0.4403346
534	29	4.8133297	1.5713891	0.1375725	1.778133
535	5	3.5065026	1.2546191	0.14407	0.4231155
536	9	4.4178574	1.4856548	0.1416554	0.6093367
537	1	4.4418675	1.4910749	0.1416554	0.0866593
538	0	4.4418675	1.4910749	0.1416554	0.0216788
539	0	3.5255597	1.2600392	0.14407	0.0263478
540	0	4.4898876	1.5018277	0.1416554	0.0214791
541	0	3.4874456	1.2491695	0.14407	0.0265855

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
542	0	4.4658776	1.4964657	0.1416554	0.0215785
543	0	4.321817	1.4636759	0.1416554	0.0221948
544	0	3.582731	1.2761253	0.14407	0.025999
545	0	3.601788	1.2814304	0.14407	0.0258848
546	6	3.5065026	1.2546191	0.14407	0.5024453
547	1	3.5446168	1.2654301	0.14407	0.1048542
548	46	4.8926703	1.5877382	0.1375725	2.7689043
549	5	3.4874456	1.2491695	0.14407	0.4250239
550	12	4.4178574	1.4856548	0.1416554	0.8051889
551	28	4.4178574	1.4856548	0.1416554	1.8497339
552	10	3.5065026	1.2546191	0.14407	0.8197648
553	2	3.5255597	1.2600392	0.14407	0.1842982
554	6	4.4658776	1.4964657	0.1416554	0.4096568
555	0	3.5065026	1.2546191	0.14407	0.0264661
556	0	3.601788	1.2814304	0.14407	0.0258848
557	5	4.4418675	1.4910749	0.1416554	0.3465813
558	0	3.5255597	1.2600392	0.14407	0.0263478
559	0	3.5065026	1.2546191	0.14407	0.0264661
560	0	4.4898876	1.5018277	0.1416554	0.0214791
561	4	4.8662235	1.5823182	0.1375725	0.2602048
562	1	4.4418675	1.4910749	0.1416554	0.0866593
563	37	4.0160507	1.390299	0.1405517	2.6438654
564	10	4.9191172	1.5931291	0.1375725	0.6146405
565	1	4.4898876	1.5018277	0.1416554	0.0858607
566	0	3.5065026	1.2546191	0.14407	0.0264661

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Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=HY24SEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 2-4 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
567	11	4.0597034	1.4011099	0.1405517	0.7952972
568	2	4.8662235	1.5823182	0.1375725	0.1401182
569	2	4.3458271	1.4692161	0.1416554	0.1545135
570	1	4.8926703	1.5877382	0.1375725	0.0796974
571	2	3.5255597	1.2600392	0.14407	0.1842982
572	6	5.0249047	1.6144065	0.1375725	0.369779
573	8	3.582731	1.2761253	0.14407	0.6494377
574	20	4.9455641	1.598491	0.1375725	1.2037873
575	25	4.8662235	1.5823182	0.1375725	1.5211134
576	5	3.582731	1.2761253	0.14407	0.4156482
577	2	4.4418675	1.4910749	0.1416554	0.1516398
578	25	4.3938473	1.4802052	0.1416554	1.6616439
579	44	4.8662235	1.5823182	0.1375725	2.6619355
580	10	4.8662235	1.5823182	0.1375725	0.6204644
581	9	4.4418675	1.4910749	0.1416554	0.6065033
582	4	4.4178574	1.4856548	0.1416554	0.2829164
583	3	3.5065026	1.2546191	0.14407	0.2644557
584	0	4.3755546	1.4760333	0.1387769	0.0219609
585	9	4.037877	1.3957191	0.1405517	0.6579542
586	1	4.1470088	1.4223873	0.1405517	0.0919056
587	0	4.0160507	1.390299	0.1405517	0.0236261
588	2	3.1875842	1.1592633	0.1476059	0.2001531
589	1	3.2222318	1.1700742	0.1476059	0.1133847
590	0	4.4236376	1.4869623	0.1387769	0.0217556
591	18	4.0160507	1.390299	0.1405517	1.2983371

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Parameter Code=HY24SEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 2-4 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
592	25	4.0160507	1.390299	0.1405517	1.7940581
593	3	4.4236376	1.4869623	0.1387769	0.2173878
594	17	3.204908	1.1646834	0.1476059	1.4801726
595	3	4.4236376	1.4869623	0.1387769	0.2173878
596	7	3.4301178	1.2325946	0.1476059	0.5924361
597	4	3.1875842	1.1592633	0.1476059	0.3716917
598	10	3.1875842	1.1592633	0.1476059	0.8863077
599	2	3.1356127	1.1428246	0.1476059	0.202833
600	1	3.9942243	1.3848494	0.1405517	0.0948799
601	8	4.4717206	1.4977733	0.1387769	0.5384097
602	0	3.1529365	1.1483342	0.1476059	0.0288687
603	2	4.8926703	1.5877382	0.1375725	0.1394575
604	4	3.1356127	1.1428246	0.1476059	0.3766684
605	5	4.0160507	1.390299	0.1405517	0.3777125
606	6	4.0160507	1.390299	0.1405517	0.4485298
607	3	4.3995961	1.4815127	0.1387769	0.2184083
608	0	4.9455641	1.598491	0.1375725	0.0197509
609	0	3.1875842	1.1592633	0.1476059	0.0286144
610	0	4.4717206	1.4977733	0.1387769	0.0215542
611	6	4.1251825	1.4171103	0.1405517	0.4384414
612	62	4.4236376	1.4869623	0.1387769	4.0648205
613	3	4.037877	1.3957191	0.1405517	0.2349967
614	0	3.204908	1.1646834	0.1476059	0.0284889
615	2	3.1702603	1.1538137	0.1476059	0.2010386
616	0	3.1875842	1.1592633	0.1476059	0.0286144

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Parameter Code=HY24SEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 2-4 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
617	2	4.3515131	1.4705236	0.1387769	0.1543404
618	1	4.037877	1.3957191	0.1405517	0.0940108
619	6	4.4236376	1.4869623	0.1387769	0.41302
620	1	3.2568795	1.1807695	0.1476059	0.1124028
621	55	4.5678866	1.5190507	0.1387769	3.5099266
622	1	3.1702603	1.1538137	0.1476059	0.1148898
623	3	4.4236376	1.4869623	0.1387769	0.2173878
624	3	4.0160507	1.390299	0.1405517	0.2360779
625	0	3.9723979	1.3793699	0.1405517	0.0238455
626	2	3.1875842	1.1592633	0.1476059	0.2001531
627	0	2.6686075	0.9815568	0.1387769	0.0329536
628	0	4.1688352	1.4276367	0.1405517	0.0228887
629	5	3.2395557	1.1754362	0.1476059	0.4514936
630	0	4.037877	1.3957191	0.1405517	0.0235179
631	4	4.3755546	1.4760333	0.1387769	0.2852642
632	0	3.204908	1.1646834	0.1476059	0.0284889
633	3	3.9942243	1.3848494	0.1405517	0.2371691
634	0	4.4957621	1.5031352	0.1387769	0.0214549
635	0	4.0160507	1.390299	0.1405517	0.0236261
636	11	3.2395557	1.1754362	0.1476059	0.9593966
637	0	3.1702603	1.1538137	0.1476059	0.028741
638	5	4.4089252	1.4836309	0.1405517	0.3488066
639	1	4.3995961	1.4815127	0.1387769	0.0873746
640	25	3.1529365	1.1483342	0.1476059	2.1921579
641	1	4.4236376	1.4869623	0.1387769	0.0869664

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Parameter Code=HY24SEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 2-4 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
642	0	4.4418675	1.4910749	0.1416554	0.0216788
643	0	3.204908	1.1646834	0.1476059	0.0284889
644	0	4.3938473	1.4802052	0.1416554	0.0218823
645	2	3.1875842	1.1592633	0.1476059	0.2001531
646	3	4.8662235	1.5823182	0.1375725	0.2001615
647	1	3.1875842	1.1592633	0.1476059	0.1143837
648	2	4.8662235	1.5823182	0.1375725	0.1401182
649	19	4.5619179	1.5177431	0.1416554	1.2277576
650	0	4.9191172	1.5931291	0.1375725	0.0198437
651	1	4.0160507	1.390299	0.1405517	0.0944434
652	1	4.4236376	1.4869623	0.1387769	0.0869664
653	17	4.4236376	1.4869623	0.1387769	1.1303379
654	11	4.9455641	1.598491	0.1375725	0.670971
655	6	4.3698372	1.4747257	0.1416554	0.4173839
656	0	4.9191172	1.5931291	0.1375725	0.0198437
657	1	4.4658776	1.4964657	0.1416554	0.0862582
658	0	4.3938473	1.4802052	0.1416554	0.0218823
659	8	5.4216077	1.6903924	0.1375725	0.455082
660	0	3.5065026	1.2546191	0.14407	0.0264661
661	4	3.2222318	1.1700742	0.1476059	0.3684454
662	0	3.8876894	1.357815	0.1375725	0.024283
663	0	6.098564	1.8080533	0.1416554	0.0164065
664	0	4.5138977	1.507161	0.1416554	0.0213805
665	2	4.6819684	1.5437186	0.1416554	0.1448998
666	10	3.601788	1.2814304	0.14407	0.8017591

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Parameter Code=HY24SEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 2-4 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
667	0	3.5446168	1.2654301	0.14407	0.0262305
668	0	2.6411104	0.9711994	0.1416554	0.0332198
669	2	4.0096858	1.3887129	0.1416554	0.1654827
670	0	3.2742033	1.1860746	0.1476059	0.0279976
671	0	4.3755546	1.4760333	0.1387769	0.0219609
672	5	3.2568795	1.1807695	0.1476059	0.4495385
673	5	3.1875842	1.1592633	0.1476059	0.4574611
674	1	4.4236376	1.4869623	0.1387769	0.0869664
675	15	4.4236376	1.4869623	0.1387769	0.9999165
676	3	4.0160507	1.390299	0.1405517	0.2360779
677	11	3.9723979	1.3793699	0.1405517	0.81007
678	4	3.4301178	1.2325946	0.1476059	0.3500854
679	3	4.3995961	1.4815127	0.1387769	0.2184083
680	16	4.0160507	1.390299	0.1405517	1.1567026
681	12	4.4476791	1.4923824	0.1387769	0.8005437
682	11	4.4236376	1.4869623	0.1387769	0.7390736
683	1	4.1470088	1.4223873	0.1405517	0.0919056
684	11	3.9287452	1.3683201	0.1405517	0.8176624
685	1	3.1875842	1.1592633	0.1476059	0.1143837
686	0	4.4957621	1.5031352	0.1387769	0.0214549
687	0	3.3261748	1.2018229	0.1476059	0.02764
688	0	3.9505716	1.3738603	0.1405517	0.0239567
689	2	4.0160507	1.390299	0.1405517	0.1652607
690	4	4.0160507	1.390299	0.1405517	0.3068952
691	0	3.9723979	1.3793699	0.1405517	0.0238455

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Parameter Code=HY24SEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 2-4 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
692	2	4.4476791	1.4923824	0.1387769	0.1514693
693	1	3.1875842	1.1592633	0.1476059	0.1143837
694	4	2.3465509	0.8529465	0.1831773	0.4722899
695	9	2.3975629	0.8744528	0.1831773	1.0008553
696	0	1.8624836	0.6219109	0.1747289	0.0429826
697	6	2.2955389	0.8309676	0.1831773	0.7017069
698	0	1.8422392	0.6109818	0.1747289	0.0433102
699	1	2.3082919	0.8365078	0.1831773	0.1471428
700	18	1.9333339	0.6592485	0.1747289	2.3010264
701	1	2.5847012	0.9496099	0.1826842	0.1350297
702	0	2.3465509	0.8529465	0.1831773	0.0363589
703	15	2.2572799	0.8141605	0.1831773	1.7202104
704	20	2.5847012	0.9496099	0.1826842	2.058788
705	1	2.3337979	0.8474969	0.1831773	0.1459372
706	0	2.3210449	0.8420175	0.1831773	0.0366581
707	0	2.5566066	0.9386808	0.1826842	0.0340648
708	7	1.882728	0.6327218	0.1747289	0.9377408
709	0	2.3465509	0.8529465	0.1831773	0.0363589
710	0	2.5847012	0.9496099	0.1826842	0.0337792
711	0	1.832117	0.6054721	0.1747289	0.0434758
712	0	1.832117	0.6054721	0.1747289	0.0434758
713	0	2.3465509	0.8529465	0.1831773	0.0363589
714	2	2.3082919	0.8365078	0.1831773	0.2574762
715	0	2.206268	0.7913024	0.1831773	0.0380658
716	4	1.8624836	0.6219109	0.1747289	0.5583292

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Parameter Code=HY24SEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 2-4 hours after meal

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
717	11	2.5706539	0.9441603	0.1826842	1.1523645
718	2	2.3337979	0.8474969	0.1831773	0.2553666
719	0	2.5847012	0.9496099	0.1826842	0.0337792
720	0	2.3465509	0.8529465	0.1831773	0.0363589
721	0	2.3465509	0.8529465	0.1831773	0.0363589
722	22	2.5706539	0.9441603	0.1826842	2.2708076
723	0	2.5706539	0.9441603	0.1826842	0.0339214
724	13	2.5847012	0.9496099	0.1826842	1.3500349
725	9	2.778381	1.0218684	0.1413803	0.8933368
726	19	4.1971126	1.4343968	0.1572262	1.3188025
727	11	3.1523699	1.1481545	0.1575848	0.9808585
728	29	4.1304918	1.4183965	0.1572262	2.0283837
729	0	3.3283905	1.2024889	0.1575848	0.0276249
730	7	4.0194571	1.3911468	0.1572262	0.5189744
731	2	4.4191821	1.4859546	0.1572262	0.152309
732	1	2.778381	1.0218684	0.1413803	0.1276431
733	8	3.3538763	1.2101168	0.1371075	0.6857572
734	0	3.3538763	1.2101168	0.1371075	0.027453
735	4	2.6765555	0.9845307	0.1413803	0.4270672
736	1	3.6135107	1.2846798	0.1384811	0.1031933
737	1	2.0946956	0.7394083	0.1413803	0.1580504
738	2	2.9283436	1.0744369	0.1575848	0.2142628
739	2	3.3538763	1.2101168	0.1371075	0.192029
740	0	3.4271851	1.2317393	0.1371075	0.02697
741	0	2.749288	1.011342	0.1413803	0.0321962

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The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
742	0	2.9603474	1.0853066	0.1575848	0.0303676
743	6	2.9603474	1.0853066	0.1575848	0.5765127
744	4	3.3722035	1.2155664	0.1371075	0.355016
745	0	3.3538763	1.2101168	0.1371075	0.027453
746	0	3.7750084	1.3284026	0.1384811	0.0248903
747	5	2.9443455	1.0798865	0.1575848	0.4875901
748	3	3.4088579	1.2263773	0.1371075	0.270682
749	4	4.0860779	1.4075856	0.1572262	0.3024302
750	5	3.83557	1.3443181	0.1384811	0.3926463
751	6	3.7095932	1.3109222	0.1580692	0.4794881
752	0	2.9443455	1.0798865	0.1575848	0.030499
753	8	3.734634	1.3176498	0.1384811	0.6273623
754	7	2.9283436	1.0744369	0.1575848	0.6733409
755	0	3.8557572	1.3495674	0.1384811	0.0244521
756	4	3.7144467	1.3122297	0.1384811	0.3277197
757	6	3.6942595	1.3067801	0.1384811	0.4811487
758	6	3.3722035	1.2155664	0.1371075	0.5188587
759	0	2.6765555	0.9845307	0.1413803	0.0328775
760	0	3.3722035	1.2155664	0.1371075	0.0273307
761	1	3.734634	1.3176498	0.1384811	0.1003961
762	0	3.3538763	1.2101168	0.1371075	0.027453
763	1	3.7144467	1.3122297	0.1384811	0.1008519
764	8	3.7750084	1.3284026	0.1384811	0.6217427
765	0	3.3538763	1.2101168	0.1371075	0.027453
766	0	3.7499149	1.3217331	0.1580692	0.0250296

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The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
767	5	3.3722035	1.2155664	0.1371075	0.4369374
768	0	2.662009	0.9790811	0.1413803	0.0330171
769	0	3.734634	1.3176498	0.1384811	0.0251153
770	1	3.5004939	1.2529041	0.1371075	0.105946
771	3	3.734634	1.3176498	0.1384811	0.2509579
772	6	3.3905307	1.2209865	0.1371075	0.5165567
773	0	3.6538851	1.295791	0.1384811	0.0255775
774	14	3.7548212	1.3230407	0.1384811	1.0741933
775	0	3.3722035	1.2155664	0.1371075	0.0273307
776	0	3.7144467	1.3122297	0.1384811	0.0252293
777	3	2.6765555	0.9845307	0.1413803	0.3285198
778	17	3.734634	1.3176498	0.1384811	1.3048903
779	0	0.8436969	-0.169962	0.1413803	0.0677493
780	0	2.6765555	0.9845307	0.1413803	0.0328775
781	0	2.9443455	1.0798865	0.1575848	0.030499
782	0	3.7548212	1.3230407	0.1384811	0.0250023
783	6	3.3722035	1.2155664	0.1371075	0.5188587
784	0	2.778381	1.0218684	0.1413803	0.0319314
785	3	3.6740723	1.3013007	0.1384811	0.2544063
786	2	2.9443455	1.0798865	0.1575848	0.2133355
787	0	2.9443455	1.0798865	0.1575848	0.030499
788	0	3.7951956	1.3337359	0.1384811	0.0247793
789	1	2.9443455	1.0798865	0.1575848	0.1219172
790	0	3.5004939	1.2529041	0.1371075	0.0265036
791	1	4.2796886	1.4538803	0.1384811	0.0894689

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Parameter Code=HY24SEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 2-4 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
792	1	2.7638345	1.016619	0.1413803	0.1281702
793	0	3.3722035	1.2155664	0.1371075	0.0273307
794	14	3.3905307	1.2209865	0.1371075	1.1690198
795	0	3.4088579	1.2263773	0.1371075	0.0270892
796	0	2.6765555	0.9845307	0.1413803	0.0328775
797	1	3.7144467	1.3122297	0.1384811	0.1008519
798	0	2.6765555	0.9845307	0.1413803	0.0328775
799	4	3.8305582	1.3430105	0.1580692	0.3193796
800	0	3.1043643	1.1328089	0.1575848	0.0292328
801	0	3.136368	1.1430654	0.1575848	0.0289919
802	7	2.9283436	1.0744369	0.1575848	0.6733409
803	0	4.0860779	1.4075856	0.1572262	0.0232824
804	0	3.7095932	1.3109222	0.1580692	0.0252568
805	0	3.8103974	1.3377335	0.1580692	0.0246964
806	0	4.2637335	1.4501452	0.1572262	0.0224533
807	5	3.7499149	1.3217331	0.1580692	0.4001509
808	0	3.9112015	1.3638446	0.1580692	0.02416
809	3	4.1304918	1.4183965	0.1572262	0.2305158
810	2	4.1749057	1.4290918	0.1572262	0.1599045
811	0	3.850719	1.3482599	0.1580692	0.024479
812	1	2.7929275	1.0270903	0.1413803	0.1271202
813	0	2.7347415	1.0060369	0.1413803	0.0323302
814	0	4.0172549	1.3905988	0.1384811	0.0236201
815	12	2.57473	0.9457447	0.1413803	1.2525113
816	5	2.691102	0.9899508	0.1413803	0.5234004

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Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=HY24SEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 2-4 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
817	0	4.0860779	1.4075856	0.1572262	0.0232824
818	0	2.632916	0.968092	0.1413803	0.0332999
819	1	3.3538763	1.2101168	0.1371075	0.109741
820	1	3.5188211	1.258126	0.1371075	0.1054898
821	0	3.5004939	1.2529041	0.1371075	0.0265036
822	0	3.9566933	1.3754086	0.1384811	0.0239254
823	0	3.6740723	1.3013007	0.1384811	0.0254604
824	0	2.691102	0.9899508	0.1413803	0.032739
825	1	2.691102	0.9899508	0.1413803	0.1308713
826	0	3.3172219	1.1991277	0.1371075	0.0277009
827	0	2.9443455	1.0798865	0.1575848	0.030499
828	2	2.9383925	1.0778627	0.1413803	0.2136795
829	6	3.6942595	1.3067801	0.1384811	0.4811487
830	2	3.8557572	1.3495674	0.1384811	0.1710385
831	3	3.5371483	1.2633208	0.1371075	0.2625596
832	10	3.3722035	1.2155664	0.1371075	0.8465441
833	4	3.7144467	1.3122297	0.1384811	0.3277197
834	0	3.7144467	1.3122297	0.1384811	0.0252293
835	4	2.7638345	1.016619	0.1413803	0.4164912
836	0	3.850719	1.3482599	0.1580692	0.024479
837	3	3.850719	1.3482599	0.1580692	0.2446003
838	2	2.9443455	1.0798865	0.1575848	0.2133355
839	0	2.9123417	1.0689575	0.1575848	0.0307653
840	0	3.7095932	1.3109222	0.1580692	0.0252568
841	0	4.1749057	1.4290918	0.1572262	0.0228604

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Parameter Code=HY24SEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 2-4 hours after meal

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
842	0	3.8708799	1.3534818	0.1580692	0.0243718
843	0	3.6894324	1.3054726	0.1580692	0.025372
844	0	2.9443455	1.0798865	0.1575848	0.030499
845	6	3.971684	1.3791902	0.1580692	0.452764
846	1	2.9603474	1.0853066	0.1575848	0.1213917
847	0	3.7095932	1.3109222	0.1580692	0.0252568
848	0	4.0860779	1.4075856	0.1572262	0.0232824
849	0	4.1304918	1.4183965	0.1572262	0.0230695
850	28	2.9443455	1.0798865	0.1575848	2.5902092
851	2	2.9763492	1.0906975	0.1575848	0.2115042
852	11	4.0860779	1.4075856	0.1572262	0.7909389
853	12	4.0860779	1.4075856	0.1572262	0.8607259
854	0	3.3722035	1.2155664	0.1371075	0.0273307
855	1	3.3722035	1.2155664	0.1371075	0.109252
856	0	3.7144467	1.3122297	0.1384811	0.0252293
857	5	3.7144467	1.3122297	0.1384811	0.4033423
858	0	2.923846	1.0728999	0.1413803	0.0306691
859	0	2.8802065	1.057862	0.1413803	0.0310373
860	5	4.0860779	1.4075856	0.1572262	0.3722172
861	1	2.9763492	1.0906975	0.1575848	0.1208707
862	0	3.6894324	1.3054726	0.1580692	0.025372
863	10	3.6538851	1.295791	0.1384811	0.7922417
864	3	4.0860779	1.4075856	0.1572262	0.2326432
865	1	3.7750084	1.3284026	0.1384811	0.0994968
866	0	3.7750084	1.3284026	0.1384811	0.0248903

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Parameter Code=HY24SEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 2-4 hours after meal

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
867	1	3.3538763	1.2101168	0.1371075	0.109741
868	0	2.8220205	1.0374531	0.1413803	0.0315421
869	12	3.7750084	1.3284026	0.1384811	0.920169
870	3	3.3355491	1.2046373	0.1371075	0.2755503
871	7	2.9443455	1.0798865	0.1575848	0.6704266
872	0	2.7056485	0.9953416	0.1413803	0.0326016
873	17	3.4088579	1.2263773	0.1371075	1.4074484
874	0	3.3905307	1.2209865	0.1371075	0.0272094
875	7	2.720195	1.0007036	0.1413803	0.7136508
876	5	2.7056485	0.9953416	0.1413803	0.5212044
877	8	3.4088579	1.2263773	0.1371075	0.67667
878	18	3.6538851	1.295791	0.1384811	1.405573
879	0	2.662009	0.9790811	0.1413803	0.0330171
880	16	3.7144467	1.3122297	0.1384811	1.2351908
881	0	2.662009	0.9790811	0.1413803	0.0330171
882	3	0.8291504	-0.187354	0.1413803	0.6820465
883	6	2.6474625	0.9736016	0.1413803	0.6294868
884	3	3.3722035	1.2155664	0.1371075	0.2730947
885	0	3.3538763	1.2101168	0.1371075	0.027453
886	5	3.7750084	1.3284026	0.1384811	0.3979231
887	1	3.3722035	1.2155664	0.1371075	0.109252
888	5	2.6765555	0.9845307	0.1413803	0.5256147
889	10	3.3722035	1.2155664	0.1371075	0.8465441
890	0	3.83557	1.3443181	0.1384811	0.0245602
891	4	3.6942595	1.3067801	0.1384811	0.3292139

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Parameter Code=HY24SEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 2-4 hours after meal

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
892	9	3.3355491	1.2046373	0.1371075	0.771498
893	1	3.734634	1.3176498	0.1384811	0.1003961
894	1	3.6942595	1.3067801	0.1384811	0.1013117
895	14	3.5188211	1.258126	0.1371075	1.1337932
896	2	3.3722035	1.2155664	0.1371075	0.1911733
897	3	4.063871	1.402136	0.1572262	0.2337217
898	4	2.7056485	0.9953416	0.1413803	0.4234839
899	0	3.5933235	1.2790775	0.1384811	0.0259354
900	13	3.7144467	1.3122297	0.1384811	1.008323
901	1	2.662009	0.9790811	0.1413803	0.1319832
902	0	2.662009	0.9790811	0.1413803	0.0330171
903	5	2.7056485	0.9953416	0.1413803	0.5212044
904	0	3.6942595	1.3067801	0.1384811	0.0253443
905	0	3.7095932	1.3109222	0.1580692	0.0252568
906	5	3.8910407	1.3586767	0.1580692	0.3879333
907	0	3.7144467	1.3122297	0.1384811	0.0252293
908	2	2.9443455	1.0798865	0.1575848	0.2133355
909	0	4.0860779	1.4075856	0.1572262	0.0232824
910	0	3.6894324	1.3054726	0.1580692	0.025372
911	1	3.6538851	1.295791	0.1384811	0.1022439
912	0	3.8305582	1.3430105	0.1580692	0.0245872
913	0	4.1082849	1.4130056	0.1572262	0.0231754
914	0	4.1304918	1.4183965	0.1572262	0.0230695
915	1	2.9923511	1.0960594	0.1575848	0.120354
916	28	3.6894324	1.3054726	0.1580692	2.1547805

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Parameter Code=HY24SEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 2-4 hours after meal

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Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
917	0	3.6894324	1.3054726	0.1580692	0.025372
918	0	2.691102	0.9899508	0.1413803	0.032739
919	0	2.7056485	0.9953416	0.1413803	0.0326016
920	1	2.9283436	1.0744369	0.1575848	0.1224472
921	8	3.3905307	1.2209865	0.1371075	0.6796725
922	0	3.0403567	1.1119749	0.1575848	0.0297267
923	0	2.691102	0.9899508	0.1413803	0.032739
924	0	3.7548212	1.3230407	0.1384811	0.0250023
925	0	2.9443455	1.0798865	0.1575848	0.030499
926	7	3.7144467	1.3122297	0.1384811	0.5545875
927	0	3.3905307	1.2209865	0.1371075	0.0272094
928	0	4.0860779	1.4075856	0.1572262	0.0232824
929	1	2.691102	0.9899508	0.1413803	0.1308713
930	2	2.9283436	1.0744369	0.1575848	0.2142628
931	0	4.041664	1.3966565	0.1572262	0.0234992
932	0	3.734634	1.3176498	0.1384811	0.0251153
933	0	2.3588174	0.8581604	0.1580692	0.0362167
934	1	2.9763492	1.0906975	0.1575848	0.1208707
935	16	2.9443455	1.0798865	0.1575848	1.4931906
936	2	3.3722035	1.2155664	0.1371075	0.1911733
937	8	2.9443455	1.0798865	0.1575848	0.7618448
938	8	4.3525613	1.4707645	0.1572262	0.5510529
939	1	3.734634	1.3176498	0.1384811	0.1003961
940	6	2.6765555	0.9845307	0.1413803	0.6241621
941	1	3.6491107	1.2944835	0.1580692	0.1023553

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
942	0	2.7929275	1.0270903	0.1413803	0.0318006
943	4	3.6740723	1.3013007	0.1384811	0.3307217
944	1	2.6765555	0.9845307	0.1413803	0.1314249
945	1	2.6474625	0.9736016	0.1413803	0.1325461
946	0	2.9443455	1.0798865	0.1575848	0.030499
947	0	4.219127	1.4396282	0.1384811	0.0226559
948	0	3.8557572	1.3495674	0.1384811	0.0244521
949	7	3.734634	1.3176498	0.1384811	0.5520815
950	6	3.8708799	1.3534818	0.1580692	0.4626855
951	0	2.691102	0.9899508	0.1413803	0.032739
952	0	3.3763962	1.2168089	0.1575848	0.0273028
953	1	3.3722035	1.2155664	0.1371075	0.109252
954	4	3.4821667	1.2476547	0.1371075	0.3457682
955	26	3.6942595	1.3067801	0.1384811	2.0004966
956	0	2.6765555	0.9845307	0.1413803	0.0328775
957	0	2.9443455	1.0798865	0.1575848	0.030499
958	2	2.632916	0.968092	0.1413803	0.2329275
959	5	3.7144467	1.3122297	0.1384811	0.4033423
960	0	3.7144467	1.3122297	0.1384811	0.0252293
961	0	2.6765555	0.9845307	0.1413803	0.0328775
962	0	2.9443455	1.0798865	0.1575848	0.030499
963	4	2.6765555	0.9845307	0.1413803	0.4270672
964	0	3.5004939	1.2529041	0.1371075	0.0265036
965	0	2.9603474	1.0853066	0.1575848	0.0303676
966	8	3.3722035	1.2155664	0.1371075	0.6827014

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
967	0	2.691102	0.9899508	0.1413803	0.032739
968	0	0.7127784	-0.338585	0.1413803	0.0724546
969	0	2.5892765	0.9513785	0.1413803	0.0337332
970	1	3.4455123	1.2370726	0.1371075	0.1073383
971	0	3.7095932	1.3109222	0.1580692	0.0252568
972	1	3.7144467	1.3122297	0.1384811	0.1008519
973	2	4.1526988	1.4237584	0.1572262	0.1606324
974	3	3.7095932	1.3109222	0.1580692	0.2523725
975	0	4.063871	1.402136	0.1572262	0.0233903
976	0	2.9443455	1.0798865	0.1575848	0.030499
977	0	3.4271851	1.2317393	0.1371075	0.02697
978	2	3.6894324	1.3054726	0.1580692	0.1774726
979	1	2.778381	1.0218684	0.1413803	0.1276431
980	9	3.8103974	1.3377335	0.1580692	0.6909237
981	0	2.9123417	1.0689575	0.1575848	0.0307653
982	0	3.1523699	1.1481545	0.1575848	0.0288729
983	3	3.5738026	1.2736302	0.1371075	0.2603267
984	1	2.662009	0.9790811	0.1413803	0.1319832
985	3	3.3538763	1.2101168	0.1371075	0.2743171
986	16	4.1082849	1.4130056	0.1572262	1.134638
987	0	3.7144467	1.3122297	0.1384811	0.0252293
988	0	3.3355491	1.2046373	0.1371075	0.0275764
989	15	3.3355491	1.2046373	0.1371075	1.2674457
990	0	2.7056485	0.9953416	0.1413803	0.0326016
991	11	3.3722035	1.2155664	0.1371075	0.9284655

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Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=HY24SEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 2-4 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
992	15	3.225586	1.1711146	0.1371075	1.3025664
993	7	3.7144467	1.3122297	0.1384811	0.5545875
994	0	3.4088579	1.2263773	0.1371075	0.0270892
995	0	3.7144467	1.3122297	0.1384811	0.0252293
996	0	3.734634	1.3176498	0.1384811	0.0251153
997	0	2.0709728	0.7280185	0.1371075	0.0398655
998	14	2.880338	1.0579076	0.1575848	1.3334346
999	0	3.5188211	1.258126	0.1371075	0.0263895
1000	3	2.691102	0.9899508	0.1413803	0.3271359
1001	0	3.0883624	1.127641	0.1575848	0.0293548
1002	18	4.063871	1.402136	0.1572262	1.2853785
1003	2	2.8773693	1.0568764	0.1371075	0.2172706
1004	0	1.4131047	0.3457892	0.1384811	0.0515503
1005	10	3.3905307	1.2209865	0.1371075	0.8427883
1006	3	2.6765555	0.9845307	0.1413803	0.3285198
1007	10	2.691102	0.9899508	0.1413803	1.0140619
1008	11	3.3722035	1.2155664	0.1371075	0.9284655
1009	4	3.4638395	1.2423777	0.1371075	0.3472763
1010	0	3.6740723	1.3013007	0.1384811	0.0254604
1011	0	2.9965785	1.0974711	0.1413803	0.030074
1012	8	2.662009	0.9790811	0.1413803	0.8247455
1013	8	2.7056485	0.9953416	0.1413803	0.8143661
1014	1	3.7548212	1.3230407	0.1384811	0.0999445
1015	0	2.691102	0.9899508	0.1413803	0.032739
1016	4	3.8153828	1.339041	0.1384811	0.3204456

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Parameter Code=HY24SEBG Parameter=Severe or BG confirmed hypoglycaemic episodes between 2-4 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
1017	5	3.6942595	1.3067801	0.1384811	0.4051813
1018	30	3.3722035	1.2155664	0.1371075	2.4849711
1019	3	2.9443455	1.0798865	0.1575848	0.3047537
1020	3	2.720195	1.0007036	0.1413803	0.324402
1021	4	3.7548212	1.3230407	0.1384811	0.3247711
1022	0	2.6765555	0.9845307	0.1413803	0.0328775
1023	9	3.3722035	1.2155664	0.1371075	0.7646228
1024	7	3.3722035	1.2155664	0.1371075	0.6007801
1025	0	3.3722035	1.2155664	0.1371075	0.0273307

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Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=HY2HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 2 hours after meal

The GENMOD Procedure

Model Information

Data Set	WORK.ENDPOINT	
Distribution	Negative Binomial	
Link Function	Log	
Dependent Variable	AVAL	Analysis Value
Offset Variable	log_offset	

Number of Observations Read	1025
Number of Observations Used	1025

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Parameter Information

Parameter	Effect	TRTPN	REGION1	BOLAD1
Prm1	Intercept			
Prm2	TRTPN	2		
Prm3	TRTPN	3		
Prm4	TRTPN	4		
Prm5	REGION1		ASIA (EXCLUDING JAPAN)	
Prm6	REGION1		EUROPE	

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Parameter Information

Parameter	Effect	TRTPN	REGION1	BOLAD1
Prm7	REGION1		JAPAN	
Prm8	REGION1		NORTH AMERICA	
Prm9	BOLAD1			BOLUS INSULIN ALGORITHM (SLIDING SCALE)
Prm10	BOLAD1			CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Criteria For Assessing Goodness Of Fit

Criterion	DF	Value	Value/DF
Deviance	1018	854.1827	0.8391
Scaled Deviance	1018	854.1827	0.8391
Pearson Chi-Square	1018	1298.8365	1.2759
Scaled Pearson X2	1018	1298.8365	1.2759
Log Likelihood		845.0679	
Full Log Likelihood		-1683.0362	
AIC (smaller is better)		3382.0724	
AICC (smaller is better)		3382.2141	
BIC (smaller is better)		3421.5320	

Algorithm converged.

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Parameter Code=HY2HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 2 hours after meal

The GENMOD Procedure

Analysis Of Maximum Likelihood Parameter Estimates

Parameter		DF	Estimate	Standard Error	Wald 95% Confidence Limits		Wald Chi-Square
Intercept		1	5.6428	0.1547	5.3396	5.9460	1330.52
TRTPN	2	1	-0.1499	0.1591	-0.4617	0.1619	0.89
TRTPN	3	1	0.0740	0.1581	-0.2358	0.3838	0.22
TRTPN	4	0	0.0000	0.0000	0.0000	0.0000	.
REGION1	ASIA (EXCLUDING JAPAN)	1	0.1247	0.2397	-0.3450	0.5945	0.27
REGION1	EUROPE	1	0.3292	0.1703	-0.0045	0.6629	3.74
REGION1	JAPAN	1	0.0320	0.1900	-0.3404	0.4043	0.03
REGION1	NORTH AMERICA	0	0.0000	0.0000	0.0000	0.0000	.
BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	1	0.2223	0.1482	-0.0681	0.5128	2.25
BOLAD1	CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY	0	0.0000	0.0000	0.0000	0.0000	.
Dispersion		1	3.6471	0.2468	3.1940	4.1645	

Analysis Of Maximum Likelihood Parameter Estimates

Parameter		Pr > ChiSq
Intercept		<.0001
TRTPN	2	0.3461
TRTPN	3	0.6396
TRTPN	4	.
REGION1	ASIA (EXCLUDING JAPAN)	0.6028
REGION1	EUROPE	0.0532
REGION1	JAPAN	0.8664
REGION1	NORTH AMERICA	.
BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.1336
BOLAD1	CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY	.
Dispersion		

NOTE: The negative binomial dispersion parameter was estimated by maximum likelihood.

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Parameter Code=HY2HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 2 hours after meal

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Coefficients for TRTPN Least Squares Means Using WORK.ENDPOINT Margins

Parameter	Geographic Region Grouping Method 1
Intercept	
Planned Treatment (N) 2	
Planned Treatment (N) 3	
Planned Treatment (N) 4	
Geographic Region Grouping Method 1 ASIA (EXCLUDING JAPAN)	ASIA (EXCLUDING JAPAN)
Geographic Region Grouping Method 1 EUROPE	EUROPE
Geographic Region Grouping Method 1 JAPAN	JAPAN
Geographic Region Grouping Method 1 NORTH AMERICA	NORTH AMERICA
Bolus Adjustment Method at Timepoint 1 BOLUS INSULIN ALGORITHM (SLIDING SCALE)	
Bolus Adjustment Method at Timepoint 1 CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY	

Coefficients for TRTPN Least Squares Means Using WORK.ENDPOINT Margins

	Planned Treatment (N)	Row1	Row2	Row3
Bolus Adjustment Method at Timepoint 1				
	1	1	1	1
	2	1		
	3		1	
	4			1
		0.1307	0.1307	0.1307
		0.3366	0.3366	0.3366
		0.239	0.239	0.239
		0.2937	0.2937	0.2937
BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.5824	0.5824	0.5824
CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0.4176	0.4176	0.4176

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TRTPN Least Squares Means

Planned Treatment (N)	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
2	WORK.ENDPOINT	5.7572	0.1127	51.07	<.0001	0.05	5.5362	5.9781
3	WORK.ENDPOINT	5.9811	0.1113	53.73	<.0001	0.05	5.7629	6.1992
4	WORK.ENDPOINT	5.9071	0.1117	52.90	<.0001	0.05	5.6882	6.1259

Differences of TRTPN Least Squares Means

Planned Treatment (N)	Planned Treatment (N)	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
2	4	WORK.ENDPOINT	-0.1499	0.1591	-0.94	0.3461	0.05	-0.4617	0.1619
3	4	WORK.ENDPOINT	0.07401	0.1581	0.47	0.6396	0.05	-0.2358	0.3838

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) / NovoRapid (meal)	WORK.ENDPOINT	-0.1499	0.1591	-0.94	0.3461	0.05	-0.4617	0.1619

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Parameter Code=HY2HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 2 hours after meal

The GENMOD Procedure

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
TRTPN	Faster aspart (post) / NovoRapid (meal)	WORK.ENDPOINT	0.07401	0.1581	0.47	0.6396	0.05	-0.2358	0.3838

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
1	0	1.2637497	0.2340832	0.1981217	0.0401681
2	0	1.2637497	0.2340832	0.1981217	0.0401681
3	0	1.2637497	0.2340832	0.1981217	0.0401681
4	0	1.2637497	0.2340832	0.1981217	0.0401681
5	0	1.2637497	0.2340832	0.1981217	0.0401681
6	7	1.5869506	0.4618143	0.1689687	0.913775
7	1	1.5808915	0.4579889	0.1953086	0.1604942
8	0	1.6238505	0.4848002	0.1953086	0.033887
9	0	1.3118271	0.2714209	0.1981217	0.0392066
10	0	0.3089235	-1.174662	0.162314	0.0683038
11	0	1.2500133	0.2231542	0.1981217	0.0404508
12	1	1.6238505	0.4848002	0.1953086	0.1574774
13	1	1.5808915	0.4579889	0.1953086	0.1604942
14	13	1.4521524	0.3730468	0.183631	1.7734382
15	0	1.2637497	0.2340832	0.1981217	0.0401681
16	0	1.4760889	0.389396	0.183631	0.036224

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Parameter Code=HY2HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 2 hours after meal

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
17	3	1.5783725	0.4563943	0.1689687	0.4128736
18	1	2.0603165	0.7228596	0.1683013	0.1320769
19	1	1.8336105	0.6062869	0.162314	0.1441887
20	8	1.4521524	0.3730468	0.183631	1.1054357
21	0	1.5783725	0.4563943	0.1689687	0.034575
22	0	0.2633024	-1.334452	0.183631	0.068519
23	0	1.5808915	0.4579889	0.1953086	0.0345362
24	0	1.97447	0.6803	0.1683013	0.0293563
25	0	1.6410341	0.4953266	0.1953086	0.0336339
26	0	1.5808915	0.4579889	0.1953086	0.0345362
27	0	1.7613194	0.5660632	0.1953086	0.0319588
28	8	1.97447	0.6803	0.1683013	0.8858861
29	3	1.2706179	0.2395033	0.1981217	0.4779908
30	26	1.8934021	0.6383753	0.162314	2.9031309
31	4	1.97447	0.6803	0.1683013	0.4576212
32	1	1.2637497	0.2340832	0.1981217	0.1866663
33	0	1.5808915	0.4579889	0.1953086	0.0345362
34	0	1.8236452	0.6008373	0.162314	0.0311527
35	0	1.6925849	0.5262569	0.1953086	0.0328957
36	1	1.4681101	0.3839759	0.183631	0.1689647
37	0	1.4681101	0.3839759	0.183631	0.036359
38	1	1.5808915	0.4579889	0.1953086	0.1604942
39	1	1.5808915	0.4579889	0.1953086	0.1604942
40	0	1.5551161	0.4415502	0.1953086	0.0349372
41	6	1.5808915	0.4579889	0.1953086	0.7902842

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
42	8	1.9959316	0.6911109	0.1683013	0.878663
43	3	1.97447	0.6803	0.1683013	0.350555
44	5	1.8336105	0.6062869	0.162314	0.5968337
45	0	1.5783725	0.4563943	0.1689687	0.034575
46	0	1.6469974	0.4989539	0.1689687	0.0335469
47	1	1.5783725	0.4563943	0.1689687	0.1606745
48	0	2.0066624	0.6964728	0.1683013	0.0289987
49	4	1.8236452	0.6008373	0.162314	0.4856248
50	2	1.5955287	0.4672052	0.1689687	0.2845956
51	5	1.5955287	0.4672052	0.1689687	0.6600204
52	0	1.97447	0.6803	0.1683013	0.0293563
53	0	1.9959316	0.6911109	0.1683013	0.0291169
54	0	1.853541	0.6170979	0.162314	0.0307799
55	1	1.9530083	0.6693709	0.1683013	0.1375528
56	3	1.5955287	0.4672052	0.1689687	0.4097372
57	0	2.1998171	0.7883742	0.1683013	0.0270199
58	6	1.612685	0.4779005	0.1689687	0.7792387
59	7	1.8435757	0.611707	0.162314	0.8198592
60	0	1.97447	0.6803	0.1683013	0.0293563
61	2	1.8635063	0.6224598	0.162314	0.2542816
62	2	1.612685	0.4779005	0.1689687	0.2824486
63	0	1.9530083	0.6693709	0.1683013	0.0295995
64	0	1.8336105	0.6062869	0.162314	0.0310275
65	8	2.028124	0.7071112	0.1683013	0.8680412
66	6	2.0066624	0.6964728	0.1683013	0.6635705

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
67	1	1.97447	0.6803	0.1683013	0.1364225
68	8	1.9530083	0.6693709	0.1683013	0.8932258
69	0	1.5526382	0.4399555	0.1689687	0.0349763
70	0	1.5783725	0.4563943	0.1689687	0.034575
71	7	1.6555755	0.5041487	0.1689687	0.8866947
72	0	1.8336105	0.6062869	0.162314	0.0310275
73	0	1.97447	0.6803	0.1683013	0.0293563
74	0	1.8336105	0.6062869	0.162314	0.0310275
75	2	1.5869506	0.4618143	0.1689687	0.2856809
76	6	1.8336105	0.6062869	0.162314	0.7099949
77	1	1.97447	0.6803	0.1683013	0.1364225
78	1	1.8336105	0.6062869	0.162314	0.1441887
79	0	1.5783725	0.4563943	0.1689687	0.034575
80	1	1.5869506	0.4618143	0.1689687	0.160062
81	0	1.8336105	0.6062869	0.162314	0.0310275
82	0	1.5783725	0.4563943	0.1689687	0.034575
83	0	1.8336105	0.6062869	0.162314	0.0310275
84	0	1.8037146	0.5898482	0.162314	0.0314062
85	4	1.5783725	0.4563943	0.1689687	0.5389731
86	0	1.9637391	0.6748504	0.1683013	0.0294774
87	5	1.5783725	0.4563943	0.1689687	0.6650726
88	0	1.97447	0.6803	0.1683013	0.0293563
89	1	1.8635063	0.6224598	0.162314	0.1424696
90	0	1.9422775	0.6638613	0.1683013	0.0297226
91	0	1.8236452	0.6008373	0.162314	0.0311527

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
92	3	1.8336105	0.6062869	0.162314	0.3705112
93	4	1.8037146	0.5898482	0.162314	0.4895757
94	0	1.8236452	0.6008373	0.162314	0.0311527
95	0	1.5783725	0.4563943	0.1689687	0.034575
96	5	1.8037146	0.5898482	0.162314	0.6041181
97	0	1.97447	0.6803	0.1683013	0.0293563
98	1	1.4681101	0.3839759	0.183631	0.1689647
99	0	1.5783725	0.4563943	0.1689687	0.034575
100	0	1.5551161	0.4415502	0.1953086	0.0349372
101	1	1.8336105	0.6062869	0.162314	0.1441887
102	0	1.2568815	0.2286336	0.1981217	0.040309
103	1	1.6066669	0.4741618	0.1953086	0.158671
104	4	1.8336105	0.6062869	0.162314	0.4836724
105	4	1.4521524	0.3730468	0.183631	0.5710337
106	0	1.4441735	0.3675372	0.183631	0.0367695
107	10	1.8336105	0.6062869	0.162314	1.1626399
108	8	1.9852008	0.6857201	0.1683013	0.8822602
109	4	1.9530083	0.6693709	0.1683013	0.4614127
110	0	1.2637497	0.2340832	0.1981217	0.0401681
111	0	1.4521524	0.3730468	0.183631	0.0366317
112	18	1.4681101	0.3839759	0.183631	2.423263
113	0	1.4681101	0.3839759	0.183631	0.036359
114	0	1.4681101	0.3839759	0.183631	0.036359
115	0	1.2637497	0.2340832	0.1981217	0.0401681
116	6	1.5808915	0.4579889	0.1953086	0.7902842

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Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=HY2HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 2 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
117	0	1.4760889	0.389396	0.183631	0.036224
118	0	1.2637497	0.2340832	0.1981217	0.0401681
119	1	1.4681101	0.3839759	0.183631	0.1689647
120	1	1.2637497	0.2340832	0.1981217	0.1866663
121	0	1.4681101	0.3839759	0.183631	0.036359
122	0	1.2637497	0.2340832	0.1981217	0.0401681
123	1	1.5551161	0.4415502	0.1953086	0.1623579
124	0	1.4681101	0.3839759	0.183631	0.036359
125	5	1.2637497	0.2340832	0.1981217	0.7726591
126	3	1.5722997	0.4525393	0.1953086	0.4139948
127	1	1.5808915	0.4579889	0.1953086	0.1604942
128	0	1.6066669	0.4741618	0.1953086	0.0341439
129	5	1.97447	0.6803	0.1683013	0.5646875
130	0	1.3118271	0.2714209	0.1981217	0.0392066
131	0	1.6641536	0.5093167	0.1689687	0.0332989
132	1	1.5808915	0.4579889	0.1953086	0.1604942
133	0	1.8730128	0.6275483	0.1953086	0.0305417
134	1	1.8834368	0.6330982	0.162314	0.1413454
135	0	1.4760889	0.389396	0.183631	0.036224
136	0	1.643645	0.4969163	0.183631	0.0335957
137	0	1.0224244	0.0221767	0.1953086	0.0457202
138	0	2.0129854	0.6996189	0.162314	0.0289294
139	1	1.2774861	0.2448941	0.1981217	0.1853692
140	6	1.4521524	0.3730468	0.183631	0.8382347
141	10	1.6410341	0.4953266	0.1953086	1.2603048

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Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=HY2HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 2 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
142	0	1.5637079	0.4470599	0.1953086	0.0348026
143	3	1.8336105	0.6062869	0.162314	0.3705112
144	3	1.5783725	0.4563943	0.1689687	0.4128736
145	1	1.5783725	0.4563943	0.1689687	0.1606745
146	1	1.8834368	0.6330982	0.162314	0.1413454
147	1	2.1247014	0.7536313	0.1683013	0.1289911
148	0	2.5753956	0.9460031	0.1683013	0.023844
149	0	1.8435757	0.611707	0.162314	0.0309032
150	0	1.5526382	0.4399555	0.1689687	0.0349763
151	5	1.97447	0.6803	0.1683013	0.5646875
152	0	1.8336105	0.6062869	0.162314	0.0310275
153	0	1.8037146	0.5898482	0.162314	0.0314062
154	0	1.9637391	0.6748504	0.1683013	0.0294774
155	10	1.8136799	0.5953579	0.162314	1.1720628
156	0	1.1237326	0.1166558	0.1689687	0.043231
157	0	1.6310839	0.4892447	0.1683013	0.03378
158	0	1.97447	0.6803	0.1683013	0.0293563
159	9	1.5955287	0.4672052	0.1689687	1.1605869
160	0	1.6041069	0.4725671	0.1689687	0.0341825
161	1	1.5783725	0.4563943	0.1689687	0.1606745
162	0	1.97447	0.6803	0.1683013	0.0293563
163	1	1.97447	0.6803	0.1683013	0.1364225
164	3	1.97447	0.6803	0.1683013	0.350555
165	0	1.2456593	0.2196649	0.162314	0.0405412
166	2	1.9530083	0.6693709	0.1683013	0.2455061

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Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=HY2HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 2 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
167	4	1.8336105	0.6062869	0.162314	0.4836724
168	1	1.853541	0.6170979	0.162314	0.1430382
169	0	1.8136799	0.5953579	0.162314	0.031279
170	1	1.5697944	0.4509447	0.1689687	0.1612915
171	2	1.9637391	0.6748504	0.1683013	0.2444934
172	0	1.6041069	0.4725671	0.1689687	0.0341825
173	0	1.5869506	0.4618143	0.1689687	0.0344432
174	0	1.8037146	0.5898482	0.162314	0.0314062
175	0	1.853541	0.6170979	0.162314	0.0307799
176	1	1.8236452	0.6008373	0.162314	0.1447707
177	1	2.0495857	0.7176377	0.1683013	0.1326053
178	1	1.6041069	0.4725671	0.1689687	0.1588503
179	0	1.97447	0.6803	0.1683013	0.0293563
180	0	1.8236452	0.6008373	0.162314	0.0311527
181	1	1.5526382	0.4399555	0.1689687	0.1625392
182	0	1.8136799	0.5953579	0.162314	0.031279
183	0	1.97447	0.6803	0.1683013	0.0293563
184	0	1.97447	0.6803	0.1683013	0.0293563
185	2	2.0066624	0.6964728	0.1683013	0.2405226
186	0	1.8236452	0.6008373	0.162314	0.0311527
187	0	1.5783725	0.4563943	0.1689687	0.034575
188	0	1.5869506	0.4618143	0.1689687	0.0344432
189	0	1.0730815	0.0705344	0.1683013	0.0444448
190	5	1.5526382	0.4399555	0.1689687	0.672791
191	3	1.4122581	0.3451899	0.183631	0.445781

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Parameter Code=HY2HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 2 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
192	0	1.8136799	0.5953579	0.162314	0.031279
193	0	1.5783725	0.4563943	0.1689687	0.034575
194	1	1.8336105	0.6062869	0.162314	0.1441887
195	4	2.0173932	0.7018062	0.1683013	0.4502176
196	7	1.4920467	0.4001488	0.183631	0.9539352
197	0	1.8336105	0.6062869	0.162314	0.0310275
198	1	1.8037146	0.5898482	0.162314	0.1459486
199	0	1.5783725	0.4563943	0.1689687	0.034575
200	0	1.8435757	0.611707	0.162314	0.0309032
201	0	1.5955287	0.4672052	0.1689687	0.0343124
202	0	0.5779859	-0.548206	0.162314	0.0598354
203	1	1.0301582	0.0297124	0.1683013	0.2115439
204	13	1.5783725	0.4563943	0.1689687	1.6738689
205	1	1.9852008	0.6857201	0.1683013	0.1358642
206	1	1.6384193	0.4937319	0.1689687	0.1564789
207	2	1.5783725	0.4563943	0.1689687	0.2867741
208	0	1.9852008	0.6857201	0.1683013	0.0292361
209	0	1.5526382	0.4399555	0.1689687	0.0349763
210	2	1.8336105	0.6062869	0.162314	0.25735
211	0	1.6410341	0.4953266	0.1953086	0.0336339
212	0	1.9530083	0.6693709	0.1683013	0.0295995
213	1	1.97447	0.6803	0.1683013	0.1364225
214	0	1.5808915	0.4579889	0.1953086	0.0345362
215	0	0.0751157	-2.588726	0.1683013	0.046283
216	0	1.2637497	0.2340832	0.1981217	0.0401681

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Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=HY2HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 2 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
217	0	1.4521524	0.3730468	0.183631	0.0366317
218	0	1.2706179	0.2395033	0.1981217	0.0400281
219	0	1.4760889	0.389396	0.183631	0.036224
220	0	1.4521524	0.3730468	0.183631	0.0366317
221	0	1.8236452	0.6008373	0.162314	0.0311527
222	3	1.5783725	0.4563943	0.1689687	0.4128736
223	5	1.97447	0.6803	0.1683013	0.5646875
224	0	2.0495857	0.7176377	0.1683013	0.0285349
225	6	1.5783725	0.4563943	0.1689687	0.7911722
226	3	1.5783725	0.4563943	0.1689687	0.4128736
227	0	1.97447	0.6803	0.1683013	0.0293563
228	1	1.8336105	0.6062869	0.162314	0.1441887
229	1	1.9033674	0.6436246	0.162314	0.1402383
230	0	1.97447	0.6803	0.1683013	0.0293563
231	0	1.9852008	0.6857201	0.1683013	0.0292361
232	1	1.8734715	0.6277932	0.162314	0.1419053
233	0	1.97447	0.6803	0.1683013	0.0293563
234	0	1.6041069	0.4725671	0.1689687	0.0341825
235	0	1.97447	0.6803	0.1683013	0.0293563
236	0	1.9852008	0.6857201	0.1683013	0.0292361
237	0	1.97447	0.6803	0.1683013	0.0293563
238	3	1.8336105	0.6062869	0.162314	0.3705112
239	1	1.97447	0.6803	0.1683013	0.1364225
240	0	1.5783725	0.4563943	0.1689687	0.034575
241	0	1.5783725	0.4563943	0.1689687	0.034575

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Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=HY2HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 2 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
242	0	1.5783725	0.4563943	0.1689687	0.034575
243	0	1.8336105	0.6062869	0.162314	0.0310275
244	0	1.7638535	0.5675009	0.162314	0.0319252
245	0	2.0495857	0.7176377	0.1683013	0.0285349
246	1	2.0118273	0.6990434	0.2024347	0.1344977
247	2	2.0118273	0.6990434	0.2024347	0.2400533
248	0	2.1663776	0.7730565	0.2068609	0.0273433
249	0	2.2195703	0.7973136	0.2024347	0.0268323
250	0	2.1663776	0.7730565	0.2068609	0.0273433
251	0	2.0118273	0.6990434	0.2024347	0.0289421
252	0	1.7976646	0.5864884	0.1917766	0.0314839
253	0	2.2134727	0.7945627	0.2068609	0.0268899
254	0	2.1781514	0.7784765	0.2068609	0.0272286
255	12	1.7317817	0.5491507	0.1917766	1.4483915
256	0	2.1899252	0.7838674	0.2068609	0.0271148
257	0	1.7317817	0.5491507	0.1917766	0.032355
258	0	2.1663776	0.7730565	0.2068609	0.0273433
259	0	2.2370203	0.8051448	0.2068609	0.0266687
260	0	2.1781514	0.7784765	0.2068609	0.0272286
261	0	2.0118273	0.6990434	0.2024347	0.0289421
262	0	2.1663776	0.7730565	0.2068609	0.0273433
263	0	1.7317817	0.5491507	0.1917766	0.032355
264	17	2.0227611	0.7044635	0.2024347	1.8158847
265	0	2.0227611	0.7044635	0.2024347	0.028823
266	0	2.0118273	0.6990434	0.2024347	0.0289421

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Parameter Code=HY2HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 2 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
267	0	2.0118273	0.6990434	0.2024347	0.0289421
268	4	2.0774304	0.7311317	0.2024347	0.4402458
269	1	1.7694291	0.5706569	0.1917766	0.1480187
270	0	2.1663776	0.7730565	0.2068609	0.0273433
271	0	1.7317817	0.5491507	0.1917766	0.032355
272	1	2.1899252	0.7838674	0.2068609	0.1260058
273	0	2.1310562	0.7566177	0.2068609	0.0276933
274	0	1.7600172	0.5653236	0.1917766	0.0319761
275	0	2.1977027	0.7874126	0.2024347	0.0270401
276	0	2.1781514	0.7784765	0.2068609	0.0272286
277	0	2.1899252	0.7838674	0.2068609	0.0271148
278	0	2.1663776	0.7730565	0.2068609	0.0273433
279	0	1.7600172	0.5653236	0.1917766	0.0319761
280	0	1.7411935	0.5545708	0.1917766	0.0322278
281	1	2.1781514	0.7784765	0.2068609	0.1265346
282	5	1.7411935	0.5545708	0.1917766	0.6199218
283	1	1.7035461	0.532712	0.1917766	0.15216
284	1	1.7317817	0.5491507	0.1917766	0.1503581
285	0	2.14283	0.7621274	0.2068609	0.0275756
286	0	2.0227611	0.7044635	0.2024347	0.028823
287	0	2.0227611	0.7044635	0.2024347	0.028823
288	0	2.033695	0.7098543	0.2024347	0.0287049
289	0	2.0227611	0.7044635	0.2024347	0.028823
290	0	2.0118273	0.6990434	0.2024347	0.0289421
291	0	2.0446288	0.7152163	0.2024347	0.0285877

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Parameter Code=HY2HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 2 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
292	0	2.1663776	0.7730565	0.2068609	0.0273433
293	1	1.7317817	0.5491507	0.1917766	0.1503581
294	0	2.0118273	0.6990434	0.2024347	0.0289421
295	0	2.1781514	0.7784765	0.2068609	0.0272286
296	0	1.9790258	0.6826047	0.2024347	0.0293052
297	0	2.0008935	0.6935938	0.2024347	0.0290621
298	6	2.1663776	0.7730565	0.2068609	0.6256904
299	0	1.2141295	0.1940274	0.1917766	0.041207
300	55	1.7317817	0.5491507	0.1917766	6.5225221
301	0	2.0118273	0.6990434	0.2024347	0.0289421
302	0	2.1663776	0.7730565	0.2068609	0.0273433
303	0	2.1899252	0.7838674	0.2068609	0.0271148
304	3	2.033695	0.7098543	0.2024347	0.3427762
305	5	1.8070765	0.5917103	0.1917766	0.6032904
306	1	1.7317817	0.5491507	0.1917766	0.1503581
307	0	1.9899596	0.6881143	0.2024347	0.0291832
308	0	1.7317817	0.5491507	0.1917766	0.032355
309	0	1.7411935	0.5545708	0.1917766	0.0322278
310	0	1.7411935	0.5545708	0.1917766	0.0322278
311	1	2.1899252	0.7838674	0.2068609	0.1260058
312	0	2.033695	0.7098543	0.2024347	0.0287049
313	14	2.0118273	0.6990434	0.2024347	1.5067203
314	0	2.2370203	0.8051448	0.2068609	0.0266687
315	0	1.7129579	0.5382217	0.1917766	0.0326126
316	0	2.033695	0.7098543	0.2024347	0.0287049

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
317	5	2.1781514	0.7784765	0.2068609	0.5237588
318	0	1.7223698	0.5437011	0.1917766	0.0324833
319	1	2.1546038	0.7676068	0.2068609	0.1276055
320	4	1.7506054	0.5599617	0.1917766	0.5004138
321	0	2.0446288	0.7152163	0.2024347	0.0285877
322	0	2.2134727	0.7945627	0.2068609	0.0268899
323	0	1.8070765	0.5917103	0.1917766	0.0313631
324	1	2.0446288	0.7152163	0.2024347	0.1328507
325	0	1.7317817	0.5491507	0.1917766	0.032355
326	0	1.7506054	0.5599617	0.1917766	0.0321014
327	0	2.0446288	0.7152163	0.2024347	0.0285877
328	0	2.0118273	0.6990434	0.2024347	0.0289421
329	0	2.0227611	0.7044635	0.2024347	0.028823
330	0	2.1781514	0.7784765	0.2068609	0.0272286
331	0	2.0118273	0.6990434	0.2024347	0.0289421
332	0	1.7506054	0.5599617	0.1917766	0.0321014
333	0	2.2016989	0.7892293	0.2068609	0.0270019
334	1	1.7976646	0.5864884	0.1917766	0.1463098
335	1	1.7317817	0.5491507	0.1917766	0.1503581
336	1	0.2514784	-1.380398	0.2024347	0.3179525
337	4	2.0118273	0.6990434	0.2024347	0.4511644
338	0	1.7411935	0.5545708	0.1917766	0.0322278
339	0	2.0883642	0.7363811	0.2024347	0.0281281
340	0	2.2016989	0.7892293	0.2068609	0.0270019
341	0	1.7694291	0.5706569	0.1917766	0.0318516

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Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=HY2HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 2 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
342	10	2.0118273	0.6990434	0.2024347	1.0844979
343	1	1.7317817	0.5491507	0.1917766	0.1503581
344	5	2.0446288	0.7152163	0.2024347	0.5499029
345	9	1.7317817	0.5491507	0.1917766	1.0943824
346	1	2.1663776	0.7730565	0.2068609	0.1270678
347	2	2.0446288	0.7152163	0.2024347	0.2371138
348	3	1.7506054	0.5599617	0.1917766	0.3833357
349	1	2.6434415	0.9720817	0.1458079	0.1084905
350	0	2.113142	0.7481759	0.1562455	0.0278741
351	0	2.0900476	0.7371868	0.1562455	0.0281107
352	1	2.1246892	0.7536256	0.1562455	0.1289917
353	0	2.1246892	0.7536256	0.1562455	0.0277573
354	0	2.113142	0.7481759	0.1562455	0.0278741
355	0	2.4682718	0.9035182	0.1597562	0.0246723
356	0	2.4682718	0.9035182	0.1597562	0.0246723
357	9	1.7011671	0.5313145	0.1753126	1.1086164
358	11	2.1280801	0.7552202	0.1634017	1.1399324
359	0	1.9977431	0.6920181	0.1688686	0.0290969
360	0	1.7011671	0.5313145	0.1753126	0.0327759
361	3	2.2090397	0.7925579	0.1634017	0.3216051
362	0	1.7011671	0.5313145	0.1753126	0.0327759
363	0	1.9547809	0.6702781	0.1688686	0.0295793
364	0	1.7289035	0.5474874	0.1753126	0.0323942
365	0	1.7011671	0.5313145	0.1753126	0.0327759
366	0	1.6826761	0.5203854	0.1753126	0.0330352

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Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=HY2HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 2 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
367	1	1.6734306	0.5148758	0.1753126	0.1541282
368	2	1.976262	0.6812072	0.1688686	0.2433218
369	3	1.6734306	0.5148758	0.1753126	0.3960521
370	2	2.0407054	0.7132955	0.1688686	0.2374617
371	1	1.6734306	0.5148758	0.1753126	0.1541282
372	0	2.1396458	0.7606403	0.1634017	0.0276074
373	3	2.2437367	0.8081426	0.1634017	0.3177158
374	3	2.1396458	0.7606403	0.1634017	0.3296701
375	0	1.7011671	0.5313145	0.1753126	0.0327759
376	6	2.1280801	0.7552202	0.1634017	0.6343827
377	3	2.1280801	0.7552202	0.1634017	0.3310529
378	0	2.1280801	0.7552202	0.1634017	0.0277232
379	0	1.976262	0.6812072	0.1688686	0.0293362
380	0	2.1512114	0.7660311	0.1634017	0.0274925
381	0	2.1280801	0.7552202	0.1634017	0.0277232
382	2	2.1280801	0.7552202	0.1634017	0.229943
383	0	1.976262	0.6812072	0.1688686	0.0293362
384	0	2.1246892	0.7536256	0.1562455	0.0277573
385	0	1.976262	0.6812072	0.1688686	0.0293362
386	0	2.1165145	0.7497706	0.1634017	0.0278399
387	0	1.7011671	0.5313145	0.1753126	0.0327759
388	0	2.1280801	0.7552202	0.1634017	0.0277232
389	1	2.1280801	0.7552202	0.1634017	0.1288331
390	0	2.1512114	0.7660311	0.1634017	0.0274925
391	0	1.976262	0.6812072	0.1688686	0.0293362

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Parameter Code=HY2HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 2 hours after meal

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
392	0	2.6578865	0.9775313	0.1458079	0.0232426
393	5	2.7445567	1.0096196	0.1458079	0.4355358
394	0	2.113142	0.7481759	0.1562455	0.0278741
395	1	2.2401615	0.806548	0.1562455	0.1237971
396	0	2.6723316	0.9829513	0.1458079	0.0231403
397	0	1.6826761	0.5203854	0.1753126	0.0330352
398	1	2.1362365	0.7590456	0.1562455	0.1284531
399	0	2.1246892	0.7536256	0.1562455	0.0277573
400	0	2.1939726	0.7857139	0.1562455	0.0270758
401	0	2.1477837	0.7644365	0.1562455	0.0275264
402	0	2.6578865	0.9775313	0.1458079	0.0232426
403	0	2.4816863	0.9089383	0.1597562	0.0245655
404	3	2.7012216	0.9937041	0.1458079	0.2739171
405	0	2.1362365	0.7590456	0.1562455	0.0276414
406	0	2.6867766	0.9883422	0.1458079	0.023039
407	1	2.1362365	0.7590456	0.1562455	0.1284531
408	0	2.1246892	0.7536256	0.1562455	0.0277573
409	0	2.1049488	0.7442912	0.1634017	0.0279576
410	0	1.6734306	0.5148758	0.1753126	0.0331663
411	0	2.1165145	0.7497706	0.1634017	0.0278399
412	3	1.7104125	0.5367346	0.1753126	0.3898586
413	0	2.1859084	0.7820315	0.1634017	0.0271535
414	0	1.9977431	0.6920181	0.1688686	0.0290969
415	0	2.1049488	0.7442912	0.1634017	0.0279576
416	2	1.9655215	0.6757576	0.1688686	0.244326

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Parameter Code=HY2HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 2 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
417	0	1.976262	0.6812072	0.1688686	0.0293362
418	0	2.1280801	0.7552202	0.1634017	0.0277232
419	0	2.1049488	0.7442912	0.1634017	0.0279576
420	22	2.4682718	0.9035182	0.1597562	2.0043018
421	1	2.6578865	0.9775313	0.1458079	0.1080112
422	4	2.4816863	0.9089383	0.1597562	0.3829398
423	6	2.4816863	0.9089383	0.1597562	0.562127
424	1	2.1362365	0.7590456	0.1562455	0.1284531
425	0	2.1015948	0.7426965	0.1562455	0.027992
426	4	2.6867766	0.9883422	0.1458079	0.3591431
427	0	2.1362365	0.7590456	0.1562455	0.0276414
428	1	2.1362365	0.7590456	0.1562455	0.1284531
429	0	2.7301117	1.0043425	0.1458079	0.0227401
430	0	2.6292461	0.9666971	0.1597562	0.023448
431	0	2.7301117	1.0043425	0.1458079	0.0227401
432	0	2.4682718	0.9035182	0.1597562	0.0246723
433	0	2.1246892	0.7536256	0.1562455	0.0277573
434	0	2.4951009	0.9143292	0.1597562	0.0244596
435	0	2.4682718	0.9035182	0.1597562	0.0246723
436	0	2.4548573	0.8980686	0.1597562	0.0247801
437	5	1.7011671	0.5313145	0.1753126	0.6304651
438	0	2.5219299	0.9250244	0.1597562	0.0242504
439	0	1.7104125	0.5367346	0.1753126	0.0326477
440	1	1.9870026	0.6866273	0.1688686	0.1357708
441	0	2.1593309	0.7697984	0.1562455	0.0274124

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Parameter Code=HY2HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 2 hours after meal

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
442	0	1.7011671	0.5313145	0.1753126	0.0327759
443	0	2.4682718	0.9035182	0.1597562	0.0246723
444	1	2.5085154	0.9196911	0.1597562	0.1131789
445	0	1.7011671	0.5313145	0.1753126	0.0327759
446	6	1.7104125	0.5367346	0.1753126	0.7470695
447	0	2.6578865	0.9775313	0.1458079	0.0232426
448	1	2.0933832	0.7387815	0.1634017	0.1304743
449	0	1.976262	0.6812072	0.1688686	0.0293362
450	0	2.1246892	0.7536256	0.1562455	0.0277573
451	0	2.4682718	0.9035182	0.1597562	0.0246723
452	0	2.6158315	0.961582	0.1597562	0.0235454
453	8	2.1396458	0.7606403	0.1634017	0.8331081
454	2	1.7751308	0.5738741	0.1753126	0.2635642
455	3	2.3825245	0.8681606	0.1634017	0.3030405
456	0	2.602417	0.9564406	0.1597562	0.0236436
457	1	1.6826761	0.5203854	0.1753126	0.1535188
458	0	2.1627771	0.7713931	0.1634017	0.0273786
459	0	2.2090397	0.7925579	0.1634017	0.026932
460	2	2.4548573	0.8980686	0.1597562	0.2055323
461	0	2.8304639	1.0404406	0.1597562	0.0220765
462	4	1.7289035	0.5474874	0.1753126	0.504977
463	17	1.976262	0.6812072	0.1688686	1.8482138
464	0	2.1246892	0.7536256	0.1562455	0.0277573
465	0	1.9655215	0.6757576	0.1688686	0.0294572
466	0	2.9467872	1.0807155	0.1458079	0.0213536

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Parameter Code=HY2HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 2 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
467	0	2.5487589	0.9356065	0.1597562	0.0240448
468	3	2.6867766	0.9883422	0.1458079	0.2751171
469	0	2.6578865	0.9775313	0.1458079	0.0232426
470	0	2.1280801	0.7552202	0.1634017	0.0277232
471	1	2.3094448	0.8370072	0.1562455	0.1208728
472	0	2.7445567	1.0096196	0.1458079	0.0226421
473	0	1.7658854	0.5686522	0.1753126	0.0318984
474	0	2.7156667	0.9990375	0.1458079	0.0228388
475	0	2.6434415	0.9720817	0.1458079	0.0233457
476	15	2.1477837	0.7644365	0.1562455	1.5334137
477	0	2.5219299	0.9250244	0.1597562	0.0242504
478	0	2.6867766	0.9883422	0.1458079	0.023039
479	0	2.1015948	0.7426965	0.1562455	0.027992
480	0	2.7012216	0.9937041	0.1458079	0.0229385
481	5	2.5085154	0.9196911	0.1597562	0.468476
482	5	2.6723316	0.9829513	0.1458079	0.445119
483	5	2.6289965	0.9666022	0.1458079	0.4510713
484	0	2.6434415	0.9720817	0.1458079	0.0233457
485	0	2.4414428	0.8925892	0.1597562	0.0248887
486	0	2.0900476	0.7371868	0.1562455	0.0281107
487	0	2.6434415	0.9720817	0.1458079	0.0233457
488	0	2.1246892	0.7536256	0.1562455	0.0277573
489	17	2.1362365	0.7590456	0.1562455	1.7414408
490	0	2.7012216	0.9937041	0.1458079	0.0229385
491	0	2.6723316	0.9829513	0.1458079	0.0231403

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Parameter Code=HY2HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 2 hours after meal

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
492	0	2.4548573	0.8980686	0.1597562	0.0247801
493	0	2.4951009	0.9143292	0.1597562	0.0244596
494	5	2.0554059	0.7204733	0.1562455	0.5476985
495	0	2.1246892	0.7536256	0.1562455	0.0277573
496	4	2.5085154	0.9196911	0.1597562	0.3796517
497	0	2.6578865	0.9775313	0.1458079	0.0232426
498	0	2.6578865	0.9775313	0.1458079	0.0232426
499	0	2.5085154	0.9196911	0.1597562	0.0243546
500	0	2.4682718	0.9035182	0.1597562	0.0246723
501	13	2.4414428	0.8925892	0.1597562	1.2049302
502	1	2.6867766	0.9883422	0.1458079	0.107065
503	0	2.1246892	0.7536256	0.1562455	0.0277573
504	0	2.6289965	0.9666022	0.1458079	0.0234498
505	0	2.5085154	0.9196911	0.1597562	0.0243546
506	0	2.5085154	0.9196911	0.1597562	0.0243546
507	0	2.6289965	0.9666022	0.1458079	0.0234498
508	0	0.4333511	-0.836207	0.1458079	0.0650783
509	4	2.6145514	0.9610925	0.1458079	0.3671833
510	1	2.6578865	0.9775313	0.1458079	0.1080112
511	4	2.4682718	0.9035182	0.1597562	0.384605
512	2	2.6578865	0.9775313	0.1458079	0.1927799
513	14	2.4682718	0.9035182	0.1597562	1.2844366
514	6	2.6723316	0.9829513	0.1458079	0.5295147
515	4	2.1246892	0.7536256	0.1562455	0.4326949
516	0	2.1246892	0.7536256	0.1562455	0.0277573

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
517	16	2.6578865	0.9775313	0.1458079	1.3795409
518	2	2.6723316	0.9829513	0.1458079	0.1919318
519	1	2.4951009	0.9143292	0.1597562	0.1136669
520	0	2.7012216	0.9937041	0.1458079	0.0229385
521	0	2.1246892	0.7536256	0.1562455	0.0277573
522	1	2.4682718	0.9035182	0.1597562	0.1146555
523	0	2.4682718	0.9035182	0.1597562	0.0246723
524	6	2.6578865	0.9775313	0.1458079	0.5318544
525	9	2.1362365	0.7590456	0.1562455	0.9349469
526	0	2.1362365	0.7590456	0.1562455	0.0276414
527	0	2.6867766	0.9883422	0.1458079	0.023039
528	0	2.1362365	0.7590456	0.1562455	0.0276414
529	0	2.1246892	0.7536256	0.1562455	0.0277573
530	1	2.1708781	0.7751318	0.1562455	0.1268635
531	0	2.4816863	0.9089383	0.1597562	0.0245655
532	2	2.1824254	0.7804368	0.1562455	0.2254971
533	16	2.6578865	0.9775313	0.1458079	1.3795409
534	12	2.6289965	0.9666022	0.1458079	1.0497414
535	0	2.1246892	0.7536256	0.1562455	0.0277573
536	3	2.4682718	0.9035182	0.1597562	0.2946218
537	0	2.4816863	0.9089383	0.1597562	0.0245655
538	0	2.4816863	0.9089383	0.1597562	0.0245655
539	0	2.1362365	0.7590456	0.1562455	0.0276414
540	0	2.5085154	0.9196911	0.1597562	0.0243546
541	0	2.113142	0.7481759	0.1562455	0.0278741

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Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
542	0	2.4951009	0.9143292	0.1597562	0.0244596
543	0	2.4146137	0.8815393	0.1597562	0.0251089
544	3	2.1708781	0.7751318	0.1562455	0.3259918
545	0	2.1824254	0.7804368	0.1562455	0.0271871
546	1	2.1246892	0.7536256	0.1562455	0.1289917
547	0	2.1477837	0.7644365	0.1562455	0.0275264
548	45	2.6723316	0.9829513	0.1458079	3.8209483
549	3	2.113142	0.7481759	0.1562455	0.3328559
550	28	2.4682718	0.9035182	0.1597562	2.5442008
551	6	2.4682718	0.9035182	0.1597562	0.5645713
552	10	2.1246892	0.7536256	0.1562455	1.0401014
553	1	2.1362365	0.7590456	0.1562455	0.1284531
554	0	2.4951009	0.9143292	0.1597562	0.0244596
555	1	2.1246892	0.7536256	0.1562455	0.1289917
556	0	2.1824254	0.7804368	0.1562455	0.0271871
557	3	2.4816863	0.9089383	0.1597562	0.2933462
558	0	2.1362365	0.7590456	0.1562455	0.0276414
559	0	2.1246892	0.7536256	0.1562455	0.0277573
560	0	2.5085154	0.9196911	0.1597562	0.0243546
561	4	2.6578865	0.9775313	0.1458079	0.3623171
562	0	2.4816863	0.9089383	0.1597562	0.0245655
563	14	1.976262	0.6812072	0.1688686	1.5272354
564	3	2.6867766	0.9883422	0.1458079	0.2751171
565	0	2.5085154	0.9196911	0.1597562	0.0243546
566	0	2.1246892	0.7536256	0.1562455	0.0277573

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Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=HY2HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 2 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
567	8	1.9977431	0.6920181	0.1688686	0.8780586
568	0	2.6578865	0.9775313	0.1458079	0.0232426
569	3	2.4280282	0.8870795	0.1597562	0.2985149
570	1	2.6723316	0.9829513	0.1458079	0.1075361
571	0	2.1362365	0.7590456	0.1562455	0.0276414
572	9	2.7445567	1.0096196	0.1458079	0.7658508
573	4	2.1708781	0.7751318	0.1562455	0.4255559
574	10	2.7012216	0.9937041	0.1458079	0.8595339
575	11	2.6578865	0.9775313	0.1458079	0.9556976
576	6	2.1708781	0.7751318	0.1562455	0.6246843
577	0	2.4816863	0.9089383	0.1597562	0.0245655
578	9	2.4548573	0.8980686	0.1597562	0.8381649
579	14	2.6578865	0.9775313	0.1458079	1.2100036
580	24	2.6578865	0.9775313	0.1458079	2.05769
581	7	2.4816863	0.9089383	0.1597562	0.6517205
582	0	2.4682718	0.9035182	0.1597562	0.0246723
583	29	2.1246892	0.7536256	0.1562455	2.9635552
584	0	2.1049488	0.7442912	0.1634017	0.0279576
585	0	1.9870026	0.6866273	0.1688686	0.0292161
586	0	2.0407054	0.7132955	0.1688686	0.0286296
587	3	1.976262	0.6812072	0.1688686	0.3503146
588	0	1.7011671	0.5313145	0.1753126	0.0327759
589	0	1.719658	0.5421254	0.1753126	0.0325204
590	2	2.1280801	0.7552202	0.1634017	0.229943
591	1	1.976262	0.6812072	0.1688686	0.136329

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Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=HY2HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 2 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
592	5	1.976262	0.6812072	0.1688686	0.5643002
593	7	2.1280801	0.7552202	0.1634017	0.7354927
594	3	1.7104125	0.5367346	0.1753126	0.3898586
595	2	2.1280801	0.7552202	0.1634017	0.229943
596	0	1.8306037	0.6046458	0.1753126	0.0310652
597	2	1.7011671	0.5313145	0.1753126	0.2718515
598	0	1.7011671	0.5313145	0.1753126	0.0327759
599	0	1.6734306	0.5148758	0.1753126	0.0331663
600	1	1.9655215	0.6757576	0.1688686	0.1368916
601	0	2.1512114	0.7660311	0.1634017	0.0274925
602	0	1.6826761	0.5203854	0.1753126	0.0330352
603	0	2.6723316	0.9829513	0.1458079	0.0231403
604	1	1.6734306	0.5148758	0.1753126	0.1541282
605	1	1.976262	0.6812072	0.1688686	0.136329
606	1	1.976262	0.6812072	0.1688686	0.136329
607	0	2.1165145	0.7497706	0.1634017	0.0278399
608	0	2.7012216	0.9937041	0.1458079	0.0229385
609	0	1.7011671	0.5313145	0.1753126	0.0327759
610	0	2.1512114	0.7660311	0.1634017	0.0274925
611	2	2.0299648	0.7080185	0.1688686	0.2384192
612	5	2.1280801	0.7552202	0.1634017	0.5332728
613	0	1.9870026	0.6866273	0.1688686	0.0292161
614	0	1.7104125	0.5367346	0.1753126	0.0326477
615	2	1.6919216	0.5258649	0.1753126	0.2729229
616	0	1.7011671	0.5313145	0.1753126	0.0327759

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Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=HY2HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 2 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
617	1	2.0933832	0.7387815	0.1634017	0.1304743
618	0	1.9870026	0.6866273	0.1688686	0.0292161
619	0	2.1280801	0.7552202	0.1634017	0.0277232
620	1	1.7381489	0.5528207	0.1753126	0.1499574
621	20	2.1974741	0.7873085	0.1634017	1.9995757
622	4	1.6919216	0.5258649	0.1753126	0.5129408
623	1	2.1280801	0.7552202	0.1634017	0.1288331
624	1	1.976262	0.6812072	0.1688686	0.136329
625	0	1.9547809	0.6702781	0.1688686	0.0295793
626	3	1.7011671	0.5313145	0.1753126	0.3913894
627	0	1.2837875	0.2498147	0.1634017	0.0397621
628	0	2.0514459	0.7185449	0.1688686	0.0285151
629	6	1.7289035	0.5474874	0.1753126	0.7412684
630	0	1.9870026	0.6866273	0.1688686	0.0292161
631	1	2.1049488	0.7442912	0.1634017	0.1299227
632	0	1.7104125	0.5367346	0.1753126	0.0326477
633	2	1.9655215	0.6757576	0.1688686	0.244326
634	0	2.1627771	0.7713931	0.1634017	0.0273786
635	0	1.976262	0.6812072	0.1688686	0.0293362
636	2	1.7289035	0.5474874	0.1753126	0.2686856
637	0	1.6919216	0.5258649	0.1753126	0.032905
638	0	2.169592	0.7745391	0.1688686	0.0273119
639	3	2.1165145	0.7497706	0.1634017	0.3324472
640	8	1.6826761	0.5203854	0.1753126	0.996904
641	1	2.1280801	0.7552202	0.1634017	0.1288331

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Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=HY2HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 2 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
642	0	2.4816863	0.9089383	0.1597562	0.0245655
643	1	1.7104125	0.5367346	0.1753126	0.151718
644	1	2.4548573	0.8980686	0.1597562	0.1151562
645	0	1.7011671	0.5313145	0.1753126	0.0327759
646	1	2.6578865	0.9775313	0.1458079	0.1080112
647	0	1.7011671	0.5313145	0.1753126	0.0327759
648	0	2.6578865	0.9775313	0.1458079	0.0232426
649	3	2.5487589	0.9356065	0.1597562	0.2871282
650	30	2.6867766	0.9883422	0.1458079	2.5438204
651	0	1.976262	0.6812072	0.1688686	0.0293362
652	0	2.1280801	0.7552202	0.1634017	0.0277232
653	10	2.1280801	0.7552202	0.1634017	1.0388224
654	2	2.7012216	0.9937041	0.1458079	0.1902576
655	9	2.4414428	0.8925892	0.1597562	0.8418405
656	0	2.6867766	0.9883422	0.1458079	0.023039
657	1	2.4951009	0.9143292	0.1597562	0.1136669
658	0	2.4548573	0.8980686	0.1597562	0.0247801
659	1	2.9612323	1.0856055	0.1458079	0.0988311
660	2	2.1246892	0.7536256	0.1562455	0.2302261
661	3	1.719658	0.5421254	0.1753126	0.3883392
662	1	2.1234202	0.7530281	0.1458079	0.1290512
663	0	3.4072883	1.2259167	0.1597562	0.0189
664	0	2.5219299	0.9250244	0.1597562	0.0242504
665	2	2.6158315	0.961582	0.1597562	0.1952915
666	0	2.1824254	0.7804368	0.1562455	0.0271871

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Parameter Code=HY2HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 2 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
667	0	2.1477837	0.7644365	0.1562455	0.0275264
668	0	1.4755973	0.3890628	0.1597562	0.0362323
669	0	2.240225	0.8065763	0.1597562	0.0266389
670	0	1.7473944	0.5581258	0.1753126	0.0321444
671	0	2.1049488	0.7442912	0.1634017	0.0279576
672	1	1.7381489	0.5528207	0.1753126	0.1499574
673	0	1.7011671	0.5313145	0.1753126	0.0327759
674	0	2.1280801	0.7552202	0.1634017	0.0277232
675	9	2.1280801	0.7552202	0.1634017	0.9377125
676	3	1.976262	0.6812072	0.1688686	0.3503146
677	1	1.9547809	0.6702781	0.1688686	0.1374588
678	0	1.8306037	0.6046458	0.1753126	0.0310652
679	1	2.1165145	0.7497706	0.1634017	0.1293757
680	4	1.976262	0.6812072	0.1688686	0.4573074
681	3	2.1396458	0.7606403	0.1634017	0.3296701
682	1	2.1280801	0.7552202	0.1634017	0.1288331
683	0	2.0407054	0.7132955	0.1688686	0.0286296
684	2	1.9332998	0.6592283	0.1688686	0.2473875
685	0	1.7011671	0.5313145	0.1753126	0.0327759
686	0	2.1627771	0.7713931	0.1634017	0.0273786
687	0	1.7751308	0.5738741	0.1753126	0.0317767
688	0	1.9440404	0.6647685	0.1688686	0.0297023
689	0	1.976262	0.6812072	0.1688686	0.0293362
690	0	1.976262	0.6812072	0.1688686	0.0293362
691	0	1.9547809	0.6702781	0.1688686	0.0295793

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Parameter Code=HY2HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 2 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
692	4	2.1396458	0.7606403	0.1634017	0.4303577
693	0	1.7011671	0.5313145	0.1753126	0.0327759
694	0	2.0118273	0.6990434	0.2024347	0.0289421
695	2	2.0555627	0.7205496	0.2024347	0.2361495
696	0	1.7317817	0.5491507	0.1917766	0.032355
697	1	1.9680919	0.6770645	0.2024347	0.1367565
698	1	1.7129579	0.5382217	0.1917766	0.1515547
699	0	1.9790258	0.6826047	0.2024347	0.0293052
700	1	1.7976646	0.5864884	0.1917766	0.1463098
701	34	2.1663776	0.7730565	0.2068609	3.4179772
702	1	2.0118273	0.6990434	0.2024347	0.1344977
703	2	1.9352904	0.6602574	0.2024347	0.2471962
704	6	2.1663776	0.7730565	0.2068609	0.6256904
705	1	2.0008935	0.6935938	0.2024347	0.1350556
706	0	1.9899596	0.6881143	0.2024347	0.0291832
707	0	2.14283	0.7621274	0.2068609	0.0275756
708	11	1.7506054	0.5599617	0.1917766	1.3199604
709	2	2.0118273	0.6990434	0.2024347	0.2400533
710	0	2.1663776	0.7730565	0.2068609	0.0273433
711	0	1.7035461	0.532712	0.1917766	0.0327428
712	0	1.7035461	0.532712	0.1917766	0.0327428
713	0	2.0118273	0.6990434	0.2024347	0.0289421
714	1	1.9790258	0.6826047	0.2024347	0.1361849
715	0	1.891555	0.6373993	0.2024347	0.0303182
716	2	1.7317817	0.5491507	0.1917766	0.2683611

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Parameter Code=HY2HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 2 hours after meal

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
717	2	2.1546038	0.7676068	0.2068609	0.2277519
718	1	2.0008935	0.6935938	0.2024347	0.1350556
719	0	2.1663776	0.7730565	0.2068609	0.0273433
720	0	2.0118273	0.6990434	0.2024347	0.0289421
721	0	2.0118273	0.6990434	0.2024347	0.0289421
722	1	2.1546038	0.7676068	0.2068609	0.1276055
723	2	2.1546038	0.7676068	0.2068609	0.2277519
724	1	2.1663776	0.7730565	0.2068609	0.1270678
725	1	1.2705491	0.2394492	0.1571028	0.1860221
726	3	1.964307	0.6751395	0.1851712	0.3519245
727	4	1.6367139	0.4926905	0.1816276	0.5252891
728	17	1.9331276	0.6591392	0.1851712	1.879222
729	0	1.728104	0.5470249	0.1816276	0.0324051
730	3	1.8811618	0.6318895	0.1851712	0.3635323
731	1	2.0682386	0.7266973	0.1851712	0.1316895
732	3	1.2705491	0.2394492	0.1571028	0.4780075
733	2	1.4141867	0.3465546	0.1546981	0.3093458
734	4	1.4141867	0.3465546	0.1546981	0.5813952
735	0	1.2239845	0.2021115	0.1571028	0.0409968
736	0	1.4895399	0.3984673	0.1584279	0.0359987
737	3	0.9579009	-0.043011	0.1571028	0.5664855
738	0	1.5203992	0.418973	0.1816276	0.0354916
739	2	1.4141867	0.3465546	0.1546981	0.3093458
740	0	1.4450979	0.3681771	0.1546981	0.0367535
741	0	1.2572449	0.2289228	0.1571028	0.0403015

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Parameter Code=HY2HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 2 hours after meal

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
742	0	1.5370156	0.4298426	0.1816276	0.0352242
743	2	1.5370156	0.4298426	0.1816276	0.2921588
744	0	1.4219145	0.3520042	0.1546981	0.0371592
745	0	1.4141867	0.3465546	0.1546981	0.0372964
746	0	1.5561115	0.4421901	0.1584279	0.0349216
747	0	1.5287074	0.4244226	0.1816276	0.0353575
748	1	1.4373701	0.3628151	0.1546981	0.1714224
749	0	1.9123412	0.6483283	0.1851712	0.0300713
750	0	1.5810759	0.4581055	0.1584279	0.0345334
751	4	1.775914	0.5743152	0.1885897	0.4951918
752	0	1.5287074	0.4244226	0.1816276	0.0353575
753	2	1.5394686	0.4314373	0.1584279	0.291834
754	3	1.5203992	0.418973	0.1816276	0.4238195
755	0	1.5893973	0.4633549	0.1584279	0.0344058
756	0	1.5311472	0.4260172	0.1584279	0.0353182
757	1	1.5228257	0.4205676	0.1584279	0.1647517
758	2	1.4219145	0.3520042	0.1546981	0.3082084
759	0	1.2239845	0.2021115	0.1571028	0.0409968
760	0	1.4219145	0.3520042	0.1546981	0.0371592
761	0	1.5394686	0.4314373	0.1584279	0.0351851
762	0	1.4141867	0.3465546	0.1546981	0.0372964
763	1	1.5311472	0.4260172	0.1584279	0.1641284
764	0	1.5561115	0.4421901	0.1584279	0.0349216
765	0	1.4141867	0.3465546	0.1546981	0.0372964
766	2	1.7952174	0.5851262	0.1885897	0.2613973

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
767	2	1.4219145	0.3520042	0.1546981	0.3082084
768	3	1.2173324	0.1966619	0.1571028	0.4912507
769	1	1.5394686	0.4314373	0.1584279	0.1635095
770	0	1.4760091	0.3893419	0.1546981	0.0362254
771	1	1.5394686	0.4314373	0.1584279	0.1635095
772	3	1.4296423	0.3574243	0.1546981	0.4421067
773	0	1.5061828	0.4095785	0.1584279	0.0357235
774	1	1.5477901	0.4368282	0.1584279	0.1628951
775	10	1.4219145	0.3520042	0.1546981	1.392405
776	0	1.5311472	0.4260172	0.1584279	0.0353182
777	0	1.2239845	0.2021115	0.1571028	0.0409968
778	11	1.5394686	0.4314373	0.1584279	1.4467542
779	1	0.3858212	-0.952381	0.1571028	0.3094341
780	4	1.2239845	0.2021115	0.1571028	0.6390792
781	1	1.5287074	0.4244226	0.1816276	0.1643106
782	1	1.5477901	0.4368282	0.1584279	0.1628951
783	13	1.4219145	0.3520042	0.1546981	1.7989787
784	1	1.2705491	0.2394492	0.1571028	0.1860221
785	0	1.5145043	0.4150882	0.1584279	0.0355875
786	0	1.5287074	0.4244226	0.1816276	0.0353575
787	0	1.5287074	0.4244226	0.1816276	0.0353575
788	0	1.564433	0.4475234	0.1584279	0.0347913
789	1	1.5287074	0.4244226	0.1816276	0.1643106
790	0	1.4760091	0.3893419	0.1546981	0.0362254
791	1	1.7641478	0.5676678	0.1584279	0.1483426

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Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=HY2HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 2 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
792	1	1.263897	0.2341998	0.1571028	0.1866523
793	0	1.4219145	0.3520042	0.1546981	0.0371592
794	1	1.4296423	0.3574243	0.1546981	0.1720509
795	0	1.4373701	0.3628151	0.1546981	0.0368878
796	0	1.2239845	0.2021115	0.1571028	0.0409968
797	0	1.5311472	0.4260172	0.1584279	0.0353182
798	0	1.2239845	0.2021115	0.1571028	0.0409968
799	6	1.8338243	0.6064036	0.1885897	0.7099337
800	1	1.6117893	0.477345	0.1816276	0.1583134
801	0	1.6284057	0.4876015	0.1816276	0.0338196
802	4	1.5203992	0.418973	0.1816276	0.5532621
803	0	1.9123412	0.6483283	0.1851712	0.0300713
804	0	1.775914	0.5743152	0.1885897	0.0317664
805	0	1.8241726	0.6011265	0.1885897	0.0311461
806	0	1.9954865	0.6908879	0.1851712	0.0291219
807	5	1.7952174	0.5851262	0.1885897	0.60622
808	0	1.8724311	0.6272376	0.1885897	0.0305488
809	1	1.9331276	0.6591392	0.1851712	0.1386162
810	0	1.9539139	0.6698345	0.1851712	0.0295892
811	0	1.843476	0.6116529	0.1885897	0.0309045
812	2	1.2772012	0.2446711	0.1571028	0.3308971
813	0	1.2505929	0.2236177	0.1571028	0.0404388
814	0	1.6559689	0.5043863	0.1584279	0.0334168
815	2	1.1774199	0.1633255	0.1571028	0.3484238
816	3	1.2306366	0.2075316	0.1571028	0.4878771

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Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=HY2HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 2 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
817	0	1.9123412	0.6483283	0.1851712	0.0300713
818	0	1.2040282	0.1856728	0.1571028	0.0414246
819	1	1.4141867	0.3465546	0.1546981	0.1733211
820	0	1.4837369	0.3945638	0.1546981	0.0360956
821	0	1.4760091	0.3893419	0.1546981	0.0362254
822	0	1.6310046	0.4891961	0.1584279	0.0337812
823	0	1.5145043	0.4150882	0.1584279	0.0355875
824	0	1.2306366	0.2075316	0.1571028	0.040856
825	1	1.2306366	0.2075316	0.1571028	0.189863
826	2	1.3987311	0.3355655	0.1546981	0.3116445
827	0	1.5287074	0.4244226	0.1816276	0.0353575
828	1	1.3437221	0.2954435	0.1571028	0.1793424
829	3	1.5228257	0.4205676	0.1584279	0.4233503
830	2	1.5893973	0.4633549	0.1584279	0.2853705
831	2	1.4914647	0.3997586	0.1546981	0.2983167
832	0	1.4219145	0.3520042	0.1546981	0.0371592
833	0	1.5311472	0.4260172	0.1584279	0.0353182
834	0	1.5311472	0.4260172	0.1584279	0.0353182
835	0	1.263897	0.2341998	0.1571028	0.0401651
836	0	1.843476	0.6116529	0.1885897	0.0309045
837	0	1.843476	0.6116529	0.1885897	0.0309045
838	0	1.5287074	0.4244226	0.1816276	0.0353575
839	0	1.512091	0.4134935	0.1816276	0.0356268
840	0	1.775914	0.5743152	0.1885897	0.0317664
841	0	1.9539139	0.6698345	0.1851712	0.0295892

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Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=HY2HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 2 hours after meal

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
842	0	1.8531277	0.6168749	0.1885897	0.030785
843	0	1.7662623	0.5688656	0.1885897	0.0318934
844	0	1.5287074	0.4244226	0.1816276	0.0353575
845	0	1.9013862	0.6425832	0.1885897	0.0302009
846	0	1.5370156	0.4298426	0.1816276	0.0352242
847	0	1.775914	0.5743152	0.1885897	0.0317664
848	0	1.9123412	0.6483283	0.1851712	0.0300713
849	1	1.9331276	0.6591392	0.1851712	0.1386162
850	9	1.5287074	0.4244226	0.1816276	1.1959361
851	0	1.5453238	0.4352335	0.1816276	0.0350919
852	0	1.9123412	0.6483283	0.1851712	0.0300713
853	6	1.9123412	0.6483283	0.1851712	0.6881152
854	0	1.4219145	0.3520042	0.1546981	0.0371592
855	1	1.4219145	0.3520042	0.1546981	0.1726838
856	0	1.5311472	0.4260172	0.1584279	0.0353182
857	4	1.5311472	0.4260172	0.1584279	0.5505587
858	0	1.33707	0.2904807	0.1571028	0.0387188
859	1	1.3171138	0.2754428	0.1571028	0.1817191
860	2	1.9123412	0.6483283	0.1851712	0.2494193
861	1	1.5453238	0.4352335	0.1816276	0.1630768
862	0	1.7662623	0.5688656	0.1885897	0.0318934
863	2	1.5061828	0.4095785	0.1584279	0.2963002
864	1	1.9123412	0.6483283	0.1851712	0.1397453
865	0	1.5561115	0.4421901	0.1584279	0.0349216
866	0	1.5561115	0.4421901	0.1584279	0.0349216

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867	0	1.4141867	0.3465546	0.1546981	0.0372964
868	0	1.2905054	0.2550339	0.1571028	0.0396277
869	1	1.5561115	0.4421901	0.1584279	0.1622851
870	3	1.4064589	0.3410751	0.1546981	0.4470195
871	0	1.5287074	0.4244226	0.1816276	0.0353575
872	5	1.2372887	0.2129224	0.1571028	0.7831997
873	0	1.4373701	0.3628151	0.1546981	0.0368878
874	0	1.4296423	0.3574243	0.1546981	0.0370231
875	0	1.2439408	0.2182844	0.1571028	0.040577
876	11	1.2372887	0.2129224	0.1571028	1.67418
877	0	1.4373701	0.3628151	0.1546981	0.0368878
878	3	1.5061828	0.4095785	0.1584279	0.4265885
879	0	1.2173324	0.1966619	0.1571028	0.0411385
880	4	1.5311472	0.4260172	0.1584279	0.5505587
881	0	1.2173324	0.1966619	0.1571028	0.0411385
882	0	0.3791691	-0.969773	0.1571028	0.0667773
883	2	1.2106803	0.1911824	0.1571028	0.342396
884	0	1.4219145	0.3520042	0.1546981	0.0371592
885	0	1.4141867	0.3465546	0.1546981	0.0372964
886	1	1.5561115	0.4421901	0.1584279	0.1622851
887	0	1.4219145	0.3520042	0.1546981	0.0371592
888	5	1.2239845	0.2021115	0.1571028	0.7885997
889	3	1.4219145	0.3520042	0.1546981	0.443733
890	0	1.5810759	0.4581055	0.1584279	0.0345334
891	0	1.5228257	0.4205676	0.1584279	0.0354524

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
892	5	1.4064589	0.3410751	0.1546981	0.7200762
893	0	1.5394686	0.4314373	0.1584279	0.0351851
894	0	1.5228257	0.4205676	0.1584279	0.0354524
895	7	1.4837369	0.3945638	0.1546981	0.957612
896	1	1.4219145	0.3520042	0.1546981	0.1726838
897	1	1.9019481	0.6428787	0.1851712	0.1403166
898	0	1.2372887	0.2129224	0.1571028	0.0407161
899	0	1.4812185	0.392865	0.1584279	0.0361378
900	8	1.5311472	0.4260172	0.1584279	1.0657992
901	2	1.2173324	0.1966619	0.1571028	0.3412133
902	0	1.2173324	0.1966619	0.1571028	0.0411385
903	4	1.2372887	0.2129224	0.1571028	0.6347029
904	40	1.5228257	0.4205676	0.1584279	5.2074243
905	0	1.775914	0.5743152	0.1885897	0.0317664
906	0	1.8627794	0.6220697	0.1885897	0.0306664
907	0	1.5311472	0.4260172	0.1584279	0.0353182
908	1	1.5287074	0.4244226	0.1816276	0.1643106
909	0	1.9123412	0.6483283	0.1851712	0.0300713
910	0	1.7662623	0.5688656	0.1885897	0.0318934
911	0	1.5061828	0.4095785	0.1584279	0.0357235
912	0	1.8338243	0.6064036	0.1885897	0.0310248
913	0	1.9227344	0.6537483	0.1851712	0.0299494
914	0	1.9331276	0.6591392	0.1851712	0.0298284
915	3	1.553632	0.4405954	0.1816276	0.4174781
916	12	1.7662623	0.5688656	0.1885897	1.4277255

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The GENMOD Procedure

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Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
917	0	1.7662623	0.5688656	0.1885897	0.0318934
918	0	1.2306366	0.2075316	0.1571028	0.040856
919	1	1.2372887	0.2129224	0.1571028	0.1892128
920	1	1.5203992	0.418973	0.1816276	0.1649343
921	2	1.4296423	0.3574243	0.1546981	0.3070788
922	0	1.5785566	0.4565109	0.1816276	0.0345722
923	0	1.2306366	0.2075316	0.1571028	0.040856
924	1	1.5477901	0.4368282	0.1584279	0.1628951
925	0	1.5287074	0.4244226	0.1816276	0.0353575
926	0	1.5311472	0.4260172	0.1584279	0.0353182
927	0	1.4296423	0.3574243	0.1546981	0.0370231
928	10	1.9123412	0.6483283	0.1851712	1.1268111
929	0	1.2306366	0.2075316	0.1571028	0.040856
930	0	1.5203992	0.418973	0.1816276	0.0354916
931	0	1.8915549	0.6373992	0.1851712	0.0303182
932	0	1.5394686	0.4314373	0.1584279	0.0351851
933	0	1.1292497	0.1215534	0.1885897	0.0431024
934	2	1.5453238	0.4352335	0.1816276	0.2910616
935	1	1.5287074	0.4244226	0.1816276	0.1643106
936	1	1.4219145	0.3520042	0.1546981	0.1726838
937	0	1.5287074	0.4244226	0.1816276	0.0353575
938	2	2.0370591	0.7115072	0.1851712	0.2377859
939	0	1.5394686	0.4314373	0.1584279	0.0351851
940	0	1.2239845	0.2021115	0.1571028	0.0409968
941	0	1.7469589	0.5578765	0.1885897	0.0321503

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Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=HY2HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 2 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
942	0	1.2772012	0.2446711	0.1571028	0.0398947
943	4	1.5145043	0.4150882	0.1584279	0.5547555
944	0	1.2239845	0.2021115	0.1571028	0.0409968
945	0	1.2106803	0.1911824	0.1571028	0.0412811
946	0	1.5287074	0.4244226	0.1816276	0.0353575
947	0	1.7391835	0.5534157	0.1584279	0.0322549
948	0	1.5893973	0.4633549	0.1584279	0.0344058
949	1	1.5394686	0.4314373	0.1584279	0.1635095
950	1	1.8531277	0.6168749	0.1885897	0.1430619
951	1	1.2306366	0.2075316	0.1571028	0.189863
952	1	1.7530286	0.5613449	0.1816276	0.1490291
953	0	1.4219145	0.3520042	0.1546981	0.0371592
954	2	1.4682813	0.3840925	0.1546981	0.3015464
955	0	1.5228257	0.4205676	0.1584279	0.0354524
956	0	1.2239845	0.2021115	0.1571028	0.0409968
957	0	1.5287074	0.4244226	0.1816276	0.0353575
958	0	1.2040282	0.1856728	0.1571028	0.0414246
959	1	1.5311472	0.4260172	0.1584279	0.1641284
960	0	1.5311472	0.4260172	0.1584279	0.0353182
961	0	1.2239845	0.2021115	0.1571028	0.0409968
962	0	1.5287074	0.4244226	0.1816276	0.0353575
963	0	1.2239845	0.2021115	0.1571028	0.0409968
964	0	1.4760091	0.3893419	0.1546981	0.0362254
965	0	1.5370156	0.4298426	0.1816276	0.0352242
966	0	1.4219145	0.3520042	0.1546981	0.0371592

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Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
967	0	1.2306366	0.2075316	0.1571028	0.040856
968	0	0.3259524	-1.121004	0.1571028	0.0680371
969	1	1.184072	0.1689593	0.1571028	0.1945318
970	0	1.4528257	0.3735104	0.1546981	0.0366201
971	0	1.775914	0.5743152	0.1885897	0.0317664
972	0	1.5311472	0.4260172	0.1584279	0.0353182
973	0	1.9435207	0.6645011	0.1851712	0.0297083
974	1	1.775914	0.5743152	0.1885897	0.1476228
975	0	1.9019481	0.6428787	0.1851712	0.0301942
976	0	1.5287074	0.4244226	0.1816276	0.0353575
977	0	1.4450979	0.3681771	0.1546981	0.0367535
978	1	1.7662623	0.5688656	0.1885897	0.1482127
979	0	1.2705491	0.2394492	0.1571028	0.0400295
980	3	1.8241726	0.6011265	0.1885897	0.3719273
981	0	1.512091	0.4134935	0.1816276	0.0356268
982	0	1.6367139	0.4926905	0.1816276	0.0336972
983	3	1.5069203	0.410068	0.1546981	0.426444
984	2	1.2173324	0.1966619	0.1571028	0.3412133
985	1	1.4141867	0.3465546	0.1546981	0.1733211
986	2	1.9227344	0.6537483	0.1851712	0.2484077
987	0	1.5311472	0.4260172	0.1584279	0.0353182
988	2	1.4064589	0.3410751	0.1546981	0.3104912
989	6	1.4064589	0.3410751	0.1546981	0.8566046
990	0	1.2372887	0.2129224	0.1571028	0.0407161
991	3	1.4219145	0.3520042	0.1546981	0.443733

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Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
992	8	1.3600921	0.3075524	0.1546981	1.1552859
993	1	1.5311472	0.4260172	0.1584279	0.1641284
994	1	1.4373701	0.3628151	0.1546981	0.1714224
995	0	1.5311472	0.4260172	0.1584279	0.0353182
996	0	1.5394686	0.4314373	0.1584279	0.0351851
997	3	0.873241	-0.135544	0.1546981	0.5954356
998	14	1.4954747	0.4024437	0.1816276	1.8689525
999	0	1.4837369	0.3945638	0.1546981	0.0360956
1000	5	1.2306366	0.2075316	0.1571028	0.7858912
1001	0	1.6034812	0.472177	0.1816276	0.0341919
1002	2	1.9019481	0.6428787	0.1851712	0.2504389
1003	1	1.213264	0.1933142	0.1546981	0.1915807
1004	1	0.5825016	-0.540423	0.1584279	0.2772888
1005	0	1.4296423	0.3574243	0.1546981	0.0370231
1006	0	1.2239845	0.2021115	0.1571028	0.0409968
1007	18	1.2306366	0.2075316	0.1571028	2.7229827
1008	5	1.4219145	0.3520042	0.1546981	0.7147821
1009	4	1.4605535	0.3788155	0.1546981	0.5687879
1010	0	1.5145043	0.4150882	0.1584279	0.0355875
1011	1	1.3703305	0.3150519	0.1571028	0.1770232
1012	0	1.2173324	0.1966619	0.1571028	0.0411385
1013	3	1.2372887	0.2129224	0.1571028	0.4862062
1014	0	1.5477901	0.4368282	0.1584279	0.0350529
1015	0	1.2306366	0.2075316	0.1571028	0.040856
1016	0	1.5727544	0.4528285	0.1584279	0.0346619

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
1017	3	1.5228257	0.4205676	0.1584279	0.4233503
1018	0	1.4219145	0.3520042	0.1546981	0.0371592
1019	0	1.5287074	0.4244226	0.1816276	0.0353575
1020	1	1.2439408	0.2182844	0.1571028	0.1885666
1021	0	1.5477901	0.4368282	0.1584279	0.0350529
1022	0	1.2239845	0.2021115	0.1571028	0.0409968
1023	1	1.4219145	0.3520042	0.1546981	0.1726838
1024	8	1.4219145	0.3520042	0.1546981	1.1213558
1025	0	1.4219145	0.3520042	0.1546981	0.0371592

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Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=HY4HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 4 hours after meal

The GENMOD Procedure

Model Information

Data Set	WORK.ENDPOINT	
Distribution	Negative Binomial	
Link Function	Log	
Dependent Variable	AVAL	Analysis Value
Offset Variable	log_offset	

Number of Observations Read	1025
Number of Observations Used	1025

Class Level Information

Class	Levels	Values
TRTPN	3	2 3 4
REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA
BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Parameter Information

Parameter	Effect	TRTPN	REGION1	BOLAD1
Prm1	Intercept			
Prm2	TRTPN	2		
Prm3	TRTPN	3		
Prm4	TRTPN	4		
Prm5	REGION1		ASIA (EXCLUDING JAPAN)	
Prm6	REGION1		EUROPE	

Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

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Parameter Information

Parameter	Effect	TRTPN	REGION1	BOLAD1
Prm7	REGION1		JAPAN	
Prm8	REGION1		NORTH AMERICA	
Prm9	BOLAD1			BOLUS INSULIN ALGORITHM (SLIDING SCALE)
Prm10	BOLAD1			CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY

Criteria For Assessing Goodness Of Fit

Criterion	DF	Value	Value/DF
Deviance	1018	1066.9775	1.0481
Scaled Deviance	1018	1066.9775	1.0481
Pearson Chi-Square	1018	958.3293	0.9414
Scaled Pearson X2	1018	958.3293	0.9414
Log Likelihood		7974.3274	
Full Log Likelihood		-2634.0085	
AIC (smaller is better)		5284.0169	
AICC (smaller is better)		5284.1586	
BIC (smaller is better)		5323.4765	

Algorithm converged.

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Analysis Of Maximum Likelihood Parameter Estimates

Parameter		DF	Estimate	Standard Error	Wald 95% Confidence Limits		Wald Chi-Square
Intercept		1	6.8531	0.1281	6.6021	7.1042	2862.43
TRTPN	2	1	-0.1980	0.1315	-0.4558	0.0598	2.27
TRTPN	3	1	0.0879	0.1306	-0.1682	0.3439	0.45
TRTPN	4	0	0.0000	0.0000	0.0000	0.0000	.
REGION1	ASIA (EXCLUDING JAPAN)	1	-0.2285	0.1979	-0.6164	0.1595	1.33
REGION1	EUROPE	1	0.2269	0.1377	-0.0430	0.4968	2.71
REGION1	JAPAN	1	0.1051	0.1565	-0.2017	0.4118	0.45
REGION1	NORTH AMERICA	0	0.0000	0.0000	0.0000	0.0000	.
BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	1	0.1433	0.1219	-0.0956	0.3822	1.38
BOLAD1	CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY	0	0.0000	0.0000	0.0000	0.0000	.
Dispersion		1	2.7193	0.1447	2.4501	3.0181	

Analysis Of Maximum Likelihood Parameter Estimates

Parameter		Pr > ChiSq
Intercept		<.0001
TRTPN	2	0.1323
TRTPN	3	0.5013
TRTPN	4	.
REGION1	ASIA (EXCLUDING JAPAN)	0.2484
REGION1	EUROPE	0.0994
REGION1	JAPAN	0.5020
REGION1	NORTH AMERICA	.
BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.2396
BOLAD1	CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY	.
Dispersion		

NOTE: The negative binomial dispersion parameter was estimated by maximum likelihood.

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Coefficients for TRTPN Least Squares Means Using WORK.ENDPOINT Margins

Parameter	Geographic Region Grouping Method 1
Intercept	
Planned Treatment (N) 2	
Planned Treatment (N) 3	
Planned Treatment (N) 4	
Geographic Region Grouping Method 1 ASIA (EXCLUDING JAPAN)	ASIA (EXCLUDING JAPAN)
Geographic Region Grouping Method 1 EUROPE	EUROPE
Geographic Region Grouping Method 1 JAPAN	JAPAN
Geographic Region Grouping Method 1 NORTH AMERICA	NORTH AMERICA
Bolus Adjustment Method at Timepoint 1 BOLUS INSULIN ALGORITHM (SLIDING SCALE)	
Bolus Adjustment Method at Timepoint 1 CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY	

Coefficients for TRTPN Least Squares Means Using WORK.ENDPOINT Margins

Bolus Adjustment Method at Timepoint 1	Planned Treatment (N)	Row1	Row2	Row3
	1	1	1	1
	2	1		
	3		1	
	4			1
		0.1307	0.1307	0.1307
		0.3366	0.3366	0.3366
		0.239	0.239	0.239
		0.2937	0.2937	0.2937
BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.5824	0.5824	0.5824
CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		0.4176	0.4176	0.4176

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Parameter Code=HY4HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 4 hours after meal

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TRTPN Least Squares Means

Planned Treatment (N)	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
2	WORK.ENDPOINT	6.8103	0.09329	73.00	<.0001	0.05	6.6274	6.9931
3	WORK.ENDPOINT	7.0961	0.09239	76.80	<.0001	0.05	6.9150	7.2772
4	WORK.ENDPOINT	7.0082	0.09238	75.87	<.0001	0.05	6.8272	7.1893

Differences of TRTPN Least Squares Means

Planned Treatment (N)	Planned Treatment (N)	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
2	4	WORK.ENDPOINT	-0.1980	0.1315	-1.51	0.1323	0.05	-0.4558	0.05984
3	4	WORK.ENDPOINT	0.08786	0.1306	0.67	0.5013	0.05	-0.1682	0.3439

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
TRTPN	Faster aspart (meal) / NovoRapid (meal)	WORK.ENDPOINT	-0.1980	0.1315	-1.51	0.1323	0.05	-0.4558	0.05984

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Parameter Code=HY4HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 4 hours after meal

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Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
TRTPN	Faster aspart (post) / NovoRapid (meal)	WORK.ENDPOINT	0.08786	0.1306	0.67	0.5013	0.05	-0.1682	0.3439

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
1	14	4.3467468	1.4694277	0.1631107	1.0332977
2	0	4.3467468	1.4694277	0.1631107	0.0264471
3	0	4.3467468	1.4694277	0.1631107	0.0264471
4	0	4.3467468	1.4694277	0.1631107	0.0264471
5	9	4.3467468	1.4694277	0.1631107	0.6737082
6	32	5.0438166	1.618163	0.1356372	2.0500703
7	8	5.7849317	1.7552565	0.1634907	0.470241
8	3	5.9421309	1.7820678	0.1634907	0.1848338
9	0	4.5121122	1.5067654	0.1631107	0.0256242
10	0	1.0302104	0.029763	0.1346849	0.0712894
11	5	4.2994996	1.4584986	0.1631107	0.3896106
12	1	5.9421309	1.7820678	0.1634907	0.0750666
13	1	5.7849317	1.7552565	0.1634907	0.0768628
14	27	5.2407637	1.6564672	0.1570978	1.6767989
15	3	4.3467468	1.4694277	0.1631107	0.2422008
16	0	5.3271499	1.6728164	0.1570978	0.022213

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
17	7	5.0165527	1.612743	0.1356372	0.4688392
18	1	6.9666288	1.9411314	0.1381409	0.0651392
19	5	6.114797	1.8107116	0.1346849	0.2872269
20	8	5.2407637	1.6564672	0.1570978	0.5126846
21	10	5.0165527	1.612743	0.1356372	0.6597413
22	0	0.9502484	-0.051032	0.1570978	0.073977
23	0	5.7849317	1.7552565	0.1634907	0.0206659
24	0	6.6763526	1.8985718	0.1381409	0.0181958
25	1	6.0050106	1.7925942	0.1634907	0.0743713
26	1	5.7849317	1.7552565	0.1634907	0.0768628
27	6	6.4451684	1.8633308	0.1634907	0.3251592
28	16	6.6763526	1.8985718	0.1381409	0.8098776
29	5	4.3703705	1.4748478	0.1631107	0.3842739
30	41	6.3141926	1.8427999	0.1346849	2.1513791
31	13	6.6763526	1.8985718	0.1381409	0.6614373
32	2	4.3467468	1.4694277	0.1631107	0.1702829
33	2	5.7849317	1.7552565	0.1634907	0.1330596
34	0	6.0815644	1.805262	0.1346849	0.019773
35	0	6.1936497	1.8235245	0.1634907	0.0194553
36	1	5.2983545	1.6673963	0.1570978	0.0830077
37	1	5.2983545	1.6673963	0.1570978	0.0830077
38	9	5.7849317	1.7552565	0.1634907	0.5264379
39	2	5.7849317	1.7552565	0.1634907	0.1330596
40	1	5.6906121	1.7388178	0.1634907	0.0779821
41	8	5.7849317	1.7552565	0.1634907	0.470241

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
42	19	6.7489216	1.9093827	0.1381409	0.9490787
43	18	6.6763526	1.8985718	0.1381409	0.9088378
44	23	6.114797	1.8107116	0.1346849	1.2504037
45	0	5.0165527	1.612743	0.1356372	0.0234008
46	0	5.2346637	1.6553026	0.1356372	0.022554
47	8	5.0165527	1.612743	0.1356372	0.5324732
48	1	6.7852062	1.9147447	0.1381409	0.0667019
49	27	6.0815644	1.805262	0.1346849	1.471533
50	4	5.0710804	1.6235539	0.1356372	0.2753527
51	13	5.0710804	1.6235539	0.1356372	0.8427341
52	3	6.6763526	1.8985718	0.1381409	0.1666362
53	0	6.7489216	1.9093827	0.1381409	0.0180204
54	0	6.1812622	1.8215225	0.1346849	0.0194899
55	5	6.6037835	1.8876427	0.1381409	0.2682072
56	11	5.0710804	1.6235539	0.1356372	0.7166493
57	8	7.4383276	2.006646	0.1381409	0.3756301
58	26	5.1256082	1.6342492	0.1356372	1.6469695
59	15	6.1480296	1.8161316	0.1346849	0.8183819
60	0	6.6763526	1.8985718	0.1381409	0.0181958
61	18	6.2144948	1.8268844	0.1346849	0.9688495
62	10	5.1256082	1.6342492	0.1356372	0.647585
63	4	6.6037835	1.8876427	0.1381409	0.2182407
64	2	6.114797	1.8107116	0.1346849	0.1266974
65	30	6.8577752	1.9253831	0.1381409	1.4668969
66	16	6.7852062	1.9147447	0.1381409	0.7982214

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
67	5	6.6763526	1.8985718	0.1381409	0.2655964
68	16	6.6037835	1.8876427	0.1381409	0.8178387
69	8	4.9347611	1.5963043	0.1356372	0.5400753
70	0	5.0165527	1.612743	0.1356372	0.0234008
71	19	5.2619275	1.6604974	0.1356372	1.1824964
72	0	6.114797	1.8107116	0.1346849	0.0196777
73	3	6.6763526	1.8985718	0.1381409	0.1666362
74	0	6.114797	1.8107116	0.1346849	0.0196777
75	9	5.0438166	1.618163	0.1356372	0.5933231
76	7	6.114797	1.8107116	0.1346849	0.3942465
77	2	6.6763526	1.8985718	0.1381409	0.1171561
78	4	6.114797	1.8107116	0.1346849	0.233717
79	0	5.0165527	1.612743	0.1356372	0.0234008
80	23	5.0438166	1.618163	0.1356372	1.4800388
81	0	6.114797	1.8107116	0.1346849	0.0196777
82	0	5.0165527	1.612743	0.1356372	0.0234008
83	0	6.114797	1.8107116	0.1346849	0.0196777
84	1	6.0150993	1.7942729	0.1346849	0.0742609
85	4	5.0165527	1.612743	0.1356372	0.277937
86	0	6.6400681	1.8931222	0.1381409	0.0182848
87	22	5.0165527	1.612743	0.1356372	1.4233499
88	0	6.6763526	1.8985718	0.1381409	0.0181958
89	1	6.2144948	1.8268844	0.1346849	0.0721447
90	0	6.567499	1.8821331	0.1381409	0.0184655
91	1	6.0815644	1.805262	0.1346849	0.0735419

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Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
92	17	6.114797	1.8107116	0.1346849	0.9293448
93	8	6.0150993	1.7942729	0.1346849	0.454323
94	0	6.0815644	1.805262	0.1346849	0.019773
95	0	5.0165527	1.612743	0.1356372	0.0234008
96	9	6.0150993	1.7942729	0.1346849	0.5086175
97	1	6.6763526	1.8985718	0.1381409	0.067676
98	6	5.2983545	1.6673963	0.1570978	0.3864562
99	3	5.0165527	1.612743	0.1356372	0.214303
100	5	5.6906121	1.7388178	0.1634907	0.3060434
101	2	6.114797	1.8107116	0.1346849	0.1266974
102	0	4.3231232	1.4639781	0.1631107	0.026569
103	5	5.8792512	1.7714294	0.1634907	0.297381
104	18	6.114797	1.8107116	0.1346849	0.9828546
105	5	5.2407637	1.6564672	0.1570978	0.328877
106	1	5.2119683	1.6509576	0.1570978	0.0842023
107	59	6.114797	1.8107116	0.1346849	3.1767574
108	40	6.7126371	1.9039919	0.1381409	1.9877252
109	11	6.6037835	1.8876427	0.1381409	0.5680062
110	1	4.3467468	1.4694277	0.1631107	0.098365
111	3	5.2407637	1.6564672	0.1570978	0.2063387
112	29	5.2983545	1.6673963	0.1570978	1.7823189
113	2	5.2983545	1.6673963	0.1570978	0.1436974
114	1	5.2983545	1.6673963	0.1570978	0.0830077
115	2	4.3467468	1.4694277	0.1631107	0.1702829
116	16	5.7849317	1.7552565	0.1634907	0.9198161

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Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
117	0	5.3271499	1.6728164	0.1570978	0.022213
118	0	4.3467468	1.4694277	0.1631107	0.0264471
119	6	5.2983545	1.6673963	0.1570978	0.3864562
120	6	4.3467468	1.4694277	0.1631107	0.4579545
121	0	5.2983545	1.6673963	0.1570978	0.0223181
122	0	4.3467468	1.4694277	0.1631107	0.0264471
123	7	5.6906121	1.7388178	0.1634907	0.420074
124	5	5.2983545	1.6673963	0.1570978	0.3257665
125	14	4.3467468	1.4694277	0.1631107	1.0332977
126	9	5.7534918	1.7498069	0.1634907	0.528969
127	4	5.7849317	1.7552565	0.1634907	0.2454534
128	0	5.8792512	1.7714294	0.1634907	0.0203734
129	11	6.6763526	1.8985718	0.1381409	0.5624771
130	0	4.5121122	1.5067654	0.1631107	0.0256242
131	0	5.2891914	1.6656654	0.1356372	0.0223517
132	2	5.7849317	1.7552565	0.1634907	0.1330596
133	0	6.8538864	1.9248159	0.1634907	0.0177726
134	2	6.28096	1.8375228	0.1346849	0.1237167
135	0	5.3271499	1.6728164	0.1570978	0.022213
136	0	5.9318534	1.7803367	0.1570978	0.0202138
137	0	3.7413417	1.3194443	0.1634907	0.0299655
138	1	6.7129837	1.9040435	0.1346849	0.067345
139	6	4.3939941	1.4802386	0.1631107	0.4537912
140	11	5.2407637	1.6564672	0.1570978	0.6964921
141	10	6.0050106	1.7925942	0.1634907	0.5637487

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Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
142	0	5.722052	1.7443275	0.1634907	0.0208656
143	5	6.114797	1.8107116	0.1346849	0.2872269
144	5	5.0165527	1.612743	0.1356372	0.3415711
145	5	5.0165527	1.612743	0.1356372	0.3415711
146	1	6.28096	1.8375228	0.1346849	0.0714657
147	4	7.1843359	1.9719031	0.1381409	0.2023263
148	9	8.708286	2.164275	0.1381409	0.3641813
149	2	6.1480296	1.8161316	0.1346849	0.1260899
150	0	4.9347611	1.5963043	0.1356372	0.0237349
151	19	6.6763526	1.8985718	0.1381409	0.9583179
152	5	6.114797	1.8107116	0.1346849	0.2872269
153	0	6.0150993	1.7942729	0.1346849	0.0199663
154	0	6.6400681	1.8931222	0.1381409	0.0182848
155	14	6.0483318	1.7997825	0.1346849	0.7762957
156	1	3.5715674	1.2730045	0.1356372	0.1157615
157	0	5.5152478	1.7075166	0.1381409	0.0215502
158	4	6.6763526	1.8985718	0.1381409	0.2161163
159	24	5.0710804	1.6235539	0.1356372	1.5362002
160	2	5.0983443	1.6289158	0.1356372	0.1485772
161	11	5.0165527	1.612743	0.1356372	0.7233753
162	2	6.6763526	1.8985718	0.1381409	0.1171561
163	4	6.6763526	1.8985718	0.1381409	0.2161163
164	10	6.6763526	1.8985718	0.1381409	0.512997
165	9	4.1540741	1.4240896	0.1346849	0.6998825
166	4	6.6037835	1.8876427	0.1381409	0.2182407

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Parameter Code=HY4HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 4 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
167	16	6.114797	1.8107116	0.1346849	0.8758349
168	4	6.1812622	1.8215225	0.1346849	0.2314863
169	3	6.0483318	1.7997825	0.1346849	0.1819606
170	5	4.9892888	1.6072934	0.1356372	0.3431814
171	3	6.6400681	1.8931222	0.1381409	0.1674512
172	0	5.0983443	1.6289158	0.1356372	0.0230759
173	0	5.0438166	1.618163	0.1356372	0.0232915
174	6	6.0150993	1.7942729	0.1346849	0.3457338
175	0	6.1812622	1.8215225	0.1346849	0.0194899
176	1	6.0815644	1.805262	0.1346849	0.0735419
177	1	6.9303443	1.9359095	0.1381409	0.0654459
178	1	5.0983443	1.6289158	0.1356372	0.0858266
179	0	6.6763526	1.8985718	0.1381409	0.0181958
180	8	6.0815644	1.805262	0.1346849	0.4499241
181	3	4.9347611	1.5963043	0.1356372	0.2173625
182	0	6.0483318	1.7997825	0.1346849	0.0198692
183	1	6.6763526	1.8985718	0.1381409	0.067676
184	0	6.6763526	1.8985718	0.1381409	0.0181958
185	11	6.7852062	1.9147447	0.1381409	0.5543816
186	2	6.0815644	1.805262	0.1346849	0.1273108
187	0	5.0165527	1.612743	0.1356372	0.0234008
188	1	5.0438166	1.618163	0.1356372	0.0866284
189	1	3.6284525	1.2888062	0.1381409	0.1142809
190	14	4.9347611	1.5963043	0.1356372	0.9273305
191	20	5.0967867	1.6286103	0.1570978	1.2784263

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
192	0	6.0483318	1.7997825	0.1346849	0.0198692
193	2	5.0165527	1.612743	0.1356372	0.1506689
194	6	6.114797	1.8107116	0.1346849	0.3407367
195	22	6.8214907	1.920078	0.1381409	1.0856206
196	18	5.3847407	1.6835692	0.1570978	1.0991366
197	0	6.114797	1.8107116	0.1346849	0.0196777
198	1	6.0150993	1.7942729	0.1346849	0.0742609
199	0	5.0165527	1.612743	0.1356372	0.0234008
200	0	6.1480296	1.8161316	0.1346849	0.0195834
201	0	5.0710804	1.6235539	0.1356372	0.0231832
202	0	1.9274904	0.6562188	0.1346849	0.0494792
203	5	3.4833144	1.2479843	0.1381409	0.4636245
204	32	5.0165527	1.612743	0.1356372	2.0596903
205	3	6.7126371	1.9039919	0.1381409	0.165829
206	1	5.2073998	1.6500807	0.1356372	0.0842664
207	2	5.0165527	1.612743	0.1356372	0.1506689
208	0	6.7126371	1.9039919	0.1381409	0.0181077
209	5	4.9347611	1.5963043	0.1356372	0.3464476
210	21	6.114797	1.8107116	0.1346849	1.1433841
211	2	6.0050106	1.7925942	0.1634907	0.1287465
212	1	6.6037835	1.8876427	0.1381409	0.0683412
213	4	6.6763526	1.8985718	0.1381409	0.2161163
214	0	5.7849317	1.7552565	0.1634907	0.0206659
215	0	0.2539917	-1.370454	0.1381409	0.0888579
216	0	4.3467468	1.4694277	0.1631107	0.0264471

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Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
217	0	5.2407637	1.6564672	0.1570978	0.0225312
218	0	4.3703705	1.4748478	0.1631107	0.0263264
219	0	5.3271499	1.6728164	0.1570978	0.022213
220	0	5.2407637	1.6564672	0.1570978	0.0225312
221	2	6.0815644	1.805262	0.1346849	0.1273108
222	6	5.0165527	1.612743	0.1356372	0.4052051
223	16	6.6763526	1.8985718	0.1381409	0.8098776
224	0	6.9303443	1.9359095	0.1381409	0.0175963
225	6	5.0165527	1.612743	0.1356372	0.4052051
226	6	5.0165527	1.612743	0.1356372	0.4052051
227	3	6.6763526	1.8985718	0.1381409	0.1666362
228	1	6.114797	1.8107116	0.1346849	0.0731876
229	1	6.3474252	1.8480492	0.1346849	0.0707994
230	0	6.6763526	1.8985718	0.1381409	0.0181958
231	0	6.7126371	1.9039919	0.1381409	0.0181077
232	1	6.2477274	1.8322178	0.1346849	0.0718036
233	1	6.6763526	1.8985718	0.1381409	0.067676
234	0	5.0983443	1.6289158	0.1356372	0.0230759
235	1	6.6763526	1.8985718	0.1381409	0.067676
236	2	6.7126371	1.9039919	0.1381409	0.1165886
237	0	6.6763526	1.8985718	0.1381409	0.0181958
238	8	6.114797	1.8107116	0.1346849	0.4477563
239	2	6.6763526	1.8985718	0.1381409	0.1171561
240	0	5.0165527	1.612743	0.1356372	0.0234008
241	0	5.0165527	1.612743	0.1356372	0.0234008

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Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
242	0	5.0165527	1.612743	0.1356372	0.0234008
243	0	6.114797	1.8107116	0.1346849	0.0196777
244	1	5.8821689	1.7719256	0.1346849	0.0757418
245	0	6.9303443	1.9359095	0.1381409	0.0175963
246	8	4.3806116	1.4771884	0.1704302	0.5978589
247	2	4.3806116	1.4771884	0.1704302	0.1691705
248	0	4.7829074	1.5650486	0.1718829	0.024381
249	0	4.8329574	1.5754586	0.1704302	0.0241642
250	0	4.7829074	1.5650486	0.1718829	0.024381
251	0	4.3806116	1.4771884	0.1704302	0.0262744
252	1	3.7305565	1.3165574	0.161143	0.1117151
253	0	4.8868836	1.5865548	0.1718829	0.0239349
254	0	4.8089014	1.5704687	0.1718829	0.0242679
255	12	3.5938346	1.2792198	0.161143	1.0414879
256	0	4.8348955	1.5758595	0.1718829	0.0241559
257	0	3.5938346	1.2792198	0.161143	0.0309675
258	0	4.7829074	1.5650486	0.1718829	0.024381
259	4	4.9388717	1.5971369	0.1718829	0.281703
260	0	4.8089014	1.5704687	0.1718829	0.0242679
261	0	4.3806116	1.4771884	0.1704302	0.0262744
262	0	4.7829074	1.5650486	0.1718829	0.024381
263	0	3.5938346	1.2792198	0.161143	0.0309675
264	19	4.4044193	1.4826084	0.1704302	1.3774607
265	0	4.4044193	1.4826084	0.1704302	0.0261542
266	1	4.3806116	1.4771884	0.1704302	0.0977224

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Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
267	0	4.3806116	1.4771884	0.1704302	0.0262744
268	7	4.5234576	1.5092767	0.1704302	0.51229
269	1	3.6719614	1.300726	0.161143	0.1131735
270	0	4.7829074	1.5650486	0.1718829	0.024381
271	0	3.5938346	1.2792198	0.161143	0.0309675
272	2	4.8348955	1.5758595	0.1718829	0.1555306
273	0	4.7049252	1.5486099	0.1718829	0.0247265
274	0	3.6524297	1.2953926	0.161143	0.0305616
275	0	4.785342	1.5655575	0.1704302	0.0243704
276	0	4.8089014	1.5704687	0.1718829	0.0242679
277	0	4.8348955	1.5758595	0.1718829	0.0241559
278	0	4.7829074	1.5650486	0.1718829	0.024381
279	0	3.6524297	1.2953926	0.161143	0.0305616
280	0	3.6133663	1.2846398	0.161143	0.030831
281	1	4.8089014	1.5704687	0.1718829	0.0902599
282	12	3.6133663	1.2846398	0.161143	1.0368985
283	1	3.5352394	1.262781	0.161143	0.116727
284	5	3.5938346	1.2792198	0.161143	0.4520176
285	0	4.7309192	1.5541195	0.1718829	0.0246103
286	0	4.4044193	1.4826084	0.1704302	0.0261542
287	0	4.4044193	1.4826084	0.1704302	0.0261542
288	0	4.428227	1.4879993	0.1704302	0.0260352
289	0	4.4044193	1.4826084	0.1704302	0.0261542
290	0	4.3806116	1.4771884	0.1704302	0.0262744
291	0	4.4520346	1.4933612	0.1704302	0.0259172

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Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
292	0	4.7829074	1.5650486	0.1718829	0.024381
293	1	3.5938346	1.2792198	0.161143	0.1151775
294	0	4.3806116	1.4771884	0.1704302	0.0262744
295	0	4.8089014	1.5704687	0.1718829	0.0242679
296	0	4.3091886	1.4607496	0.1704302	0.0266414
297	0	4.3568039	1.4717387	0.1704302	0.0263956
298	16	4.7829074	1.5650486	0.1718829	1.0851719
299	0	2.5195905	0.9240964	0.161143	0.0408714
300	55	3.5938346	1.2792198	0.161143	4.6625195
301	0	4.3806116	1.4771884	0.1704302	0.0262744
302	0	4.7829074	1.5650486	0.1718829	0.024381
303	0	4.8348955	1.5758595	0.1718829	0.0241559
304	6	4.428227	1.4879993	0.1704302	0.4508212
305	26	3.7500882	1.3217794	0.161143	2.1444672
306	1	3.5938346	1.2792198	0.161143	0.1151775
307	0	4.3329963	1.4662593	0.1704302	0.0265179
308	4	3.5938346	1.2792198	0.161143	0.3678076
309	0	3.6133663	1.2846398	0.161143	0.030831
310	0	3.6133663	1.2846398	0.161143	0.030831
311	1	4.8348955	1.5758595	0.1718829	0.0898433
312	2	4.428227	1.4879993	0.1704302	0.1676305
313	14	4.3806116	1.4771884	0.1704302	1.0265473
314	0	4.9388717	1.5971369	0.1718829	0.0237179
315	0	3.5547711	1.2682907	0.161143	0.031244
316	0	4.428227	1.4879993	0.1704302	0.0260352

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
317	14	4.8089014	1.5704687	0.1718829	0.9481557
318	5	3.5743029	1.2737702	0.161143	0.454027
319	6	4.7569133	1.559599	0.1718829	0.4241535
320	9	3.632898	1.2900307	0.161143	0.7819356
321	0	4.4520346	1.4933612	0.1704302	0.0259172
322	0	4.8868836	1.5865548	0.1718829	0.0239349
323	0	3.7500882	1.3217794	0.161143	0.029908
324	7	4.4520346	1.4933612	0.1704302	0.5192552
325	0	3.5938346	1.2792198	0.161143	0.0309675
326	0	3.632898	1.2900307	0.161143	0.0306957
327	1	4.4520346	1.4933612	0.1704302	0.0963941
328	0	4.3806116	1.4771884	0.1704302	0.0262744
329	0	4.4044193	1.4826084	0.1704302	0.0261542
330	0	4.8089014	1.5704687	0.1718829	0.0242679
331	0	4.3806116	1.4771884	0.1704302	0.0262744
332	0	3.632898	1.2900307	0.161143	0.0306957
333	0	4.8608895	1.5812215	0.1718829	0.0240449
334	1	3.7305565	1.3165574	0.161143	0.1117151
335	1	3.5938346	1.2792198	0.161143	0.1151775
336	1	0.5475765	-0.602253	0.1704302	0.3287358
337	5	4.3806116	1.4771884	0.1704302	0.3835147
338	1	3.6133663	1.2846398	0.161143	0.11467
339	0	4.5472653	1.514526	0.1704302	0.0254557
340	0	4.8608895	1.5812215	0.1718829	0.0240449
341	0	3.6719614	1.300726	0.161143	0.0304286

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
342	13	4.3806116	1.4771884	0.1704302	0.9550992
343	7	3.5938346	1.2792198	0.161143	0.6204377
344	12	4.4520346	1.4933612	0.1704302	0.8716395
345	21	3.5938346	1.2792198	0.161143	1.7993782
346	1	4.7829074	1.5650486	0.1718829	0.0906804
347	6	4.4520346	1.4933612	0.1704302	0.4487784
348	27	3.632898	1.2900307	0.161143	2.2844155
349	3	7.5001872	2.014928	0.1265874	0.1500485
350	0	5.6355747	1.7290991	0.1336812	0.0211465
351	0	5.5739838	1.71811	0.1336812	0.0213513
352	3	5.6663702	1.7345487	0.1336812	0.1927341
353	0	5.6663702	1.7345487	0.1336812	0.0210456
354	0	5.6355747	1.7290991	0.1336812	0.0211465
355	0	6.9068753	1.9325173	0.133482	0.01765
356	0	6.9068753	1.9325173	0.133482	0.01765
357	25	4.9098013	1.5912335	0.1411644	1.6444622
358	38	6.534281	1.8770623	0.132362	1.9353209
359	0	6.049726	1.800013	0.1349303	0.0198651
360	1	4.9098013	1.5912335	0.1411644	0.0886637
361	13	6.7828677	1.9144	0.132362	0.6521192
362	0	4.9098013	1.5912335	0.1411644	0.0238388
363	4	5.9196244	1.778273	0.1349303	0.2405222
364	0	4.9898524	1.6074063	0.1411644	0.0235089
365	0	4.9098013	1.5912335	0.1411644	0.0238388
366	0	4.8564339	1.5803044	0.1411644	0.0240639

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
367	4	4.8297502	1.5747947	0.1411644	0.2871677
368	5	5.9846752	1.7892021	0.1349303	0.2927493
369	8	4.8297502	1.5747947	0.1411644	0.5501575
370	2	6.1798277	1.8212904	0.1349303	0.125514
371	1	4.8297502	1.5747947	0.1411644	0.0899254
372	1	6.5697933	1.8824824	0.132362	0.0686573
373	9	6.8894049	1.9299847	0.132362	0.4506366
374	11	6.5697933	1.8824824	0.132362	0.5706334
375	0	4.9098013	1.5912335	0.1411644	0.0238388
376	20	6.534281	1.8770623	0.132362	1.0273765
377	3	6.534281	1.8770623	0.132362	0.1698734
378	0	6.534281	1.8770623	0.132362	0.0185493
379	5	5.9846752	1.7892021	0.1349303	0.2927493
380	0	6.6053057	1.8878732	0.132362	0.0183709
381	0	6.534281	1.8770623	0.132362	0.0185493
382	2	6.534281	1.8770623	0.132362	0.119432
383	0	5.9846752	1.7892021	0.1349303	0.0200561
384	0	5.6663702	1.7345487	0.1336812	0.0210456
385	0	5.9846752	1.7892021	0.1349303	0.0200561
386	0	6.4987686	1.8716127	0.132362	0.0186398
387	0	4.9098013	1.5912335	0.1411644	0.0238388
388	4	6.534281	1.8770623	0.132362	0.2203148
389	1	6.534281	1.8770623	0.132362	0.0689907
390	1	6.6053057	1.8878732	0.132362	0.0683271
391	0	5.9846752	1.7892021	0.1349303	0.0200561

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Parameter Code=HY4HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 4 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
392	0	7.5411718	2.0203776	0.1265874	0.0163038
393	9	7.7870796	2.0524659	0.1265874	0.4033873
394	0	5.6355747	1.7290991	0.1336812	0.0211465
395	2	5.9743251	1.7874711	0.1336812	0.1293311
396	1	7.5821564	2.0257976	0.1265874	0.0603414
397	0	4.8564339	1.5803044	0.1411644	0.0240639
398	6	5.6971657	1.7399688	0.1336812	0.3626917
399	1	5.6663702	1.7345487	0.1336812	0.0782751
400	0	5.8511432	1.7666371	0.1336812	0.0204597
401	0	5.7279612	1.7453597	0.1336812	0.0208466
402	0	7.5411718	2.0203776	0.1265874	0.0163038
403	0	6.9444127	1.9379374	0.133482	0.0175642
404	8	7.6641257	2.0365504	0.1265874	0.3655775
405	0	5.6971657	1.7399688	0.1336812	0.0209456
406	3	7.6231411	2.0311885	0.1265874	0.1478512
407	2	5.6971657	1.7399688	0.1336812	0.134861
408	0	5.6663702	1.7345487	0.1336812	0.0210456
409	0	6.4632562	1.8661332	0.132362	0.0187312
410	0	4.8297502	1.5747947	0.1411644	0.024178
411	0	6.4987686	1.8716127	0.132362	0.0186398
412	18	4.936485	1.5966535	0.1411644	1.1851441
413	0	6.7118429	1.9038736	0.132362	0.0181096
414	0	6.049726	1.800013	0.1349303	0.0198651
415	0	6.4632562	1.8661332	0.132362	0.0187312
416	4	5.9521498	1.7837525	0.1349303	0.2393609

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Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=HY4HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 4 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
417	0	5.9846752	1.7892021	0.1349303	0.0200561
418	1	6.534281	1.8770623	0.132362	0.0689907
419	0	6.4632562	1.8661332	0.132362	0.0187312
420	63	6.9068753	1.9325173	0.133482	3.0413842
421	1	7.5411718	2.0203776	0.1265874	0.0606388
422	16	6.9444127	1.9379374	0.133482	0.7817633
423	22	6.9444127	1.9379374	0.133482	1.0683379
424	3	5.6971657	1.7399688	0.1336812	0.1918187
425	1	5.6047793	1.7236197	0.1336812	0.0790294
426	7	7.6231411	2.0311885	0.1265874	0.3234599
427	0	5.6971657	1.7399688	0.1336812	0.0209456
428	10	5.6971657	1.7399688	0.1336812	0.5905224
429	0	7.746095	2.0471888	0.1265874	0.0159116
430	0	7.3573237	1.9956962	0.133482	0.0166724
431	0	7.746095	2.0471888	0.1265874	0.0159116
432	0	6.9068753	1.9325173	0.133482	0.01765
433	0	5.6663702	1.7345487	0.1336812	0.0210456
434	2	6.9819501	1.9433283	0.133482	0.1125419
435	0	6.9068753	1.9325173	0.133482	0.01765
436	0	6.869338	1.9270677	0.133482	0.0177366
437	5	4.9098013	1.5912335	0.1411644	0.3479635
438	0	7.0570248	1.9540235	0.133482	0.0173117
439	3	4.936485	1.5966535	0.1411644	0.2172972
440	1	6.0172006	1.7946221	0.1349303	0.074238
441	0	5.7587567	1.7507216	0.1336812	0.0207485

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Parameter Code=HY4HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 4 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
442	0	4.9098013	1.5912335	0.1411644	0.0238388
443	1	6.9068753	1.9325173	0.133482	0.0656458
444	1	7.0194874	1.9486902	0.133482	0.0646975
445	3	4.9098013	1.5912335	0.1411644	0.2183136
446	9	4.936485	1.5966535	0.1411644	0.6044359
447	0	7.5411718	2.0203776	0.1265874	0.0163038
448	1	6.4277438	1.8606236	0.132362	0.0700105
449	1	5.9846752	1.7892021	0.1349303	0.0745947
450	0	5.6663702	1.7345487	0.1336812	0.0210456
451	1	6.9068753	1.9325173	0.133482	0.0656458
452	0	7.3197864	1.9905811	0.133482	0.0167497
453	8	6.5697933	1.8824824	0.132362	0.4200406
454	5	5.1232709	1.6337931	0.1411644	0.3354098
455	15	7.3155537	1.9900027	0.132362	0.7003318
456	5	7.282249	1.9854397	0.133482	0.2456275
457	5	4.8564339	1.5803044	0.1411644	0.3512491
458	0	6.6408181	1.8932352	0.132362	0.018283
459	0	6.7828677	1.9144	0.132362	0.0179395
460	5	6.869338	1.9270677	0.133482	0.2588937
461	0	7.9203842	2.0694397	0.133482	0.0155925
462	6	4.9898524	1.6074063	0.1411644	0.4070757
463	19	5.9846752	1.7892021	0.1349303	1.0562903
464	0	5.6663702	1.7345487	0.1336812	0.0210456
465	0	5.9521498	1.7837525	0.1349303	0.0201529
466	0	8.3608644	2.1235618	0.1265874	0.0148404

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Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=HY4HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 4 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
467	0	7.1320995	1.9646057	0.133482	0.0171473
468	7	7.6231411	2.0311885	0.1265874	0.3234599
469	0	7.5411718	2.0203776	0.1265874	0.0163038
470	0	6.534281	1.8770623	0.132362	0.0185493
471	1	6.1590981	1.8179304	0.1336812	0.0727205
472	0	7.7870796	2.0524659	0.1265874	0.0158354
473	2	5.0965872	1.6285711	0.1411644	0.1486215
474	1	7.7051103	2.0418838	0.1265874	0.0594662
475	3	7.5001872	2.014928	0.1265874	0.1500485
476	22	5.7279612	1.7453597	0.1336812	1.2679915
477	2	7.0570248	1.9540235	0.133482	0.1114633
478	0	7.6231411	2.0311885	0.1265874	0.0161446
479	0	5.6047793	1.7236197	0.1336812	0.0212484
480	2	7.6641257	2.0365504	0.1265874	0.103444
481	14	7.0194874	1.9486902	0.133482	0.6796299
482	17	7.5821564	2.0257976	0.1265874	0.766222
483	11	7.4592025	2.0094485	0.1265874	0.509007
484	0	7.5001872	2.014928	0.1265874	0.0163846
485	0	6.8318006	1.9215883	0.133482	0.0178241
486	0	5.5739838	1.71811	0.1336812	0.0213513
487	0	7.5001872	2.014928	0.1265874	0.0163846
488	2	5.6663702	1.7345487	0.1336812	0.1355046
489	30	5.6971657	1.7399688	0.1336812	1.7296758
490	0	7.6641257	2.0365504	0.1265874	0.0160662
491	0	7.5821564	2.0257976	0.1265874	0.0162238

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Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=HY4HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 4 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
492	0	6.869338	1.9270677	0.133482	0.0177366
493	1	6.9819501	1.9433283	0.133482	0.0650106
494	13	5.4815973	1.7013965	0.1336812	0.7875775
495	10	5.6663702	1.7345487	0.1336812	0.5933406
496	20	7.0194874	1.9486902	0.133482	0.9634448
497	1	7.5411718	2.0203776	0.1265874	0.0606388
498	0	7.5411718	2.0203776	0.1265874	0.0163038
499	1	7.0194874	1.9486902	0.133482	0.0646975
500	0	6.9068753	1.9325173	0.133482	0.01765
501	34	6.8318006	1.9215883	0.133482	1.6657818
502	7	7.6231411	2.0311885	0.1265874	0.3234599
503	0	5.6663702	1.7345487	0.1336812	0.0210456
504	0	7.4592025	2.0094485	0.1265874	0.0164661
505	0	7.0194874	1.9486902	0.133482	0.017395
506	0	7.0194874	1.9486902	0.133482	0.017395
507	0	7.4592025	2.0094485	0.1265874	0.0164661
508	0	1.2295389	0.2066392	0.1265874	0.0651724
509	9	7.4182179	2.0039389	0.1265874	0.4215527
510	3	7.5411718	2.0203776	0.1265874	0.1493088
511	6	6.9068753	1.9325173	0.133482	0.3056247
512	8	7.5411718	2.0203776	0.1265874	0.3709839
513	32	6.9068753	1.9325173	0.133482	1.553515
514	19	7.5821564	2.0257976	0.1265874	0.8544571
515	17	5.6663702	1.7345487	0.1336812	0.9939471
516	0	5.6663702	1.7345487	0.1336812	0.0210456

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Parameter Code=HY4HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 4 hours after meal

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
517	25	7.5411718	2.0203776	0.1265874	1.1246792
518	3	7.5821564	2.0257976	0.1265874	0.1485764
519	11	6.9819501	1.9433283	0.133482	0.5403241
520	0	7.6641257	2.0365504	0.1265874	0.0160662
521	2	5.6663702	1.7345487	0.1336812	0.1355046
522	4	6.9068753	1.9325173	0.133482	0.2096331
523	0	6.9068753	1.9325173	0.133482	0.01765
524	6	7.5411718	2.0203776	0.1265874	0.2823139
525	11	5.6971657	1.7399688	0.1336812	0.6474801
526	0	5.6971657	1.7399688	0.1336812	0.0209456
527	0	7.6231411	2.0311885	0.1265874	0.0161446
528	0	5.6971657	1.7399688	0.1336812	0.0209456
529	0	5.6663702	1.7345487	0.1336812	0.0210456
530	7	5.7895522	1.7560549	0.1336812	0.4137531
531	0	6.9444127	1.9379374	0.133482	0.0175642
532	3	5.8203477	1.76136	0.1336812	0.1882418
533	23	7.5411718	2.0203776	0.1265874	1.0360092
534	41	7.4592025	2.0094485	0.1265874	1.8523004
535	5	5.6663702	1.7345487	0.1336812	0.3071931
536	12	6.9068753	1.9325173	0.133482	0.5935994
537	1	6.9444127	1.9379374	0.133482	0.0653266
538	0	6.9444127	1.9379374	0.133482	0.0175642
539	0	5.6971657	1.7399688	0.1336812	0.0209456
540	0	7.0194874	1.9486902	0.133482	0.017395
541	0	5.6355747	1.7290991	0.1336812	0.0211465

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The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
542	0	6.9819501	1.9433283	0.133482	0.0174792
543	0	6.7567259	1.9105384	0.133482	0.0180018
544	3	5.7895522	1.7560549	0.1336812	0.1891235
545	0	5.8203477	1.76136	0.1336812	0.0205551
546	7	5.6663702	1.7345487	0.1336812	0.4216521
547	1	5.7279612	1.7453597	0.1336812	0.077535
548	91	7.5821564	2.0257976	0.1265874	4.0309202
549	8	5.6355747	1.7290991	0.1336812	0.4811779
550	40	6.9068753	1.9325173	0.133482	1.9374812
551	34	6.9068753	1.9325173	0.133482	1.6495065
552	20	5.6663702	1.7345487	0.1336812	1.1656356
553	3	5.6971657	1.7399688	0.1336812	0.1918187
554	6	6.9819501	1.9433283	0.133482	0.3026673
555	1	5.6663702	1.7345487	0.1336812	0.0782751
556	0	5.8203477	1.76136	0.1336812	0.0205551
557	8	6.9444127	1.9379374	0.133482	0.3996637
558	0	5.6971657	1.7399688	0.1336812	0.0209456
559	0	5.6663702	1.7345487	0.1336812	0.0210456
560	0	7.0194874	1.9486902	0.133482	0.017395
561	8	7.5411718	2.0203776	0.1265874	0.3709839
562	1	6.9444127	1.9379374	0.133482	0.0653266
563	51	5.9846752	1.7892021	0.1349303	2.8015269
564	13	7.6231411	2.0311885	0.1265874	0.586873
565	1	7.0194874	1.9486902	0.133482	0.0646975
566	0	5.6663702	1.7345487	0.1336812	0.0210456

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Parameter Code=HY4HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 4 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
567	19	6.049726	1.800013	0.1349303	1.0462344
568	2	7.5411718	2.0203776	0.1265874	0.1049738
569	5	6.7942632	1.9160786	0.133482	0.2614607
570	2	7.5821564	2.0257976	0.1265874	0.1044589
571	2	5.6971657	1.7399688	0.1336812	0.134861
572	15	7.7870796	2.0524659	0.1265874	0.6617553
573	12	5.7895522	1.7560549	0.1336812	0.6945401
574	30	7.6641257	2.0365504	0.1265874	1.3267336
575	36	7.5411718	2.0203776	0.1265874	1.6123644
576	11	5.7895522	1.7560549	0.1336812	0.6383827
577	2	6.9444127	1.9379374	0.133482	0.1130891
578	34	6.869338	1.9270677	0.133482	1.6576043
579	58	7.5411718	2.0203776	0.1265874	2.5877348
580	34	7.5411718	2.0203776	0.1265874	1.5236944
581	16	6.9444127	1.9379374	0.133482	0.7817633
582	4	6.9068753	1.9325173	0.133482	0.2096331
583	32	5.6663702	1.7345487	0.1336812	1.8523897
584	0	6.4632562	1.8661332	0.132362	0.0187312
585	9	6.0172006	1.7946221	0.1349303	0.5084604
586	1	6.1798277	1.8212904	0.1349303	0.0725039
587	3	5.9846752	1.7892021	0.1349303	0.183672
588	2	4.9098013	1.5912335	0.1411644	0.1534886
589	1	4.9631687	1.6020444	0.1411644	0.0878419
590	2	6.534281	1.8770623	0.132362	0.119432
591	19	5.9846752	1.7892021	0.1349303	1.0562903

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The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
592	30	5.9846752	1.7892021	0.1349303	1.6562154
593	10	6.534281	1.8770623	0.132362	0.5229629
594	20	4.936485	1.5966535	0.1411644	1.3141904
595	5	6.534281	1.8770623	0.132362	0.2707561
596	7	5.2833731	1.6645647	0.1411644	0.4482488
597	6	4.9098013	1.5912335	0.1411644	0.4127884
598	10	4.9098013	1.5912335	0.1411644	0.6720882
599	2	4.8297502	1.5747947	0.1411644	0.1556729
600	2	5.9521498	1.7837525	0.1349303	0.1297569
601	8	6.6053057	1.8878732	0.132362	0.4180205
602	0	4.8564339	1.5803044	0.1411644	0.0240639
603	2	7.5821564	2.0257976	0.1265874	0.1044589
604	5	4.8297502	1.5747947	0.1411644	0.3529152
605	6	5.9846752	1.7892021	0.1349303	0.3472879
606	7	5.9846752	1.7892021	0.1349303	0.4018266
607	3	6.4987686	1.8716127	0.132362	0.1707023
608	0	7.6641257	2.0365504	0.1265874	0.0160662
609	0	4.9098013	1.5912335	0.1411644	0.0238388
610	0	6.6053057	1.8878732	0.132362	0.0183709
611	8	6.1473022	1.8160133	0.1349303	0.445656
612	67	6.534281	1.8770623	0.132362	3.3981203
613	3	6.0172006	1.7946221	0.1349303	0.1827936
614	0	4.936485	1.5966535	0.1411644	0.0237278
615	4	4.8831176	1.5857839	0.1411644	0.2844691
616	0	4.9098013	1.5912335	0.1411644	0.0238388

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Parameter Code=HY4HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 4 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
617	3	6.4277438	1.8606236	0.132362	0.1723844
618	1	6.0172006	1.7946221	0.1349303	0.074238
619	6	6.534281	1.8770623	0.132362	0.3211975
620	2	5.0165361	1.6127397	0.1411644	0.1506693
621	75	6.7473553	1.9091506	0.132362	3.6940191
622	5	4.8831176	1.5857839	0.1411644	0.3495986
623	4	6.534281	1.8770623	0.132362	0.2203148
624	4	5.9846752	1.7892021	0.1349303	0.2382106
625	0	5.9196244	1.778273	0.1349303	0.0202507
626	5	4.9098013	1.5912335	0.1411644	0.3479635
627	0	3.941876	1.3716568	0.132362	0.0287018
628	0	6.2123531	1.8265397	0.1349303	0.0194033
629	11	4.9898524	1.6074063	0.1411644	0.7267148
630	0	6.0172006	1.7946221	0.1349303	0.0199602
631	5	6.4632562	1.8661332	0.132362	0.2734112
632	0	4.936485	1.5966535	0.1411644	0.0237278
633	5	5.9521498	1.7837525	0.1349303	0.2941629
634	0	6.6408181	1.8932352	0.132362	0.018283
635	0	5.9846752	1.7892021	0.1349303	0.0200561
636	13	4.9898524	1.6074063	0.1411644	0.8545704
637	0	4.8831176	1.5857839	0.1411644	0.0239508
638	5	6.5701326	1.882534	0.1349303	0.2694353
639	4	6.4987686	1.8716127	0.132362	0.2213897
640	33	4.8564339	1.5803044	0.1411644	2.1834865
641	2	6.534281	1.8770623	0.132362	0.119432

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Parameter Code=HY4HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 4 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
642	0	6.9444127	1.9379374	0.133482	0.0175642
643	1	4.936485	1.5966535	0.1411644	0.0882509
644	1	6.869338	1.9270677	0.133482	0.065968
645	2	4.9098013	1.5912335	0.1411644	0.1534886
646	4	7.5411718	2.0203776	0.1265874	0.1936439
647	1	4.9098013	1.5912335	0.1411644	0.0886637
648	2	7.5411718	2.0203776	0.1265874	0.1049738
649	22	7.1320995	1.9646057	0.133482	1.0429826
650	30	7.6231411	2.0311885	0.1265874	1.3332102
651	1	5.9846752	1.7892021	0.1349303	0.0745947
652	1	6.534281	1.8770623	0.132362	0.0689907
653	27	6.534281	1.8770623	0.132362	1.380466
654	13	7.6641257	2.0365504	0.1265874	0.5840221
655	15	6.8318006	1.9215883	0.133482	0.7448643
656	0	7.6231411	2.0311885	0.1265874	0.0161446
657	2	6.9819501	1.9433283	0.133482	0.1125419
658	0	6.869338	1.9270677	0.133482	0.0177366
659	9	8.401849	2.1284518	0.1265874	0.3763507
660	2	5.6663702	1.7345487	0.1336812	0.1355046
661	7	4.9631687	1.6020444	0.1411644	0.4731865
662	1	6.0247405	1.7958744	0.1265874	0.0741557
663	0	9.5344909	2.2549158	0.133482	0.0131497
664	0	7.0570248	1.9540235	0.133482	0.0173117
665	4	7.3197864	1.9905811	0.133482	0.1989406
666	10	5.8203477	1.76136	0.1336812	0.5795109

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Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=HY4HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 4 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
667	0	5.7279612	1.7453597	0.1336812	0.0208466
668	0	4.1291103	1.4180619	0.133482	0.0276136
669	2	6.2687401	1.8355754	0.133482	0.1239311
670	0	5.0432198	1.6180447	0.1411644	0.0232939
671	0	6.4632562	1.8661332	0.132362	0.0187312
672	6	5.0165361	1.6127397	0.1411644	0.4052063
673	5	4.9098013	1.5912335	0.1411644	0.3479635
674	1	6.534281	1.8770623	0.132362	0.0689907
675	24	6.534281	1.8770623	0.132362	1.2291419
676	6	5.9846752	1.7892021	0.1349303	0.3472879
677	12	5.9196244	1.778273	0.1349303	0.6810653
678	4	5.2833731	1.6645647	0.1411644	0.2657306
679	4	6.4987686	1.8716127	0.132362	0.2213897
680	20	5.9846752	1.7892021	0.1349303	1.1108289
681	15	6.5697933	1.8824824	0.132362	0.7714239
682	12	6.534281	1.8770623	0.132362	0.6238456
683	1	6.1798277	1.8212904	0.1349303	0.0725039
684	13	5.8545736	1.7672232	0.1349303	0.743346
685	1	4.9098013	1.5912335	0.1411644	0.0886637
686	0	6.6408181	1.8932352	0.132362	0.018283
687	0	5.1232709	1.6337931	0.1411644	0.0229787
688	0	5.887099	1.7727633	0.1349303	0.0203494
689	2	5.9846752	1.7892021	0.1349303	0.1291334
690	4	5.9846752	1.7892021	0.1349303	0.2382106
691	0	5.9196244	1.778273	0.1349303	0.0202507

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Parameter Code=HY4HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 4 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
692	6	6.5697933	1.8824824	0.132362	0.3196454
693	1	4.9098013	1.5912335	0.1411644	0.0886637
694	4	4.3806116	1.4771884	0.1704302	0.3120666
695	11	4.4758423	1.4986946	0.1704302	0.7975484
696	0	3.5938346	1.2792198	0.161143	0.0309675
697	7	4.2853809	1.4552094	0.1704302	0.5362614
698	1	3.5547711	1.2682907	0.161143	0.116206
699	1	4.3091886	1.4607496	0.1704302	0.0990876
700	19	3.7305565	1.3165574	0.161143	1.5819301
701	35	4.7829074	1.5650486	0.1718829	2.3448612
702	1	4.3806116	1.4771884	0.1704302	0.0977224
703	17	4.2139579	1.4384023	0.1704302	1.2821005
704	26	4.7829074	1.5650486	0.1718829	1.7481663
705	2	4.3568039	1.4717387	0.1704302	0.169951
706	0	4.3329963	1.4662593	0.1704302	0.0265179
707	0	4.7309192	1.5541195	0.1718829	0.0246103
708	18	3.632898	1.2900307	0.161143	1.5331755
709	2	4.3806116	1.4771884	0.1704302	0.1691705
710	0	4.7829074	1.5650486	0.1718829	0.024381
711	0	3.5352394	1.262781	0.161143	0.0313841
712	0	3.5352394	1.262781	0.161143	0.0313841
713	0	4.3806116	1.4771884	0.1704302	0.0262744
714	3	4.3091886	1.4607496	0.1704302	0.2439799
715	0	4.1187272	1.4155442	0.1704302	0.0276718
716	6	3.5938346	1.2792198	0.161143	0.5362277

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The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
717	13	4.7569133	1.559599	0.1718829	0.8904217
718	3	4.3568039	1.4717387	0.1704302	0.2417288
719	0	4.7829074	1.5650486	0.1718829	0.024381
720	0	4.3806116	1.4771884	0.1704302	0.0262744
721	0	4.3806116	1.4771884	0.1704302	0.0262744
722	23	4.7569133	1.559599	0.1718829	1.5565191
723	2	4.7569133	1.559599	0.1718829	0.1577146
724	14	4.7829074	1.5650486	0.1718829	0.9525731
725	10	4.0620779	1.4016947	0.1318324	0.7892273
726	22	6.1737865	1.8203123	0.1498395	1.1867439
727	15	4.8352857	1.5759402	0.1491715	1.0093963
728	46	6.0757899	1.804312	0.1498395	2.4952409
729	0	5.1052763	1.6302746	0.1491715	0.0230488
730	10	5.9124622	1.7770624	0.1498395	0.5715401
731	3	6.5004419	1.8718702	0.1498395	0.170663
732	4	4.0620779	1.4016947	0.1318324	0.3324871
733	10	4.7439778	1.556876	0.128092	0.6922047
734	4	4.7439778	1.556876	0.128092	0.2916132
735	4	3.913206	1.364357	0.1318324	0.3429664
736	1	5.0664272	1.6226359	0.1304537	0.0862941
737	4	3.062509	1.1192345	0.1318324	0.4180463
738	2	4.4916614	1.5022226	0.1491715	0.1656216
739	4	4.7439778	1.556876	0.128092	0.2916132
740	0	4.8476713	1.5784984	0.128092	0.0241012
741	0	4.0195431	1.3911682	0.1318324	0.0282402

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The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
742	0	4.5407506	1.5130923	0.1491715	0.0254868
743	8	4.5407506	1.5130923	0.1491715	0.5799378
744	4	4.7699011	1.5623256	0.128092	0.2902553
745	0	4.7439778	1.556876	0.128092	0.0245523
746	0	5.2928597	1.6663587	0.1304537	0.0223382
747	5	4.516206	1.5076723	0.1491715	0.3737361
748	4	4.8217479	1.5731365	0.128092	0.2875768
749	4	6.0104588	1.7935011	0.1498395	0.2373066
750	5	5.3777719	1.6822741	0.1304537	0.3215718
751	10	5.5049124	1.7056408	0.1514856	0.6085657
752	0	4.516206	1.5076723	0.1491715	0.0256044
753	10	5.2362515	1.6556059	0.1304537	0.6356985
754	10	4.4916614	1.5022226	0.1491715	0.7252155
755	0	5.4060759	1.6875235	0.1304537	0.02193
756	4	5.2079475	1.6501858	0.1304537	0.2690717
757	7	5.1796434	1.6447362	0.1304537	0.4560362
758	8	4.7699011	1.5623256	0.128092	0.5560727
759	0	3.913206	1.364357	0.1318324	0.0288759
760	0	4.7699011	1.5623256	0.128092	0.024438
761	1	5.2362515	1.6556059	0.1304537	0.0838631
762	0	4.7439778	1.556876	0.128092	0.0245523
763	2	5.2079475	1.6501858	0.1304537	0.1458631
764	8	5.2928597	1.6663587	0.1304537	0.5082942
765	0	4.7439778	1.556876	0.128092	0.0245523
766	2	5.5647484	1.7164518	0.1514856	0.1376725

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Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
767	7	4.7699011	1.5623256	0.128092	0.4896183
768	3	3.8919386	1.3589074	0.1318324	0.2656394
769	1	5.2362515	1.6556059	0.1304537	0.0838631
770	1	4.9513648	1.5996632	0.128092	0.0880224
771	4	5.2362515	1.6556059	0.1304537	0.2678082
772	9	4.7958245	1.5677456	0.128092	0.6196414
773	0	5.1230353	1.6337471	0.1304537	0.0229796
774	15	5.2645556	1.6609967	0.1304537	0.9378694
775	10	4.7699011	1.5623256	0.128092	0.6889813
776	0	5.2079475	1.6501858	0.1304537	0.0226544
777	3	3.913206	1.364357	0.1318324	0.2644437
778	28	5.2362515	1.6556059	0.1304537	1.7393693
779	1	1.2335106	0.2098642	0.1318324	0.2419743
780	4	3.913206	1.364357	0.1318324	0.3429664
781	1	4.516206	1.5076723	0.1491715	0.0952308
782	1	5.2645556	1.6609967	0.1304537	0.0834711
783	19	4.7699011	1.5623256	0.128092	1.2870704
784	1	4.0620779	1.4016947	0.1318324	0.104117
785	3	5.1513394	1.6392567	0.1304537	0.2094436
786	2	4.516206	1.5076723	0.1491715	0.1648571
787	0	4.516206	1.5076723	0.1491715	0.0256044
788	0	5.3211637	1.671692	0.1304537	0.0222348
789	2	4.516206	1.5076723	0.1491715	0.1648571
790	0	4.9513648	1.5996632	0.128092	0.0236663
791	2	6.0004612	1.7918363	0.1304537	0.1288329

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Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
792	2	4.0408105	1.3964453	0.1318324	0.1810308
793	0	4.7699011	1.5623256	0.128092	0.024438
794	15	4.7958245	1.5677456	0.128092	1.0165192
795	0	4.8217479	1.5731365	0.128092	0.0242124
796	0	3.913206	1.364357	0.1318324	0.0288759
797	1	5.2079475	1.6501858	0.1304537	0.0842587
798	0	3.913206	1.364357	0.1318324	0.0288759
799	10	5.6844204	1.7377292	0.1514856	0.5916855
800	1	4.7616519	1.5605947	0.1491715	0.0910272
801	0	4.8107411	1.5708512	0.1491715	0.02426
802	11	4.4916614	1.5022226	0.1491715	0.7951647
803	0	6.0104588	1.7935011	0.1498395	0.01998
804	0	5.5049124	1.7056408	0.1514856	0.0215856
805	0	5.6545024	1.7324521	0.1514856	0.0210844
806	0	6.2717831	1.8360607	0.1498395	0.0192398
807	10	5.5647484	1.7164518	0.1514856	0.6028335
808	0	5.8040924	1.7585633	0.1514856	0.0206058
809	4	6.0757899	1.804312	0.1498395	0.2350463
810	2	6.141121	1.8150073	0.1498395	0.1262157
811	0	5.7143384	1.7429785	0.1514856	0.0208903
812	3	4.0833454	1.4069166	0.1318324	0.2552492
813	0	3.9982757	1.3858632	0.1318324	0.0283652
814	0	5.6325084	1.7285549	0.1304537	0.0211566
815	14	3.764334	1.325571	0.1318324	1.1648819
816	8	3.9344734	1.369777	0.1318324	0.6541124

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Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=HY4HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 4 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
817	0	6.0104588	1.7935011	0.1498395	0.01998
818	0	3.8494037	1.3479183	0.1318324	0.0292711
819	2	4.7439778	1.556876	0.128092	0.1580828
820	1	4.9772881	1.6048852	0.128092	0.087627
821	0	4.9513648	1.5996632	0.128092	0.0236663
822	0	5.5475962	1.7133647	0.1304537	0.0214402
823	0	5.1513394	1.6392567	0.1304537	0.0228702
824	0	3.9344734	1.369777	0.1318324	0.0287466
825	2	3.9344734	1.369777	0.1318324	0.185088
826	2	4.692131	1.5458869	0.128092	0.1595757
827	0	4.516206	1.5076723	0.1491715	0.0256044
828	3	4.2960196	1.4576889	0.1318324	0.2446099
829	9	5.1796434	1.6447362	0.1304537	0.5798289
830	4	5.4060759	1.6875235	0.1304537	0.2604681
831	5	5.0032115	1.61008	0.128092	0.3423572
832	10	4.7699011	1.5623256	0.128092	0.6889813
833	4	5.2079475	1.6501858	0.1304537	0.2690717
834	0	5.2079475	1.6501858	0.1304537	0.0226544
835	4	4.0408105	1.3964453	0.1318324	0.3339452
836	0	5.7143384	1.7429785	0.1514856	0.0208903
837	3	5.7143384	1.7429785	0.1514856	0.1913119
838	2	4.516206	1.5076723	0.1491715	0.1648571
839	0	4.4671168	1.4967432	0.1491715	0.025843
840	0	5.5049124	1.7056408	0.1514856	0.0215856
841	0	6.141121	1.8150073	0.1498395	0.0196029

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Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=HY4HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 4 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
842	0	5.7442564	1.7482005	0.1514856	0.0207946
843	0	5.4749944	1.7001912	0.1514856	0.0216887
844	0	4.516206	1.5076723	0.1491715	0.0256044
845	6	5.8938464	1.7739088	0.1514856	0.3520116
846	1	4.5407506	1.5130923	0.1491715	0.0947931
847	0	5.5049124	1.7056408	0.1514856	0.0215856
848	0	6.0104588	1.7935011	0.1498395	0.01998
849	1	6.0757899	1.804312	0.1498395	0.0736038
850	37	4.516206	1.5076723	0.1491715	2.6017787
851	2	4.5652952	1.5184832	0.1491715	0.1633488
852	11	6.0104588	1.7935011	0.1498395	0.6176283
853	18	6.0104588	1.7935011	0.1498395	0.9979499
854	0	4.7699011	1.5623256	0.128092	0.024438
855	2	4.7699011	1.5623256	0.128092	0.1573466
856	0	5.2079475	1.6501858	0.1304537	0.0226544
857	9	5.2079475	1.6501858	0.1304537	0.5770934
858	0	4.2747522	1.4527261	0.1318324	0.026822
859	1	4.2109499	1.4376883	0.1318324	0.1010282
860	7	6.0104588	1.7935011	0.1498395	0.4003016
861	2	4.5652952	1.5184832	0.1491715	0.1633488
862	0	5.4749944	1.7001912	0.1514856	0.0216887
863	12	5.1230353	1.6337471	0.1304537	0.772844
864	4	6.0104588	1.7935011	0.1498395	0.2373066
865	1	5.2928597	1.6663587	0.1304537	0.0830827
866	0	5.2928597	1.6663587	0.1304537	0.0223382

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Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=HY4HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 4 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
867	1	4.7439778	1.556876	0.128092	0.0913175
868	0	4.1258802	1.4172794	0.1318324	0.0276317
869	13	5.2928597	1.6663587	0.1304537	0.8120168
870	6	4.7180544	1.5513965	0.128092	0.4271419
871	7	4.516206	1.5076723	0.1491715	0.5129888
872	5	3.9557408	1.3751679	0.1318324	0.4177281
873	17	4.8217479	1.5731365	0.128092	1.1435109
874	0	4.7958245	1.5677456	0.128092	0.0243247
875	7	3.9770083	1.3805298	0.1318324	0.5708251
876	16	3.9557408	1.3751679	0.1318324	1.2737698
877	8	4.8217479	1.5731365	0.128092	0.5509411
878	21	5.1230353	1.6337471	0.1304537	1.3352423
879	0	3.8919386	1.3589074	0.1318324	0.0290065
880	20	5.2079475	1.6501858	0.1304537	1.254741
881	0	3.8919386	1.3589074	0.1318324	0.0290065
882	3	1.2122432	0.1924725	0.1318324	0.6014018
883	8	3.8706711	1.3534279	0.1318324	0.6630248
884	3	4.7699011	1.5623256	0.128092	0.223801
885	0	4.7439778	1.556876	0.128092	0.0245523
886	6	5.2928597	1.6663587	0.1304537	0.3868052
887	1	4.7699011	1.5623256	0.128092	0.0908923
888	10	3.913206	1.364357	0.1318324	0.814102
889	13	4.7699011	1.5623256	0.128092	0.8883443
890	0	5.3777719	1.6822741	0.1304537	0.0220307
891	4	5.1796434	1.6447362	0.1304537	0.2703472

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Parameter Code=HY4HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 4 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
892	14	4.7180544	1.5513965	0.128092	0.9637742
893	1	5.2362515	1.6556059	0.1304537	0.0838631
894	1	5.1796434	1.6447362	0.1304537	0.0846581
895	21	4.9772881	1.6048852	0.128092	1.3689667
896	3	4.7699011	1.5623256	0.128092	0.223801
897	4	5.9777933	1.7880515	0.1498395	0.2384531
898	4	3.9557408	1.3751679	0.1318324	0.3399062
899	0	5.0381231	1.6170336	0.1304537	0.0233143
900	21	5.2079475	1.6501858	0.1304537	1.3163453
901	3	3.8919386	1.3589074	0.1318324	0.2656394
902	0	3.8919386	1.3589074	0.1318324	0.0290065
903	9	3.9557408	1.3751679	0.1318324	0.729016
904	40	5.1796434	1.6447362	0.1304537	2.4986155
905	0	5.5049124	1.7056408	0.1514856	0.0215856
906	5	5.7741744	1.7533953	0.1514856	0.302145
907	0	5.2079475	1.6501858	0.1304537	0.0226544
908	3	4.516206	1.5076723	0.1491715	0.2344834
909	0	6.0104588	1.7935011	0.1498395	0.01998
910	0	5.4749944	1.7001912	0.1514856	0.0216887
911	1	5.1230353	1.6337471	0.1304537	0.0854683
912	0	5.6844204	1.7377292	0.1514856	0.0209869
913	0	6.0431244	1.7989212	0.1498395	0.0198844
914	0	6.0757899	1.804312	0.1498395	0.0197897
915	4	4.5898398	1.5238451	0.1491715	0.2999552
916	40	5.4749944	1.7001912	0.1514856	2.3808242

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Hypoglycaemic episodes related to meals - treatment emergent - statistical analysis - on-treatment - full analysis set

Parameter Code=HY4HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 4 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
917	0	5.4749944	1.7001912	0.1514856	0.0216887
918	0	3.9344734	1.369777	0.1318324	0.0287466
919	1	3.9557408	1.3751679	0.1318324	0.1064403
920	2	4.4916614	1.5022226	0.1491715	0.1656216
921	10	4.7958245	1.5677456	0.128092	0.6857877
922	0	4.6634735	1.5397606	0.1491715	0.0249142
923	0	3.9344734	1.369777	0.1318324	0.0287466
924	1	5.2645556	1.6609967	0.1304537	0.0834711
925	0	4.516206	1.5076723	0.1491715	0.0256044
926	7	5.2079475	1.6501858	0.1304537	0.4538847
927	0	4.7958245	1.5677456	0.128092	0.0243247
928	10	6.0104588	1.7935011	0.1498395	0.5632966
929	1	3.9344734	1.369777	0.1318324	0.1069173
930	2	4.4916614	1.5022226	0.1491715	0.1656216
931	0	5.9451278	1.782572	0.1498395	0.0201739
932	0	5.2362515	1.6556059	0.1304537	0.022548
933	0	3.5004062	1.252879	0.1514856	0.031637
934	3	4.5652952	1.5184832	0.1491715	0.2323382
935	17	4.516206	1.5076723	0.1491715	1.2092521
936	3	4.7699011	1.5623256	0.128092	0.223801
937	8	4.516206	1.5076723	0.1491715	0.5826151
938	10	6.4024453	1.85668	0.1498395	0.5325623
939	1	5.2362515	1.6556059	0.1304537	0.0838631
940	6	3.913206	1.364357	0.1318324	0.5000116
941	1	5.4151584	1.6892021	0.1514856	0.0814452

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Parameter Code=HY4HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 4 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
942	0	4.0833454	1.4069166	0.1318324	0.0278719
943	8	5.1513394	1.6392567	0.1304537	0.5203992
944	1	3.913206	1.364357	0.1318324	0.1073985
945	1	3.8706711	1.3534279	0.1318324	0.1083741
946	0	4.516206	1.5076723	0.1491715	0.0256044
947	0	5.915549	1.7775843	0.1304537	0.020263
948	0	5.4060759	1.6875235	0.1304537	0.02193
949	8	5.2362515	1.6556059	0.1304537	0.5130684
950	7	5.7442564	1.7482005	0.1514856	0.4166232
951	1	3.9344734	1.369777	0.1318324	0.1069173
952	1	5.1789101	1.6445946	0.1491715	0.0846685
953	1	4.7699011	1.5623256	0.128092	0.0908923
954	6	4.9254414	1.5944139	0.128092	0.4116598
955	26	5.1796434	1.6447362	0.1304537	1.6320667
956	0	3.913206	1.364357	0.1318324	0.0288759
957	0	4.516206	1.5076723	0.1491715	0.0256044
958	2	3.8494037	1.3479183	0.1318324	0.1884657
959	6	5.2079475	1.6501858	0.1304537	0.3922804
960	0	5.2079475	1.6501858	0.1304537	0.0226544
961	0	3.913206	1.364357	0.1318324	0.0288759
962	0	4.516206	1.5076723	0.1491715	0.0256044
963	4	3.913206	1.364357	0.1318324	0.3429664
964	0	4.9513648	1.5996632	0.128092	0.0236663
965	0	4.5407506	1.5130923	0.1491715	0.0254868
966	8	4.7699011	1.5623256	0.128092	0.5560727

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Parameter Code=HY4HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 4 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
967	0	3.9344734	1.369777	0.1318324	0.0287466
968	0	1.0421038	0.0412415	0.1318324	0.0709009
969	1	3.7856014	1.3312048	0.1318324	0.1103786
970	1	4.8735946	1.5838318	0.128092	0.08923
971	0	5.5049124	1.7056408	0.1514856	0.0215856
972	1	5.2079475	1.6501858	0.1304537	0.0842587
973	2	6.1084554	1.809674	0.1498395	0.126814
974	4	5.5049124	1.7056408	0.1514856	0.2563776
975	0	5.9777933	1.7880515	0.1498395	0.0200765
976	0	4.516206	1.5076723	0.1491715	0.0256044
977	0	4.8476713	1.5784984	0.128092	0.0241012
978	3	5.4749944	1.7001912	0.1514856	0.1986239
979	1	4.0620779	1.4016947	0.1318324	0.104117
980	12	5.6545024	1.7324521	0.1514856	0.7091038
981	0	4.4671168	1.4967432	0.1491715	0.025843
982	0	4.8352857	1.5759402	0.1491715	0.0241542
983	6	5.0550583	1.6203894	0.128092	0.4025373
984	3	3.8919386	1.3589074	0.1318324	0.2656394
985	4	4.7439778	1.556876	0.128092	0.2916132
986	18	6.0431244	1.7989212	0.1498395	0.9931746
987	0	5.2079475	1.6501858	0.1304537	0.0226544
988	2	4.7180544	1.5513965	0.128092	0.1588258
989	21	4.7180544	1.5513965	0.128092	1.4333275
990	0	3.9557408	1.3751679	0.1318324	0.0286183
991	14	4.7699011	1.5623256	0.128092	0.9547987

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Parameter Code=HY4HSEBG Parameter=Severe or BG confirmed hypoglycaemic episodes within 4 hours after meal

The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
992	23	4.5625141	1.5178738	0.128092	1.6129608
993	8	5.2079475	1.6501858	0.1304537	0.5154891
994	1	4.8217479	1.5731365	0.128092	0.0900535
995	0	5.2079475	1.6501858	0.1304537	0.0226544
996	0	5.2362515	1.6556059	0.1304537	0.022548
997	3	2.9293415	1.0747776	0.128092	0.3337265
998	28	4.4180276	1.4856933	0.1491715	2.012294
999	0	4.9772881	1.6048852	0.128092	0.02356
1000	8	3.9344734	1.369777	0.1318324	0.6541124
1001	0	4.7371073	1.5554267	0.1491715	0.0245828
1002	20	5.9777933	1.7880515	0.1498395	1.1119596
1003	3	4.06997	1.4036356	0.128092	0.255949
1004	1	1.9812844	0.6837453	0.1304537	0.1805996
1005	10	4.7958245	1.5677456	0.128092	0.6857877
1006	3	3.913206	1.364357	0.1318324	0.2644437
1007	28	3.9344734	1.369777	0.1318324	2.217527
1008	16	4.7699011	1.5623256	0.128092	1.0877073
1009	8	4.899518	1.5891368	0.128092	0.5434178
1010	0	5.1513394	1.6392567	0.1304537	0.0228702
1011	1	4.3810893	1.4772974	0.1318324	0.0977134
1012	8	3.8919386	1.3589074	0.1318324	0.6600274
1013	11	3.9557408	1.3751679	0.1318324	0.88466
1014	1	5.2645556	1.6609967	0.1304537	0.0834711
1015	0	3.9344734	1.369777	0.1318324	0.0287466
1016	4	5.3494678	1.6769971	0.1304537	0.26287

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The GENMOD Procedure

Observation Statistics

Observation	AVAL	Predicted Value	Linear Predictor	Standard Error of the Linear Predictor	HessWgt
1017	8	5.1796434	1.6447362	0.1304537	0.5179325
1018	30	4.7699011	1.5623256	0.128092	2.0180681
1019	3	4.516206	1.5076723	0.1491715	0.2344834
1020	4	3.9770083	1.3805298	0.1318324	0.3383963
1021	4	5.2645556	1.6609967	0.1304537	0.2665564
1022	0	3.913206	1.364357	0.1318324	0.0288759
1023	10	4.7699011	1.5623256	0.128092	0.6889813
1024	15	4.7699011	1.5623256	0.128092	1.021253
1025	0	4.7699011	1.5623256	0.128092	0.024438

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09FEB2018:20:27:18 - a_stat_hypo_meal.sas/a_hypo_te_meal_stat_on_fas_app.txt

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The MI Procedure with MCMC
Model Information

Parameter Code=HDL_SU Planned Treatment for Period 30 (N)=2

Obs	PARAM	Description	Value
1	HDL cholesterol (mg/dL)	Data Set	WORK.ENDPOINT_PARAM
2	HDL cholesterol (mg/dL)	Method	Monotone-data_MCMC
3	HDL cholesterol (mg/dL)	Multiple Imputation Chain	Multiple Chains
4	HDL cholesterol (mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
5	HDL cholesterol (mg/dL)	Start	Starting Value
6	HDL cholesterol (mg/dL)	Prior	Jeffreys
7	HDL cholesterol (mg/dL)	Number of Imputations	10000
8	HDL cholesterol (mg/dL)	Number of Burn-in Iterations	200
9	HDL cholesterol (mg/dL)	Seed for random number generator	144500

Parameter Code=HDL_SU Planned Treatment for Period 30 (N)=3

Obs	PARAM	Description	Value
10	HDL cholesterol (mg/dL)	Data Set	WORK.ENDPOINT_PARAM
11	HDL cholesterol (mg/dL)	Method	Monotone-data_MCMC
12	HDL cholesterol (mg/dL)	Multiple Imputation Chain	Multiple Chains
13	HDL cholesterol (mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
14	HDL cholesterol (mg/dL)	Start	Starting Value
15	HDL cholesterol (mg/dL)	Prior	Jeffreys
16	HDL cholesterol (mg/dL)	Number of Imputations	10000
17	HDL cholesterol (mg/dL)	Number of Burn-in Iterations	200
18	HDL cholesterol (mg/dL)	Seed for random number generator	593026444

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The MI Procedure with MCMC
Model Information

Parameter Code=HDL_SU Planned Treatment for Period 30 (N)=4

Obs	PARAM	Description	Value
19	HDL cholesterol (mg/dL)	Data Set	WORK.ENDPOINT_PARAM
20	HDL cholesterol (mg/dL)	Method	Monotone-data MCMC
21	HDL cholesterol (mg/dL)	Multiple Imputation Chain	Multiple Chains
22	HDL cholesterol (mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
23	HDL cholesterol (mg/dL)	Start	Starting Value
24	HDL cholesterol (mg/dL)	Prior	Jeffreys
25	HDL cholesterol (mg/dL)	Number of Imputations	10000
26	HDL cholesterol (mg/dL)	Number of Burn-in Iterations	200
27	HDL cholesterol (mg/dL)	Seed for random number generator	656090614

nn1218/nn1218-4131/ctr_20180214_er
09FEB2018:20:27:21 - a_stat_ratio.sas/a_lip_stat_in_fas_app.txt

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The MI Procedure with MCMC
Missing data pattern

Parameter Code=HDL_SU Planned Treatment for Period 30 (N)=2

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
1	HDL cholesterol (mg/dL)	1	X	X	X	328	95.91	4.094036	-0.004322	-0.020527
2	HDL cholesterol (mg/dL)	2	X	X	O	6	1.75	3.887059	0.022474	.
3	HDL cholesterol (mg/dL)	3	X	.	X	6	1.75	4.149010	.	0.013531
4	HDL cholesterol (mg/dL)	4	X	O	O	2	0.58	4.051724	.	.

Parameter Code=HDL_SU Planned Treatment for Period 30 (N)=3

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
5	HDL cholesterol (mg/dL)	1	X	X	X	332	97.36	4.098319	0.004224	-0.001050
6	HDL cholesterol (mg/dL)	2	X	X	O	7	2.05	4.200772	-0.015993	.
7	HDL cholesterol (mg/dL)	3	X	.	X	1	0.29	4.110936	.	-0.106768
8	HDL cholesterol (mg/dL)	4	X	O	O	1	0.29	3.953616	.	.

Parameter Code=HDL_SU Planned Treatment for Period 30 (N)=4

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
9	HDL cholesterol (mg/dL)	1	X	X	X	325	95.03	4.091979	0.001413	-0.003690
10	HDL cholesterol (mg/dL)	2	X	X	O	10	2.92	4.187310	0.032508	.
11	HDL cholesterol (mg/dL)	3	X	.	X	6	1.75	3.819294	.	0.098766
12	HDL cholesterol (mg/dL)	4	X	O	O	1	0.29	4.395449	.	.

nn1218/nn1218-4131/ctr_20180214_er
09FEB2018:20:27:21 - a_stat_ratio.sas/a_lip_stat_in_fas_app.txt

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The MI Procedure with Monotone Regression
Model Information

Parameter Code=HDL_SU Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM	Description	Value
1	1	HDL cholesterol (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	HDL cholesterol (mg/dL)	Method	Monotone
3	1	HDL cholesterol (mg/dL)	Number of Imputations	1
4	1	HDL cholesterol (mg/dL)	Seed for random number generator	144800

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The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=HDL_SU Planned Treatment for Period 30 (N)=2

O b s	I m p u t a t i o n	P A R A M E T E R	G r o u p	R E G I S T E R E D I T I O N A L	B O L U S I N G	B I N D I C A T O R	B I N D I C A T O R	B I N D I C A T O R	B I N D I C A T O R	F r e q	P e r c e n t	B A S E	v i s i t s	v i s i t s
1	1	HDL cholesterol (mg/dL)	1	X	X	X	X	X		334	97.66	4.095024	-0.004114	-0.019915
2	1	HDL cholesterol (mg/dL)	2	X	X	X	X	.		6	1.75	3.887059	0.022474	.
3	1	HDL cholesterol (mg/dL)	3	X	X	X	.	.		2	0.58	4.051724	.	.

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nn1218/nn1218-4131/ctr_20180214_er
09FEB2018:20:27:21 - a stat ratio.sas/a lip stat in_fas app.txt
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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=HDL_SU Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

O b s _	i	P A R A M _	E f f e c t	R E G I O N 1	B O L A D 1	O b s _	T
7	1	HDL cholesterol (mg/dL)	Intercept			0.02167	0.033661
8	1	HDL cholesterol (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)		-0.05071	-0.050442
9	1	HDL cholesterol (mg/dL)	REGION1	EUROPE		-0.02913	0.042691
10	1	HDL cholesterol (mg/dL)	REGION1	JAPAN		0.18469	0.188128
11	1	HDL cholesterol (mg/dL)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.06143	-0.098243
12	1	HDL cholesterol (mg/dL)	BASE			-0.05526	-0.045622
13	1	HDL cholesterol (mg/dL)	visit2200			0.59062	0.561392

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The MI Procedure with Monotone Regression
Model Information

Parameter Code=HDL_SU Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM	Description	Value
1	1	HDL cholesterol (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	HDL cholesterol (mg/dL)	Method	Monotone
3	1	HDL cholesterol (mg/dL)	Number of Imputations	1
4	1	HDL cholesterol (mg/dL)	Seed for random number generator	144801

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The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=HDL_SU Planned Treatment for Period 30 (N)=3

O b s	I m p u t a t i o n	P A R A M	G r o u p	R E G I O N 1	B O L 1	B L A D 1	B L A D 2	B L A D 3	F r e q	P e r c e n t	B A S E	v i s i t 2 0	v i s i t 3 6 0 0
1	1	HDL cholesterol (mg/dL)	1	X	X	X	X	X	333	97.65	4.098357	0.004188	-0.001368
2	1	HDL cholesterol (mg/dL)	2	X	X	X	X	.	7	2.05	4.200772	-0.015993	.
3	1	HDL cholesterol (mg/dL)	3	X	X	X	.	.	1	0.29	3.953616	.	.

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nn1218/nn1218-4131/ctr_20180214_er
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The MI Procedure with Monotone Regression
Model Information

Parameter Code=HDL_SU Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM	Description	Value
1	1	HDL cholesterol (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	HDL cholesterol (mg/dL)	Method	Monotone
3	1	HDL cholesterol (mg/dL)	Number of Imputations	1
4	1	HDL cholesterol (mg/dL)	Seed for random number generator	144802

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The MI Procedure with MCMC
Model Information

Parameter Code=C105587S Planned Treatment for Period 30 (N)=2

Obs	PARAM	Description	Value
1	HDL cholesterol (mmol/L)	Data Set	WORK.ENDPOINT_PARAM
2	HDL cholesterol (mmol/L)	Method	Monotone-data_MCMC
3	HDL cholesterol (mmol/L)	Multiple Imputation Chain	Multiple Chains
4	HDL cholesterol (mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
5	HDL cholesterol (mmol/L)	Start	Starting Value
6	HDL cholesterol (mmol/L)	Prior	Jeffreys
7	HDL cholesterol (mmol/L)	Number of Imputations	10000
8	HDL cholesterol (mmol/L)	Number of Burn-in Iterations	200
9	HDL cholesterol (mmol/L)	Seed for random number generator	144500

Parameter Code=C105587S Planned Treatment for Period 30 (N)=3

Obs	PARAM	Description	Value
10	HDL cholesterol (mmol/L)	Data Set	WORK.ENDPOINT_PARAM
11	HDL cholesterol (mmol/L)	Method	Monotone-data_MCMC
12	HDL cholesterol (mmol/L)	Multiple Imputation Chain	Multiple Chains
13	HDL cholesterol (mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
14	HDL cholesterol (mmol/L)	Start	Starting Value
15	HDL cholesterol (mmol/L)	Prior	Jeffreys
16	HDL cholesterol (mmol/L)	Number of Imputations	10000
17	HDL cholesterol (mmol/L)	Number of Burn-in Iterations	200
18	HDL cholesterol (mmol/L)	Seed for random number generator	593026444

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The MI Procedure with MCMC
Model Information

Parameter Code=C105587S Planned Treatment for Period 30 (N)=4

Obs	PARAM	Description	Value
19	HDL cholesterol (mmol/L)	Data Set	WORK.ENDPOINT_PARAM
20	HDL cholesterol (mmol/L)	Method	Monotone-data MCMC
21	HDL cholesterol (mmol/L)	Multiple Imputation Chain	Multiple Chains
22	HDL cholesterol (mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
23	HDL cholesterol (mmol/L)	Start	Starting Value
24	HDL cholesterol (mmol/L)	Prior	Jeffreys
25	HDL cholesterol (mmol/L)	Number of Imputations	10000
26	HDL cholesterol (mmol/L)	Number of Burn-in Iterations	200
27	HDL cholesterol (mmol/L)	Seed for random number generator	656090614

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The MI Procedure with MCMC
Missing data pattern

Parameter Code=C105587S Planned Treatment for Period 30 (N)=2

Obs	PARAM	Group	BASE_ Miss_	visit2200_ Miss_	visit3600_ Miss_	Freq	Percent	BASE	visit2200	visit3600
1	HDL cholesterol (mmol/L)	1	X	X	X	328	95.91	0.440525	-0.004322	-0.020527
2	HDL cholesterol (mmol/L)	2	X	X	O	6	1.75	0.233548	0.022474	.
3	HDL cholesterol (mmol/L)	3	X	.	X	6	1.75	0.495499	.	0.013531
4	HDL cholesterol (mmol/L)	4	X	O	O	2	0.58	0.398213	.	.

Parameter Code=C105587S Planned Treatment for Period 30 (N)=3

Obs	PARAM	Group	BASE_ Miss_	visit2200_ Miss_	visit3600_ Miss_	Freq	Percent	BASE	visit2200	visit3600
5	HDL cholesterol (mmol/L)	1	X	X	X	332	97.36	0.444808	0.004224	-0.001050
6	HDL cholesterol (mmol/L)	2	X	X	O	7	2.05	0.547261	-0.015993	.
7	HDL cholesterol (mmol/L)	3	X	.	X	1	0.29	0.457425	.	-0.106768
8	HDL cholesterol (mmol/L)	4	X	O	O	1	0.29	0.300105	.	.

Parameter Code=C105587S Planned Treatment for Period 30 (N)=4

Obs	PARAM	Group	BASE_ Miss_	visit2200_ Miss_	visit3600_ Miss_	Freq	Percent	BASE	visit2200	visit3600
9	HDL cholesterol (mmol/L)	1	X	X	X	325	95.03	0.438468	0.001413	-0.003690
10	HDL cholesterol (mmol/L)	2	X	X	O	10	2.92	0.533799	0.032508	.
11	HDL cholesterol (mmol/L)	3	X	.	X	6	1.75	0.165783	.	0.098766
12	HDL cholesterol (mmol/L)	4	X	O	O	1	0.29	0.741937	.	.

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The MI Procedure with Monotone Regression
Model Information

Parameter Code=C105587S Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM	Description	Value
1	1	HDL cholesterol (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	HDL cholesterol (mmol/L)	Method	Monotone
3	1	HDL cholesterol (mmol/L)	Number of Imputations	1
4	1	HDL cholesterol (mmol/L)	Seed for random number generator	144800

Lipids 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=C105587S Planned Treatment for Period 30 (N)=2

O b s	I m p u t a t i o n	P A R A M E T E R	G r o u p	R E G I O N 1	B O L 1	B L A D E	B L A D E	B L A D E	B L A D E	F r e q	P e r c e n t	B A S E	v i s i t 2 0 0	v i s i t 3 6 0 0
1	1	HDL cholesterol (mmol/L)	1	X	X	X	X	X	X	334	97.66	0.441513	-0.004114	-0.019915
2	1	HDL cholesterol (mmol/L)	2	X	X	X	X	X	.	6	1.75	0.233548	0.022474	.
3	1	HDL cholesterol (mmol/L)	3	X	X	X	.	.	.	2	0.58	0.398213	.	.

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=C105587S Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	HDL cholesterol (mmol/L)	Intercept	
2	1	HDL cholesterol (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	HDL cholesterol (mmol/L)	REGION1	EUROPE
4	1	HDL cholesterol (mmol/L)	REGION1	JAPAN
5	1	HDL cholesterol (mmol/L)	BOLAD1	
6	1	HDL cholesterol (mmol/L)	BASE	

Obs		BOLAD1	ObsVal	_1
1			0.03248	0.089941
2			-0.00337	-0.134086
3			-0.05955	0.064519
4			0.11087	0.200824
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.11520	-0.200447
6			-0.25848	-0.307746

Parameter Code=C105587S Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	HDL cholesterol (mmol/L)	Intercept			0.02167	0.033661
8	1	HDL cholesterol (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)		-0.05071	-0.050442
9	1	HDL cholesterol (mmol/L)	REGION1	EUROPE		-0.02913	0.042691

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=C105587S Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
10	1	HDL cholesterol (mmol/L)	REGION1	JAPAN		0.18469	0.188128
11	1	HDL cholesterol (mmol/L)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.06143	-0.098243
12	1	HDL cholesterol (mmol/L)	BASE			-0.05526	-0.045622
13	1	HDL cholesterol (mmol/L)	visit2200			0.59062	0.561392

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The MI Procedure with Monotone Regression
Model Information

Parameter Code=C105587S Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM	Description	Value
1	1	HDL cholesterol (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	HDL cholesterol (mmol/L)	Method	Monotone
3	1	HDL cholesterol (mmol/L)	Number of Imputations	1
4	1	HDL cholesterol (mmol/L)	Seed for random number generator	144801

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The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=C105587S Planned Treatment for Period 30 (N)=3

O b s	I m p u t a t i o n	P A R A M E T E R	G r o u p	R E G I O N 1	B O L 1	B L A D E	B L A D E	B L A D E	B L A D E	F r e q	P e r c e n t	B A S E	v i s i t 2 0 0	v i s i t 3 6 0 0
1	1	HDL cholesterol (mmol/L)	1	X	X	X	X	X	X	333	97.65	0.444846	0.004188	-0.001368
2	1	HDL cholesterol (mmol/L)	2	X	X	X	X	.	.	7	2.05	0.547261	-0.015993	.
3	1	HDL cholesterol (mmol/L)	3	X	X	X	.	.	.	1	0.29	0.300105	.	.

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=C105587S Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	HDL cholesterol (mmol/L)	Intercept	
2	1	HDL cholesterol (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	HDL cholesterol (mmol/L)	REGION1	EUROPE
4	1	HDL cholesterol (mmol/L)	REGION1	JAPAN
5	1	HDL cholesterol (mmol/L)	BOLAD1	
6	1	HDL cholesterol (mmol/L)	BASE	

Obs		BOLAD1	ObsVal	_1
1			-0.01792	-0.011225
2			-0.15943	-0.165480
3			-0.08323	-0.111579
4			0.41576	0.540992
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.04402	0.119363
6			-0.20467	-0.283995

Parameter Code=C105587S Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	HDL cholesterol (mmol/L)	Intercept			0.01024	-0.047781
8	1	HDL cholesterol (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)		-0.01994	-0.184912
9	1	HDL cholesterol (mmol/L)	REGION1	EUROPE		-0.08226	-0.147318

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Parameter Code=C105587S Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
10	1	HDL cholesterol (mmol/L)	REGION1	JAPAN		0.34904	0.513141
11	1	HDL cholesterol (mmol/L)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.04356	-0.051945
12	1	HDL cholesterol (mmol/L)	BASE			-0.18500	-0.163343
13	1	HDL cholesterol (mmol/L)	visit2200			0.44095	0.413904

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Lipids 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=C105587S Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM	Description	Value
1	1	HDL cholesterol (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	HDL cholesterol (mmol/L)	Method	Monotone
3	1	HDL cholesterol (mmol/L)	Number of Imputations	1
4	1	HDL cholesterol (mmol/L)	Seed for random number generator	144802

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Lipids 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=C105587S Planned Treatment for Period 30 (N)=4

O b s	I m p u t a t i o n	P A R A M M	G r o u p	R E G I O N 1	B O L 1	B L A D E	v i s i t 2	v i s i t 3	F r e q	P e r c e n t	B A S E	v i s i t 2	v i s i t 3
1	1	HDL cholesterol (mmol/L)	1	X	X	X	X	X	331	96.78	0.433525	0.003248	-0.001833
2	1	HDL cholesterol (mmol/L)	2	X	X	X	X	.	10	2.92	0.533799	0.032508	.
3	1	HDL cholesterol (mmol/L)	3	X	X	X	.	.	1	0.29	0.741937	.	.

Fast-acting insulin aspart
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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=C105587S Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	HDL cholesterol (mmol/L)	Intercept	
2	1	HDL cholesterol (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	HDL cholesterol (mmol/L)	REGION1	EUROPE
4	1	HDL cholesterol (mmol/L)	REGION1	JAPAN
5	1	HDL cholesterol (mmol/L)	BOLAD1	
6	1	HDL cholesterol (mmol/L)	BASE	

Obs		BOLAD1	ObsVal	_1
1			-0.00784	-0.016044
2			-0.03403	0.099684
3			-0.03704	0.057995
4			0.11078	-0.034671
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.04138	-0.067557
6			-0.29760	-0.273973

Parameter Code=C105587S Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	HDL cholesterol (mmol/L)	Intercept			0.01406	0.122682
8	1	HDL cholesterol (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)		-0.06984	0.039860
9	1	HDL cholesterol (mmol/L)	REGION1	EUROPE		-0.03363	-0.039231

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=C105587S Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
10	1	HDL cholesterol (mmol/L)	REGION1	JAPAN		0.25160	0.299061
11	1	HDL cholesterol (mmol/L)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.05248	-0.116952
12	1	HDL cholesterol (mmol/L)	BASE			-0.17314	-0.161543
13	1	HDL cholesterol (mmol/L)	visit2200			0.66033	0.628806

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The MI Procedure with MCMC
Model Information

Parameter Code=LDL_SU Planned Treatment for Period 30 (N)=2

Obs	PARAM	Description	Value
1	LDL cholesterol (mg/dL)	Data Set	WORK.ENDPOINT_PARAM
2	LDL cholesterol (mg/dL)	Method	Monotone-data MCMC
3	LDL cholesterol (mg/dL)	Multiple Imputation Chain	Multiple Chains
4	LDL cholesterol (mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
5	LDL cholesterol (mg/dL)	Start	Starting Value
6	LDL cholesterol (mg/dL)	Prior	Jeffreys
7	LDL cholesterol (mg/dL)	Number of Imputations	10000
8	LDL cholesterol (mg/dL)	Number of Burn-in Iterations	200
9	LDL cholesterol (mg/dL)	Seed for random number generator	144500

Parameter Code=LDL_SU Planned Treatment for Period 30 (N)=3

Obs	PARAM	Description	Value
10	LDL cholesterol (mg/dL)	Data Set	WORK.ENDPOINT_PARAM
11	LDL cholesterol (mg/dL)	Method	Monotone-data MCMC
12	LDL cholesterol (mg/dL)	Multiple Imputation Chain	Multiple Chains
13	LDL cholesterol (mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
14	LDL cholesterol (mg/dL)	Start	Starting Value
15	LDL cholesterol (mg/dL)	Prior	Jeffreys
16	LDL cholesterol (mg/dL)	Number of Imputations	10000
17	LDL cholesterol (mg/dL)	Number of Burn-in Iterations	200
18	LDL cholesterol (mg/dL)	Seed for random number generator	593026444

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The MI Procedure with MCMC
Model Information

Parameter Code=LDL_SU Planned Treatment for Period 30 (N)=4

Obs	PARAM	Description	Value
19	LDL cholesterol (mg/dL)	Data Set	WORK.ENDPOINT_PARAM
20	LDL cholesterol (mg/dL)	Method	Monotone-data MCMC
21	LDL cholesterol (mg/dL)	Multiple Imputation Chain	Multiple Chains
22	LDL cholesterol (mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
23	LDL cholesterol (mg/dL)	Start	Starting Value
24	LDL cholesterol (mg/dL)	Prior	Jeffreys
25	LDL cholesterol (mg/dL)	Number of Imputations	10000
26	LDL cholesterol (mg/dL)	Number of Burn-in Iterations	200
27	LDL cholesterol (mg/dL)	Seed for random number generator	656090614

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Lipids 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with MCMC
Missing data pattern

Parameter Code=LDL_SU Planned Treatment for Period 30 (N)=2

Obs	PARAM	Group	BASE_ Miss_	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
1	LDL cholesterol (mg/dL)	1	X	X	X	328	95.91	4.587561	0.034253	0.024147
2	LDL cholesterol (mg/dL)	2	X	X	O	6	1.75	4.581979	-0.003744	.
3	LDL cholesterol (mg/dL)	3	X	.	X	6	1.75	4.564432	.	0.055554
4	LDL cholesterol (mg/dL)	4	X	O	O	2	0.58	4.602141	.	.

Parameter Code=LDL_SU Planned Treatment for Period 30 (N)=3

Obs	PARAM	Group	BASE_ Miss_	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
5	LDL cholesterol (mg/dL)	1	X	X	X	332	97.36	4.605306	0.039291	0.051057
6	LDL cholesterol (mg/dL)	2	X	X	O	7	2.05	4.374732	0.064987	.
7	LDL cholesterol (mg/dL)	3	X	.	X	1	0.29	4.356609	.	0.014742
8	LDL cholesterol (mg/dL)	4	X	O	O	1	0.29	4.788134	.	.

Parameter Code=LDL_SU Planned Treatment for Period 30 (N)=4

Obs	PARAM	Group	BASE_ Miss_	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
9	LDL cholesterol (mg/dL)	1	X	X	X	324	94.74	4.576914	0.040338	0.057372
10	LDL cholesterol (mg/dL)	2	X	X	O	11	3.22	4.648385	0.050884	.
11	LDL cholesterol (mg/dL)	3	X	.	X	6	1.75	4.338394	.	0.243440
12	LDL cholesterol (mg/dL)	4	X	O	O	1	0.29	4.624290	.	.

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The MI Procedure with Monotone Regression
Model Information

Parameter Code=LDL_SU Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM	Description	Value
1	1	LDL cholesterol (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	LDL cholesterol (mg/dL)	Method	Monotone
3	1	LDL cholesterol (mg/dL)	Number of Imputations	1
4	1	LDL cholesterol (mg/dL)	Seed for random number generator	144800

Lipids 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=LDL_SU Planned Treatment for Period 30 (N)=2

O b s	I m p u t a t i o n	P A R A M M	G r o u p	R E G I O N 1	B O L 1	B L A D E	v i s i t 2	v i s i t 3	F r e q	P e r c e n t	B A S E	v i s i t 2	v i s i t 3
1	1	LDL cholesterol (mg/dL)	1	X	X	X	X	X	334	97.66	4.587145	0.034541	0.024712
2	1	LDL cholesterol (mg/dL)	2	X	X	X	X	.	6	1.75	4.581979	-0.003744	.
3	1	LDL cholesterol (mg/dL)	3	X	X	X	.	.	2	0.58	4.602141	.	.

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=LDL_SU Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2200

Imputed		R		B		O		T	
a		E		O		b		I	
t		f		L		s		T	
i		e		A		V		T	
O o		R		A		D		T	
b n		A		N		1		T	
s _		M		t		1		T	
1	1	LDL cholesterol (mg/dL)	Intercept					-0.01883	0.036654
2	1	LDL cholesterol (mg/dL)	REGION1 ASIA (EXCLUDING JAPAN)					-0.16317	-0.286596
3	1	LDL cholesterol (mg/dL)	REGION1 EUROPE					0.01108	0.131989
4	1	LDL cholesterol (mg/dL)	REGION1 JAPAN					0.23404	0.316863
5	1	LDL cholesterol (mg/dL)	BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)				0.05921	-0.022837
6	1	LDL cholesterol (mg/dL)	BASE					-0.35985	-0.401573

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The MI Procedure with Monotone Regression
Model Information

Parameter Code=LDL_SU Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM	Description	Value
1	1	LDL cholesterol (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	LDL cholesterol (mg/dL)	Method	Monotone
3	1	LDL cholesterol (mg/dL)	Number of Imputations	1
4	1	LDL cholesterol (mg/dL)	Seed for random number generator	144801


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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=LDL_SU Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2200

Imputed		R		B		O	
a		E		O		b	
t		f		L		s	
i		e		A		V	
O o		R		D		a	
b n		A		1		l	
s _		M		1		1	
1	1	LDL cholesterol (mg/dL)	Intercept			-0.01466	-0.007994
2	1	LDL cholesterol (mg/dL)	REGION1 ASIA (EXCLUDING JAPAN)			-0.12730	-0.133264
3	1	LDL cholesterol (mg/dL)	REGION1 EUROPE			-0.14877	-0.176605
4	1	LDL cholesterol (mg/dL)	REGION1 JAPAN			0.27205	0.392210
5	1	LDL cholesterol (mg/dL)	BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.06054	0.136837
6	1	LDL cholesterol (mg/dL)	BASE			-0.24321	-0.309312

Lipids 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=LDL_SU Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

O b s _	P A R A M E T E R	E F F E C T	R E G I O N	B O L A D 1	O b s V a l	T
7 1	LDL cholesterol (mg/dL)	Intercept			-0.01560	-0.074814
8 1	LDL cholesterol (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)		-0.10726	-0.274408
9 1	LDL cholesterol (mg/dL)	REGION1	EUROPE		0.02094	-0.043777
10 1	LDL cholesterol (mg/dL)	REGION1	JAPAN		0.17826	0.333620
11 1	LDL cholesterol (mg/dL)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.03967	0.033553
12 1	LDL cholesterol (mg/dL)	BASE			-0.22731	-0.184293
13 1	LDL cholesterol (mg/dL)	visit2200			0.40942	0.387463

Fast-acting insulin aspart
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The MI Procedure with Monotone Regression
Model Information

Parameter Code=LDL_SU Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM	Description	Value
1	1	LDL cholesterol (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	LDL cholesterol (mg/dL)	Method	Monotone
3	1	LDL cholesterol (mg/dL)	Number of Imputations	1
4	1	LDL cholesterol (mg/dL)	Seed for random number generator	144802

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=LDL_SU Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2200

Imputed		R		B		O		T	
a		E		O		b		I	
t		f		L		s		T	
i		e		A		V		T	
O o		R		D		a		T	
b n		A		N		l		T	
s _		M		1					
1	1	LDL cholesterol (mg/dL)	Intercept				0.00257		-0.004108
2	1	LDL cholesterol (mg/dL)	REGION1 ASIA (EXCLUDING JAPAN)				0.05272		0.158488
3	1	LDL cholesterol (mg/dL)	REGION1 EUROPE				-0.00970		0.064455
4	1	LDL cholesterol (mg/dL)	REGION1 JAPAN				0.02394		-0.080478
5	1	LDL cholesterol (mg/dL)	BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)			0.02535		-0.067272
6	1	LDL cholesterol (mg/dL)	BASE				-0.62926		-0.624024

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=LDL_SU Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

Imputed		Effect		Regression		Observation		Mean	
Visit		Parameter		Estimate		Standard Error		t-value	
Obs		Parameter		Estimate		Standard Error		t-value	
s _		Parameter		Estimate		Standard Error		t-value	
7	1	LDL cholesterol (mg/dL)	Intercept					-0.01535	0.076158
8	1	LDL cholesterol (mg/dL)	REGION1 ASIA (EXCLUDING JAPAN)					-0.09960	-0.009121
9	1	LDL cholesterol (mg/dL)	REGION1 EUROPE					0.05344	0.047627
10	1	LDL cholesterol (mg/dL)	REGION1 JAPAN					0.13386	0.175413
11	1	LDL cholesterol (mg/dL)	BOLAD1					0.02046	-0.032593
12	1	LDL cholesterol (mg/dL)	BASE					-0.18094	-0.164626
13	1	LDL cholesterol (mg/dL)	visit2200					0.67652	0.657011

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The MI Procedure with MCMC
Model Information

Parameter Code=C105588S Planned Treatment for Period 30 (N)=2

Obs	PARAM	Description	Value
1	LDL cholesterol (mmol/L)	Data Set	WORK.ENDPOINT_PARAM
2	LDL cholesterol (mmol/L)	Method	Monotone-data_MCMC
3	LDL cholesterol (mmol/L)	Multiple Imputation Chain	Multiple Chains
4	LDL cholesterol (mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
5	LDL cholesterol (mmol/L)	Start	Starting Value
6	LDL cholesterol (mmol/L)	Prior	Jeffreys
7	LDL cholesterol (mmol/L)	Number of Imputations	10000
8	LDL cholesterol (mmol/L)	Number of Burn-in Iterations	200
9	LDL cholesterol (mmol/L)	Seed for random number generator	144500

Parameter Code=C105588S Planned Treatment for Period 30 (N)=3

Obs	PARAM	Description	Value
10	LDL cholesterol (mmol/L)	Data Set	WORK.ENDPOINT_PARAM
11	LDL cholesterol (mmol/L)	Method	Monotone-data_MCMC
12	LDL cholesterol (mmol/L)	Multiple Imputation Chain	Multiple Chains
13	LDL cholesterol (mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
14	LDL cholesterol (mmol/L)	Start	Starting Value
15	LDL cholesterol (mmol/L)	Prior	Jeffreys
16	LDL cholesterol (mmol/L)	Number of Imputations	10000
17	LDL cholesterol (mmol/L)	Number of Burn-in Iterations	200
18	LDL cholesterol (mmol/L)	Seed for random number generator	593026444

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The MI Procedure with MCMC
Model Information

Parameter Code=C105588S Planned Treatment for Period 30 (N)=4

Obs	PARAM	Description	Value
19	LDL cholesterol (mmol/L)	Data Set	WORK.ENDPOINT_PARAM
20	LDL cholesterol (mmol/L)	Method	Monotone-data_MCMC
21	LDL cholesterol (mmol/L)	Multiple Imputation Chain	Multiple Chains
22	LDL cholesterol (mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
23	LDL cholesterol (mmol/L)	Start	Starting Value
24	LDL cholesterol (mmol/L)	Prior	Jeffreys
25	LDL cholesterol (mmol/L)	Number of Imputations	10000
26	LDL cholesterol (mmol/L)	Number of Burn-in Iterations	200
27	LDL cholesterol (mmol/L)	Seed for random number generator	656090614

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The MI Procedure with MCMC
Missing data pattern

Parameter Code=C105588S Planned Treatment for Period 30 (N)=2

Obs	PARAM	Group	BASE_ Miss_	visit2200_ Miss_	visit3600_ Miss_	Freq	Percent	BASE	visit2200	visit3600
1	LDL cholesterol (mmol/L)	1	X	X	X	328	95.91	0.934049	0.034253	0.024147
2	LDL cholesterol (mmol/L)	2	X	X	O	6	1.75	0.928468	-0.003744	.
3	LDL cholesterol (mmol/L)	3	X	.	X	6	1.75	0.910920	.	0.055554
4	LDL cholesterol (mmol/L)	4	X	O	O	2	0.58	0.948630	.	.

Parameter Code=C105588S Planned Treatment for Period 30 (N)=3

Obs	PARAM	Group	BASE_ Miss_	visit2200_ Miss_	visit3600_ Miss_	Freq	Percent	BASE	visit2200	visit3600
5	LDL cholesterol (mmol/L)	1	X	X	X	332	97.36	0.951795	0.039291	0.051057
6	LDL cholesterol (mmol/L)	2	X	X	O	7	2.05	0.721220	0.064987	.
7	LDL cholesterol (mmol/L)	3	X	.	X	1	0.29	0.703098	.	0.014742
8	LDL cholesterol (mmol/L)	4	X	O	O	1	0.29	1.134623	.	.

Parameter Code=C105588S Planned Treatment for Period 30 (N)=4

Obs	PARAM	Group	BASE_ Miss_	visit2200_ Miss_	visit3600_ Miss_	Freq	Percent	BASE	visit2200	visit3600
9	LDL cholesterol (mmol/L)	1	X	X	X	324	94.74	0.923402	0.040338	0.057372
10	LDL cholesterol (mmol/L)	2	X	X	O	11	3.22	0.994874	0.050884	.
11	LDL cholesterol (mmol/L)	3	X	.	X	6	1.75	0.684883	.	0.243440
12	LDL cholesterol (mmol/L)	4	X	O	O	1	0.29	0.970779	.	.

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The MI Procedure with Monotone Regression
Model Information

Parameter Code=C105588S Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM	Description	Value
1	1	LDL cholesterol (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	LDL cholesterol (mmol/L)	Method	Monotone
3	1	LDL cholesterol (mmol/L)	Number of Imputations	1
4	1	LDL cholesterol (mmol/L)	Seed for random number generator	144800

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The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=C105588S Planned Treatment for Period 30 (N)=2

O b s	I m p u t a t i o n	P A R A M E T E R	G r o u p	R E G I O N 1	B O L 1	B L A D E	B L A D E	B L A D E	B L A D E	F r e q	P e r c e n t	B A S E	v i s i t 2 0 0	v i s i t 3 6 0 0
1	1	LDL cholesterol (mmol/L)	1	X	X	X	X	X	X	334	97.66	0.933634	0.034541	0.024712
2	1	LDL cholesterol (mmol/L)	2	X	X	X	X	X	.	6	1.75	0.928468	-0.003744	.
3	1	LDL cholesterol (mmol/L)	3	X	X	X	.	.	.	2	0.58	0.948630	.	.

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=C105588S Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	LDL cholesterol (mmol/L)	Intercept	
2	1	LDL cholesterol (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	LDL cholesterol (mmol/L)	REGION1	EUROPE
4	1	LDL cholesterol (mmol/L)	REGION1	JAPAN
5	1	LDL cholesterol (mmol/L)	BOLAD1	
6	1	LDL cholesterol (mmol/L)	BASE	

Obs		BOLAD1	ObsVal	_1
1			-0.01883	0.036654
2			-0.16317	-0.286596
3			0.01108	0.131989
4			0.23404	0.316863
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.05921	-0.022837
6			-0.35985	-0.401573

Parameter Code=C105588S Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	LDL cholesterol (mmol/L)	Intercept			-0.04077	-0.029311
8	1	LDL cholesterol (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)		-0.26881	-0.268463
9	1	LDL cholesterol (mmol/L)	REGION1	EUROPE		0.16806	0.236341

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=C105588S Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
10	1	LDL cholesterol (mmol/L)	REGION1	JAPAN		0.26656	0.271177
11	1	LDL cholesterol (mmol/L)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.03666	0.001464
12	1	LDL cholesterol (mmol/L)	BASE			-0.20925	-0.202459
13	1	LDL cholesterol (mmol/L)	visit2200			0.52634	0.500772

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The MI Procedure with Monotone Regression
Model Information

Parameter Code=C105588S Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM	Description	Value
1	1	LDL cholesterol (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	LDL cholesterol (mmol/L)	Method	Monotone
3	1	LDL cholesterol (mmol/L)	Number of Imputations	1
4	1	LDL cholesterol (mmol/L)	Seed for random number generator	144801

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The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=C105588S Planned Treatment for Period 30 (N)=3

O b s	I m p u t a t i o n	P A R A M E T E R	G r o u p	R E G I O N 1	B O L 1	B L A D E	B L A D E	B L A D E	B L A D E	F r e q	P e r c e n t	B A S E	v i s i t 2 0 0	v i s i t 3 6 0 0
1	1	LDL cholesterol (mmol/L)	1	X	X	X	X	X	X	333	97.65	0.951048	0.039420	0.050948
2	1	LDL cholesterol (mmol/L)	2	X	X	X	X	X	.	7	2.05	0.721220	0.064987	.
3	1	LDL cholesterol (mmol/L)	3	X	X	X	.	.	.	1	0.29	1.134623	.	.

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=C105588S Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	LDL cholesterol (mmol/L)	Intercept	
2	1	LDL cholesterol (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	LDL cholesterol (mmol/L)	REGION1	EUROPE
4	1	LDL cholesterol (mmol/L)	REGION1	JAPAN
5	1	LDL cholesterol (mmol/L)	BOLAD1	
6	1	LDL cholesterol (mmol/L)	BASE	

Obs		BOLAD1	ObsVal	_1
1			-0.01466	-0.007994
2			-0.12730	-0.133264
3			-0.14877	-0.176605
4			0.27205	0.392210
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.06054	0.136837
6			-0.24321	-0.309312

Parameter Code=C105588S Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	LDL cholesterol (mmol/L)	Intercept			-0.01560	-0.074814
8	1	LDL cholesterol (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)		-0.10726	-0.274408
9	1	LDL cholesterol (mmol/L)	REGION1	EUROPE		0.02094	-0.043777

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=C105588S Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
10	1	LDL cholesterol (mmol/L)	REGION1	JAPAN		0.17826	0.333620
11	1	LDL cholesterol (mmol/L)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.03967	0.033553
12	1	LDL cholesterol (mmol/L)	BASE			-0.22731	-0.184293
13	1	LDL cholesterol (mmol/L)	visit2200			0.40942	0.387463

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The MI Procedure with Monotone Regression
Model Information

Parameter Code=C105588S Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM	Description	Value
1	1	LDL cholesterol (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	LDL cholesterol (mmol/L)	Method	Monotone
3	1	LDL cholesterol (mmol/L)	Number of Imputations	1
4	1	LDL cholesterol (mmol/L)	Seed for random number generator	144802

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The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=C105588S Planned Treatment for Period 30 (N)=4

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1	1	LDL cholesterol (mmol/L)			1	X	X	X	X	X		330	96.49	0.919066	0.043816	0.060755
2	1	LDL cholesterol (mmol/L)			2	X	X	X	X	.		11	3.22	0.994874	0.050884	.
3	1	LDL cholesterol (mmol/L)			3	X	X	X	.	.		1	0.29	0.970779	.	.

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=C105588S Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	LDL cholesterol (mmol/L)	Intercept	
2	1	LDL cholesterol (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	LDL cholesterol (mmol/L)	REGION1	EUROPE
4	1	LDL cholesterol (mmol/L)	REGION1	JAPAN
5	1	LDL cholesterol (mmol/L)	BOLAD1	
6	1	LDL cholesterol (mmol/L)	BASE	

Obs		BOLAD1	ObsVal	_1
1			0.00257	-0.004108
2			0.05272	0.158488
3			-0.00970	0.064455
4			0.02394	-0.080478
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.02535	-0.067272
6			-0.62926	-0.624024

Parameter Code=C105588S Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	LDL cholesterol (mmol/L)	Intercept			-0.01535	0.076158
8	1	LDL cholesterol (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)		-0.09960	-0.009121
9	1	LDL cholesterol (mmol/L)	REGION1	EUROPE		0.05344	0.047627

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=C105588S Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
10	1	LDL cholesterol (mmol/L)	REGION1	JAPAN		0.13386	0.175413
11	1	LDL cholesterol (mmol/L)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.02046	-0.032593
12	1	LDL cholesterol (mmol/L)	BASE			-0.18094	-0.164626
13	1	LDL cholesterol (mmol/L)	visit2200			0.67652	0.657011

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The MI Procedure with MCMC
Model Information

Parameter Code=T_CHOL_U Planned Treatment for Period 30 (N)=2

Obs	PARAM	Description	Value
1	Total cholesterol (mg/dL)	Data Set	WORK.ENDPOINT_PARAM
2	Total cholesterol (mg/dL)	Method	Monotone-data_MCMC
3	Total cholesterol (mg/dL)	Multiple Imputation Chain	Multiple Chains
4	Total cholesterol (mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
5	Total cholesterol (mg/dL)	Start	Starting Value
6	Total cholesterol (mg/dL)	Prior	Jeffreys
7	Total cholesterol (mg/dL)	Number of Imputations	10000
8	Total cholesterol (mg/dL)	Number of Burn-in Iterations	200
9	Total cholesterol (mg/dL)	Seed for random number generator	144500

Parameter Code=T_CHOL_U Planned Treatment for Period 30 (N)=3

Obs	PARAM	Description	Value
10	Total cholesterol (mg/dL)	Data Set	WORK.ENDPOINT_PARAM
11	Total cholesterol (mg/dL)	Method	Monotone-data_MCMC
12	Total cholesterol (mg/dL)	Multiple Imputation Chain	Multiple Chains
13	Total cholesterol (mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
14	Total cholesterol (mg/dL)	Start	Starting Value
15	Total cholesterol (mg/dL)	Prior	Jeffreys
16	Total cholesterol (mg/dL)	Number of Imputations	10000
17	Total cholesterol (mg/dL)	Number of Burn-in Iterations	200
18	Total cholesterol (mg/dL)	Seed for random number generator	593026444

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The MI Procedure with MCMC
Model Information

Parameter Code=T_CHOL_U Planned Treatment for Period 30 (N)=4

Obs	PARAM	Description	Value
19	Total cholesterol (mg/dL)	Data Set	WORK.ENDPOINT_PARAM
20	Total cholesterol (mg/dL)	Method	Monotone-data_MCMC
21	Total cholesterol (mg/dL)	Multiple Imputation Chain	Multiple Chains
22	Total cholesterol (mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
23	Total cholesterol (mg/dL)	Start	Starting Value
24	Total cholesterol (mg/dL)	Prior	Jeffreys
25	Total cholesterol (mg/dL)	Number of Imputations	10000
26	Total cholesterol (mg/dL)	Number of Burn-in Iterations	200
27	Total cholesterol (mg/dL)	Seed for random number generator	656090614

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The MI Procedure with MCMC
Missing data pattern

Parameter Code=T_CHOL_U Planned Treatment for Period 30 (N)=2

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
1	Total cholesterol (mg/dL)	1	X	X	X	328	95.91	5.150077	0.022273	0.001426
2	Total cholesterol (mg/dL)	2	X	X	O	6	1.75	5.107101	-0.001575	.
3	Total cholesterol (mg/dL)	3	X	.	X	6	1.75	5.120558	.	0.039451
4	Total cholesterol (mg/dL)	4	X	O	O	2	0.58	5.120275	.	.

Parameter Code=T_CHOL_U Planned Treatment for Period 30 (N)=3

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
5	Total cholesterol (mg/dL)	1	X	X	X	332	97.36	5.156148	0.030255	0.029428
6	Total cholesterol (mg/dL)	2	X	X	O	7	2.05	5.051777	0.044005	.
7	Total cholesterol (mg/dL)	3	X	.	X	1	0.29	5.029755	.	-0.051825
8	Total cholesterol (mg/dL)	4	X	O	O	1	0.29	5.307923	.	.

Parameter Code=T_CHOL_U Planned Treatment for Period 30 (N)=4

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
9	Total cholesterol (mg/dL)	1	X	X	X	324	94.74	5.153476	0.019979	0.015969
10	Total cholesterol (mg/dL)	2	X	X	O	11	3.22	5.226838	0.049450	.
11	Total cholesterol (mg/dL)	3	X	.	X	6	1.75	4.897076	.	0.166369
12	Total cholesterol (mg/dL)	4	X	O	O	1	0.29	5.236605	.	.

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The MI Procedure with Monotone Regression
Model Information

Parameter Code=T_CHOL_U Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM	Description	Value
1	1	Total cholesterol (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	Total cholesterol (mg/dL)	Method	Monotone
3	1	Total cholesterol (mg/dL)	Number of Imputations	1
4	1	Total cholesterol (mg/dL)	Seed for random number generator	144800

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The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=T_CHOL_U Planned Treatment for Period 30 (N)=2

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1	1	Total cholesterol (mg/dL)	1	X	X	X	X	X	334	97.66	5.149547	0.022651	0.002109
2	1	Total cholesterol (mg/dL)	2	X	X	X	X	.	6	1.75	5.107101	-0.001575	.
3	1	Total cholesterol (mg/dL)	3	X	X	X	.	.	2	0.58	5.120275	.	.

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=T_CHOL_U Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	Total cholesterol (mg/dL)	Intercept	
2	1	Total cholesterol (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	Total cholesterol (mg/dL)	REGION1	EUROPE
4	1	Total cholesterol (mg/dL)	REGION1	JAPAN
5	1	Total cholesterol (mg/dL)	BOLAD1	
6	1	Total cholesterol (mg/dL)	BASE	

Obs		BOLAD1	ObsVal	_1
1			-0.04689	0.009001
2			-0.36582	-0.492190
3			0.13900	0.260933
4			0.31425	0.401482
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.01480	-0.069428
6			-0.34032	-0.394892

Parameter Code=T_CHOL_U Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	Total cholesterol (mg/dL)	Intercept			-0.04978	-0.038204
8	1	Total cholesterol (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)		-0.31829	-0.317943
9	1	Total cholesterol (mg/dL)	REGION1	EUROPE		0.14229	0.211290

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=T_CHOL_U Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
10	1	Total cholesterol (mg/dL)	REGION1	JAPAN		0.26390	0.269280
11	1	Total cholesterol (mg/dL)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.03953	0.003465
12	1	Total cholesterol (mg/dL)	BASE			-0.14895	-0.145680
13	1	Total cholesterol (mg/dL)	visit2200			0.55622	0.524609

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The MI Procedure with Monotone Regression
Model Information

Parameter Code=T_CHOL_U Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM	Description	Value
1	1	Total cholesterol (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	Total cholesterol (mg/dL)	Method	Monotone
3	1	Total cholesterol (mg/dL)	Number of Imputations	1
4	1	Total cholesterol (mg/dL)	Seed for random number generator	144801

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The MI Procedure with Monotone Regression Missing Data Pattern

Parameter Code=T_CHOL U Planned Treatment for Period 30 (N)=3

Obs	I m p u t a t i o n _	P A R A M	G r o u p	R E G I O N 1					B O L A S S E					v i s i t 2		v i s i t 3		P e r c e n t	B A S E	v i s i t 2	v i s i t 3
				M _	M _	M _	M _	M _	F r e q	M _	M _	M _	M _	M _							
1	1	Total cholesterol (mg/dL)	1	X	X	X	X	X	333	97.65	5.155768	0.030264	0.029184								
2	1	Total cholesterol (mg/dL)	2	X	X	X	X	.	7	2.05	5.051777	0.044005	.								
3	1	Total cholesterol (mg/dL)	3	X	X	X	.	.	1	0.29	5.307923	.	.								

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=T_CHOL_U Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	Total cholesterol (mg/dL)	Intercept	
2	1	Total cholesterol (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	Total cholesterol (mg/dL)	REGION1	EUROPE
4	1	Total cholesterol (mg/dL)	REGION1	JAPAN
5	1	Total cholesterol (mg/dL)	BOLAD1	
6	1	Total cholesterol (mg/dL)	BASE	

Obs		BOLAD1	ObsVal	_1
1			-0.06577	-0.059119
2			-0.38508	-0.391054
3			0.07594	0.048048
4			0.36653	0.488553
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.04273	0.118132
6			-0.25838	-0.331855

Parameter Code=T_CHOL_U Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	Total cholesterol (mg/dL)	Intercept			-0.02077	-0.078340
8	1	Total cholesterol (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)		-0.16335	-0.329481
9	1	Total cholesterol (mg/dL)	REGION1	EUROPE		0.0001786	-0.061601

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Lipids 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=T_CHOL_U Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
10	1	Total cholesterol (mg/dL)	REGION1	JAPAN		0.29927	0.457359
11	1	Total cholesterol (mg/dL)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.02410	0.016455
12	1	Total cholesterol (mg/dL)	BASE			-0.27153	-0.245047
13	1	Total cholesterol (mg/dL)	visit2200			0.41445	0.390094

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Fast-acting insulin aspart
NN1218-4131

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Lipids 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=T_CHOL_U Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM	Description	Value
1	1	Total cholesterol (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	Total cholesterol (mg/dL)	Method	Monotone
3	1	Total cholesterol (mg/dL)	Number of Imputations	1
4	1	Total cholesterol (mg/dL)	Seed for random number generator	144802

nn1218/nn1218-4131/ctr_20180214_er
09FEB2018:20:27:21 - a_stat_ratio.sas/a_lip_stat_in_fas_app.txt

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nn1218/nn1218-4131/ctr_20180214_er
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Fast-acting insulin aspart
NN1218-4131

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=T_CHOL_U Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	Total cholesterol (mg/dL)	Intercept	
2	1	Total cholesterol (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	Total cholesterol (mg/dL)	REGION1	EUROPE
4	1	Total cholesterol (mg/dL)	REGION1	JAPAN
5	1	Total cholesterol (mg/dL)	BOLAD1	
6	1	Total cholesterol (mg/dL)	BASE	

Obs		BOLAD1	ObsVal	_1
1			-0.00949	-0.017205
2			-0.20105	-0.078282
3			0.03177	0.117310
4			0.23624	0.113336
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.04721	-0.154044
6			-0.43757	-0.424651

Parameter Code=T_CHOL_U Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	Total cholesterol (mg/dL)	Intercept			-0.02764	0.092029
8	1	Total cholesterol (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)		-0.20078	-0.080281
9	1	Total cholesterol (mg/dL)	REGION1	EUROPE		-0.01455	-0.022530

nn1218/nn1218-4131/ctr_20180214_er
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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=T_CHOL_U Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
10	1	Total cholesterol (mg/dL)	REGION1	JAPAN		0.20340	0.255843
11	1	Total cholesterol (mg/dL)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.05295	-0.017076
12	1	Total cholesterol (mg/dL)	BASE			-0.14734	-0.128193
13	1	Total cholesterol (mg/dL)	visit2200			0.56442	0.530202

nn1218/nn1218-4131/ctr_20180214_er
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The MI Procedure with MCMC
Model Information

Parameter Code=C105586S Planned Treatment for Period 30 (N)=2

Obs	PARAM	Description	Value
1	Total cholesterol (mmol/L)	Data Set	WORK.ENDPOINT_PARAM
2	Total cholesterol (mmol/L)	Method	Monotone-data_MCMC
3	Total cholesterol (mmol/L)	Multiple Imputation Chain	Multiple Chains
4	Total cholesterol (mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
5	Total cholesterol (mmol/L)	Start	Starting Value
6	Total cholesterol (mmol/L)	Prior	Jeffreys
7	Total cholesterol (mmol/L)	Number of Imputations	10000
8	Total cholesterol (mmol/L)	Number of Burn-in Iterations	200
9	Total cholesterol (mmol/L)	Seed for random number generator	144500

Parameter Code=C105586S Planned Treatment for Period 30 (N)=3

Obs	PARAM	Description	Value
10	Total cholesterol (mmol/L)	Data Set	WORK.ENDPOINT_PARAM
11	Total cholesterol (mmol/L)	Method	Monotone-data_MCMC
12	Total cholesterol (mmol/L)	Multiple Imputation Chain	Multiple Chains
13	Total cholesterol (mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
14	Total cholesterol (mmol/L)	Start	Starting Value
15	Total cholesterol (mmol/L)	Prior	Jeffreys
16	Total cholesterol (mmol/L)	Number of Imputations	10000
17	Total cholesterol (mmol/L)	Number of Burn-in Iterations	200
18	Total cholesterol (mmol/L)	Seed for random number generator	593026444

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The MI Procedure with MCMC
Model Information

Parameter Code=C105586S Planned Treatment for Period 30 (N)=4

Obs	PARAM	Description	Value
19	Total cholesterol (mmol/L)	Data Set	WORK.ENDPOINT_PARAM
20	Total cholesterol (mmol/L)	Method	Monotone-data_MCMC
21	Total cholesterol (mmol/L)	Multiple Imputation Chain	Multiple Chains
22	Total cholesterol (mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
23	Total cholesterol (mmol/L)	Start	Starting Value
24	Total cholesterol (mmol/L)	Prior	Jeffreys
25	Total cholesterol (mmol/L)	Number of Imputations	10000
26	Total cholesterol (mmol/L)	Number of Burn-in Iterations	200
27	Total cholesterol (mmol/L)	Seed for random number generator	656090614

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The MI Procedure with MCMC
Missing data pattern

Parameter Code=C105586S Planned Treatment for Period 30 (N)=2

Obs	PARAM	Group	BASE_ Miss_	visit2200_ Miss_	visit3600_ Miss_	Freq	Percent	BASE	visit2200	visit3600
1	Total cholesterol (mmol/L)	1	X	X	X	328	95.91	1.496566	0.022273	0.001426
2	Total cholesterol (mmol/L)	2	X	X	O	6	1.75	1.453590	-0.001575	.
3	Total cholesterol (mmol/L)	3	X	.	X	6	1.75	1.467046	.	0.039451
4	Total cholesterol (mmol/L)	4	X	O	O	2	0.58	1.466764	.	.

Parameter Code=C105586S Planned Treatment for Period 30 (N)=3

Obs	PARAM	Group	BASE_ Miss_	visit2200_ Miss_	visit3600_ Miss_	Freq	Percent	BASE	visit2200	visit3600
5	Total cholesterol (mmol/L)	1	X	X	X	332	97.36	1.502636	0.030255	0.029428
6	Total cholesterol (mmol/L)	2	X	X	O	7	2.05	1.398266	0.044005	.
7	Total cholesterol (mmol/L)	3	X	.	X	1	0.29	1.376244	.	-0.051825
8	Total cholesterol (mmol/L)	4	X	O	O	1	0.29	1.654411	.	.

Parameter Code=C105586S Planned Treatment for Period 30 (N)=4

Obs	PARAM	Group	BASE_ Miss_	visit2200_ Miss_	visit3600_ Miss_	Freq	Percent	BASE	visit2200	visit3600
9	Total cholesterol (mmol/L)	1	X	X	X	324	94.74	1.499965	0.019979	0.015969
10	Total cholesterol (mmol/L)	2	X	X	O	11	3.22	1.573327	0.049450	.
11	Total cholesterol (mmol/L)	3	X	.	X	6	1.75	1.243564	.	0.166369
12	Total cholesterol (mmol/L)	4	X	O	O	1	0.29	1.583094	.	.

nn1218/nn1218-4131/ctr_20180214_er
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The MI Procedure with Monotone Regression
Model Information

Parameter Code=C105586S Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM	Description	Value
1	1	Total cholesterol (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	Total cholesterol (mmol/L)	Method	Monotone
3	1	Total cholesterol (mmol/L)	Number of Imputations	1
4	1	Total cholesterol (mmol/L)	Seed for random number generator	144800

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The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=C105586S Planned Treatment for Period 30 (N)=2

O b s	I m p u t a t i o n	P A R A M	G r o u p	R E G I O N 1	E B O L 1	B O L 1	B O L 1	B O L 1	B O L 1	F r e q	P e r c e n t	B A S E	v i s i t 2 0 0	v i s i t 3 6 0 0
1	1	Total cholesterol (mmol/L)	1	X	X	X	X	X	X	334	97.66	1.496035	0.022651	0.002109
2	1	Total cholesterol (mmol/L)	2	X	X	X	X	X	.	6	1.75	1.453590	-0.001575	.
3	1	Total cholesterol (mmol/L)	3	X	X	X	.	.	.	2	0.58	1.466764	.	.

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=C105586S Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	Total cholesterol (mmol/L)	Intercept	
2	1	Total cholesterol (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	Total cholesterol (mmol/L)	REGION1	EUROPE
4	1	Total cholesterol (mmol/L)	REGION1	JAPAN
5	1	Total cholesterol (mmol/L)	BOLAD1	
6	1	Total cholesterol (mmol/L)	BASE	

Obs		BOLAD1	ObsVal	_1
1			-0.04689	0.009001
2			-0.36582	-0.492190
3			0.13900	0.260933
4			0.31425	0.401482
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.01480	-0.069428
6			-0.34032	-0.394892

Parameter Code=C105586S Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	Total cholesterol (mmol/L)	Intercept			-0.04978	-0.038204
8	1	Total cholesterol (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)		-0.31829	-0.317943
9	1	Total cholesterol (mmol/L)	REGION1	EUROPE		0.14229	0.211290

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=C105586S Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
10	1	Total cholesterol (mmol/L)	REGION1	JAPAN		0.26390	0.269280
11	1	Total cholesterol (mmol/L)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.03953	0.003465
12	1	Total cholesterol (mmol/L)	BASE			-0.14895	-0.145680
13	1	Total cholesterol (mmol/L)	visit2200			0.55622	0.524609

nn1218/nn1218-4131/ctr_20180214_er
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The MI Procedure with Monotone Regression
Model Information

Parameter Code=C105586S Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM	Description	Value
1	1	Total cholesterol (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	Total cholesterol (mmol/L)	Method	Monotone
3	1	Total cholesterol (mmol/L)	Number of Imputations	1
4	1	Total cholesterol (mmol/L)	Seed for random number generator	144801

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Lipids 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=C105586S Planned Treatment for Period 30 (N)=3

O b s	I m p u t a t i o n _	P A R A M _	G r o u p	R E G I O N 1	B O L 1	B L A D 1	B L A D 2	B L A D 3	B L A D 4	F r e q	P e r c e n t	B A S E	v i s i t 2 0 0	v i s i t 3 6 0 0
1	1	Total cholesterol (mmol/L)	1	X	X	X	X	X		333	97.65	1.502257	0.030264	0.029184
2	1	Total cholesterol (mmol/L)	2	X	X	X	X	.		7	2.05	1.398266	0.044005	.
3	1	Total cholesterol (mmol/L)	3	X	X	X	.	.		1	0.29	1.654411	.	.

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=C105586S Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	Total cholesterol (mmol/L)	Intercept	
2	1	Total cholesterol (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	Total cholesterol (mmol/L)	REGION1	EUROPE
4	1	Total cholesterol (mmol/L)	REGION1	JAPAN
5	1	Total cholesterol (mmol/L)	BOLAD1	
6	1	Total cholesterol (mmol/L)	BASE	

Obs		BOLAD1	ObsVal	_1
1			-0.06577	-0.059119
2			-0.38508	-0.391054
3			0.07594	0.048048
4			0.36653	0.488553
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.04273	0.118132
6			-0.25838	-0.331855

Parameter Code=C105586S Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	Total cholesterol (mmol/L)	Intercept			-0.02077	-0.078340
8	1	Total cholesterol (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)		-0.16335	-0.329481
9	1	Total cholesterol (mmol/L)	REGION1	EUROPE		0.0001786	-0.061601

nn1218/nn1218-4131/ctr_20180214_er
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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=C105586S Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
10	1	Total cholesterol (mmol/L)	REGION1	JAPAN		0.29927	0.457359
11	1	Total cholesterol (mmol/L)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.02410	0.016455
12	1	Total cholesterol (mmol/L)	BASE			-0.27153	-0.245047
13	1	Total cholesterol (mmol/L)	visit2200			0.41445	0.390094

nn1218/nn1218-4131/ctr_20180214_er
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The MI Procedure with Monotone Regression
Model Information

Parameter Code=C105586S Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM	Description	Value
1	1	Total cholesterol (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	Total cholesterol (mmol/L)	Method	Monotone
3	1	Total cholesterol (mmol/L)	Number of Imputations	1
4	1	Total cholesterol (mmol/L)	Seed for random number generator	144802

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Lipids 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=C105586S Planned Treatment for Period 30 (N)=4

O b s	I m p u t a t i o n _	P A R A M _	G r o u p	R E G I O N 1	E B O L A 1	B O L A 1	B O L A 1	B O L A 1	B O L A 1	F r e q	P e r c e n t	B A S E	v i s i t 2 0 0	v i s i t 3 6 0 0
1	1	Total cholesterol (mmol/L)	1	X	X	X	X	X	X	330	96.49	1.495303	0.022471	0.018703
2	1	Total cholesterol (mmol/L)	2	X	X	X	X	X	.	11	3.22	1.573327	0.049450	.
3	1	Total cholesterol (mmol/L)	3	X	X	X	.	.	.	1	0.29	1.583094	.	.

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=C105586S Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	Total cholesterol (mmol/L)	Intercept	
2	1	Total cholesterol (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	Total cholesterol (mmol/L)	REGION1	EUROPE
4	1	Total cholesterol (mmol/L)	REGION1	JAPAN
5	1	Total cholesterol (mmol/L)	BOLAD1	
6	1	Total cholesterol (mmol/L)	BASE	

Obs		BOLAD1	ObsVal	_1
1			-0.00949	-0.017205
2			-0.20105	-0.078282
3			0.03177	0.117310
4			0.23624	0.113336
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.04721	-0.154044
6			-0.43757	-0.424651

Parameter Code=C105586S Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	Total cholesterol (mmol/L)	Intercept			-0.02764	0.092029
8	1	Total cholesterol (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)		-0.20078	-0.080281
9	1	Total cholesterol (mmol/L)	REGION1	EUROPE		-0.01455	-0.022530

nn1218/nn1218-4131/ctr_20180214_er
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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=C105586S Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
10	1	Total cholesterol (mmol/L)	REGION1	JAPAN		0.20340	0.255843
11	1	Total cholesterol (mmol/L)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.05295	-0.017076
12	1	Total cholesterol (mmol/L)	BASE			-0.14734	-0.128193
13	1	Total cholesterol (mmol/L)	visit2200			0.56442	0.530202

nn1218/nn1218-4131/ctr_20180214_er
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The Mixed procedure
Model Information

Parameter Code=C105586S Parameter=Total cholesterol (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Data Set	WORK.IMPUTE
2	1	NN1218-4131	Dependent Variable	eotVisit
3	1	NN1218-4131	Covariance Structure	Diagonal
4	1	NN1218-4131	Estimation Method	REML
5	1	NN1218-4131	Residual Variance Method	Profile
6	1	NN1218-4131	Fixed Effects SE Method	Model-Based
7	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=C105587S Parameter=HDL cholesterol (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
8	1	NN1218-4131	Data Set	WORK.IMPUTE
9	1	NN1218-4131	Dependent Variable	eotVisit
10	1	NN1218-4131	Covariance Structure	Diagonal
11	1	NN1218-4131	Estimation Method	REML
12	1	NN1218-4131	Residual Variance Method	Profile
13	1	NN1218-4131	Fixed Effects SE Method	Model-Based
14	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=C105588S Parameter=LDL cholesterol (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
15	1	NN1218-4131	Data Set	WORK.IMPUTE
16	1	NN1218-4131	Dependent Variable	eotVisit
17	1	NN1218-4131	Covariance Structure	Diagonal

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Parameter Code=C105588S Parameter=LDL cholesterol (mmol/L)

(continued)

Obs	_Imputation_	STUDYID	Descr	Value
18	1	NN1218-4131	Estimation Method	REML
19	1	NN1218-4131	Residual Variance Method	Profile
20	1	NN1218-4131	Fixed Effects SE Method	Model-Based
21	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=HDL_SU Parameter=HDL cholesterol (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
22	1	NN1218-4131	Data Set	WORK.IMPUTE
23	1	NN1218-4131	Dependent Variable	eotVisit
24	1	NN1218-4131	Covariance Structure	Diagonal
25	1	NN1218-4131	Estimation Method	REML
26	1	NN1218-4131	Residual Variance Method	Profile
27	1	NN1218-4131	Fixed Effects SE Method	Model-Based
28	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=LDL_SU Parameter=LDL cholesterol (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
29	1	NN1218-4131	Data Set	WORK.IMPUTE
30	1	NN1218-4131	Dependent Variable	eotVisit
31	1	NN1218-4131	Covariance Structure	Diagonal
32	1	NN1218-4131	Estimation Method	REML

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Model Information

Parameter Code=LDL_SU Parameter=LDL cholesterol (mg/dL)

(continued)

Obs	_Imputation_	STUDYID	Descr	Value
33	1	NN1218-4131	Residual Variance Method	Profile
34	1	NN1218-4131	Fixed Effects SE Method	Model-Based
35	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=T_CHOL_U Parameter=Total cholesterol (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
36	1	NN1218-4131	Data Set	WORK.IMPUTE
37	1	NN1218-4131	Dependent Variable	eotVisit
38	1	NN1218-4131	Covariance Structure	Diagonal
39	1	NN1218-4131	Estimation Method	REML
40	1	NN1218-4131	Residual Variance Method	Profile
41	1	NN1218-4131	Fixed Effects SE Method	Model-Based
42	1	NN1218-4131	Degrees of Freedom Method	Residual

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The Mixed procedure
Class Level Information

Parameter Code=C105586S Parameter=Total cholesterol (mmol/L)

O b s		I m p u t a t i o n s		S t a t i s t i c s		L e v e l s		V a r i a t i o n s		m i n	
1	1	NN1218-4131	TRTPN	3	2	3	4			5	
2	1	NN1218-4131	REGION1	4	ASIA (EXCLUDING JAPAN)	EUROPE	JAPAN	NORTH AMERICA		49	
3	1	NN1218-4131	BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	CARBOHYDRATE COUNTING (FLEXIBLE)	BOLUS INSULI			85	

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The Mixed procedure
Class Level Information

Parameter Code=C105587S Parameter=HDL cholesterol (mmol/L)

		Input		Study		Level		Variable		Minimum	
		Obs		n		Y		I		D	
4	1	NN1218-4131	TRTPN	3	2	3	4				5
5	1	NN1218-4131	REGION1	4	ASIA (EXCLUDING JAPAN)	EUROPE	JAPAN	NORTH AMERICA			49
6	1	NN1218-4131	BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	CARBOHYDRATE COUNTING (FLEXIBLE)	BOLUS INSULI				85

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The Mixed procedure
Class Level Information

Parameter Code=C105588S Parameter=LDL cholesterol (mmol/L)

Ob- s	—	Input on ID	STUDY ID	Class s	Level s	Val ues	mi n T e g r a t e d
7	1	NN1218-4131	TRTPN		3 2 3 4		5
8	1	NN1218-4131	REGION1		4 ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA		49
9	1	NN1218-4131	BOLAD1		2 BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULI		85

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The Mixed procedure
Class Level Information

Parameter Code=HDL_SU Parameter=HDL cholesterol (mg/dL)

Obs	Inpution	STUDY ID	Classs	Level	Values	Unit
10	1	NN1218-4131	TRTPN	3 2 3 4		5
11	1	NN1218-4131	REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA	49
12	1	NN1218-4131	BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULI	85

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The Mixed procedure
Class Level Information

Parameter Code=LDL_SU Parameter=LDL cholesterol (mg/dL)

		Input		SUT		CL		Lev		V		Level		m	
		Obs		n		Y		I		e		u		g	
		s		—		D		s		s		s		t	
														h	
13	1	NN1218-4131	TRTPN					3	2	3	4				5
14	1	NN1218-4131	REGION1					4	ASIA (EXCLUDING JAPAN)	EUROPE	JAPAN	NORTH AMERICA			49
15	1	NN1218-4131	BOLAD1					2	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	CARBOHYDRATE COUNTING (FLEXIBLE)	BOLUS	INSULI			85

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The Mixed procedure
Class Level Information

Parameter Code=T_CHOL_U Parameter=Total cholesterol (mg/dL)

		Input		Stat		Level		Variable		Minimum	
		Obs		on		Y		I		e	
		s		-		D		s		s	
16	1	NN1218-4131	TRTPN	3	2	3	4				5
17	1	NN1218-4131	REGION1	4	ASIA (EXCLUDING JAPAN)	EUROPE	JAPAN	NORTH AMERICA			49
18	1	NN1218-4131	BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	CARBOHYDRATE COUNTING (FLEXIBLE)	BOLUS INSULI				85

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The Mixed procedure
Dimensions

Parameter Code=C105586S Parameter=Total cholesterol (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Covariance Parameters	1
2	1	NN1218-4131	Columns in X	10
3	1	NN1218-4131	Columns in Z	0
4	1	NN1218-4131	Subjects	1
5	1	NN1218-4131	Max Obs per Subject	1025

Parameter Code=C105587S Parameter=HDL cholesterol (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
6	1	NN1218-4131	Covariance Parameters	1
7	1	NN1218-4131	Columns in X	10
8	1	NN1218-4131	Columns in Z	0
9	1	NN1218-4131	Subjects	1
10	1	NN1218-4131	Max Obs per Subject	1025

Parameter Code=C105588S Parameter=LDL cholesterol (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
11	1	NN1218-4131	Covariance Parameters	1
12	1	NN1218-4131	Columns in X	10
13	1	NN1218-4131	Columns in Z	0
14	1	NN1218-4131	Subjects	1
15	1	NN1218-4131	Max Obs per Subject	1025

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The Mixed procedure
Dimensions

Parameter Code=HDL_SU Parameter=HDL cholesterol (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
16	1	NN1218-4131	Covariance Parameters	1
17	1	NN1218-4131	Columns in X	10
18	1	NN1218-4131	Columns in Z	0
19	1	NN1218-4131	Subjects	1
20	1	NN1218-4131	Max Obs per Subject	1025

Parameter Code=LDL_SU Parameter=LDL cholesterol (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
21	1	NN1218-4131	Covariance Parameters	1
22	1	NN1218-4131	Columns in X	10
23	1	NN1218-4131	Columns in Z	0
24	1	NN1218-4131	Subjects	1
25	1	NN1218-4131	Max Obs per Subject	1025

Parameter Code=T_CHOL_U Parameter=Total cholesterol (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
26	1	NN1218-4131	Covariance Parameters	1
27	1	NN1218-4131	Columns in X	10
28	1	NN1218-4131	Columns in Z	0
29	1	NN1218-4131	Subjects	1
30	1	NN1218-4131	Max Obs per Subject	1025

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Number of Observations

Parameter Code=C105586S Parameter=Total cholesterol (mmol/L)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
1	1	NN1218-4131	Number of Observations Read	1025	1025	1025	1025	1025
2	1	NN1218-4131	Number of Observations Used	1025	1025	1025	1025	1025
3	1	NN1218-4131	Number of Observations Not Used	0	1025	1025	1025	1025

Parameter Code=C105587S Parameter=HDL cholesterol (mmol/L)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
4	1	NN1218-4131	Number of Observations Read	1025	1025	1025	1025	1025
5	1	NN1218-4131	Number of Observations Used	1025	1025	1025	1025	1025
6	1	NN1218-4131	Number of Observations Not Used	0	1025	1025	1025	1025

Parameter Code=C105588S Parameter=LDL cholesterol (mmol/L)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
7	1	NN1218-4131	Number of Observations Read	1025	1025	1025	1025	1025
8	1	NN1218-4131	Number of Observations Used	1025	1025	1025	1025	1025
9	1	NN1218-4131	Number of Observations Not Used	0	1025	1025	1025	1025

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The Mixed procedure
Number of Observations

Parameter Code=HDL_SU Parameter=HDL cholesterol (mg/dL)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
10	1	NN1218-4131	Number of Observations Read	1025	1025	1025	1025	1025
11	1	NN1218-4131	Number of Observations Used	1025	1025	1025	1025	1025
12	1	NN1218-4131	Number of Observations Not Used	0	1025	1025	1025	1025

Parameter Code=LDL_SU Parameter=LDL cholesterol (mg/dL)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
13	1	NN1218-4131	Number of Observations Read	1025	1025	1025	1025	1025
14	1	NN1218-4131	Number of Observations Used	1025	1025	1025	1025	1025
15	1	NN1218-4131	Number of Observations Not Used	0	1025	1025	1025	1025

Parameter Code=T_CHOL_U Parameter=Total cholesterol (mg/dL)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
16	1	NN1218-4131	Number of Observations Read	1025	1025	1025	1025	1025
17	1	NN1218-4131	Number of Observations Used	1025	1025	1025	1025	1025
18	1	NN1218-4131	Number of Observations Not Used	0	1025	1025	1025	1025

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Covariance Parameter Estimates

Parameter Code=C105586S Parameter=Total cholesterol (mmol/L)

Obs	_Imputation_	STUDYID	CovParm	Estimate
1	1	NN1218-4131	Residual	0.01976

Parameter Code=C105587S Parameter=HDL cholesterol (mmol/L)

Obs	_Imputation_	STUDYID	CovParm	Estimate
10001	1	NN1218-4131	Residual	0.02965

Parameter Code=C105588S Parameter=LDL cholesterol (mmol/L)

Obs	_Imputation_	STUDYID	CovParm	Estimate
20001	1	NN1218-4131	Residual	0.04312

Parameter Code=HDL_SU Parameter=HDL cholesterol (mg/dL)

Obs	_Imputation_	STUDYID	CovParm	Estimate
30001	1	NN1218-4131	Residual	0.02965

Parameter Code=LDL_SU Parameter=LDL cholesterol (mg/dL)

Obs	_Imputation_	STUDYID	CovParm	Estimate
40001	1	NN1218-4131	Residual	0.04312

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The Mixed procedure
Covariance Parameter Estimates

Parameter Code=T_CHOL_U Parameter=Total cholesterol (mg/dL)

Obs	_Imputation_	STUDYID	CovParm	Estimate
50001	1	NN1218-4131	Residual	0.01976

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The Mixed procedure
Fit Statistics

Parameter Code=C105586S Parameter=Total cholesterol (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	-2 Res Log Likelihood	-1063.1
2	1	NN1218-4131	AIC (Smaller is Better)	-1061.1
3	1	NN1218-4131	AICC (Smaller is Better)	-1061.1
4	1	NN1218-4131	BIC (Smaller is Better)	-1056.1

Parameter Code=C105587S Parameter=HDL cholesterol (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
5	1	NN1218-4131	-2 Res Log Likelihood	-649.7
6	1	NN1218-4131	AIC (Smaller is Better)	-647.7
7	1	NN1218-4131	AICC (Smaller is Better)	-647.7
8	1	NN1218-4131	BIC (Smaller is Better)	-642.8

Parameter Code=C105588S Parameter=LDL cholesterol (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
9	1	NN1218-4131	-2 Res Log Likelihood	-268.7
10	1	NN1218-4131	AIC (Smaller is Better)	-266.7
11	1	NN1218-4131	AICC (Smaller is Better)	-266.7
12	1	NN1218-4131	BIC (Smaller is Better)	-261.7

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Fit Statistics

Parameter Code=HDL_SU Parameter=HDL cholesterol (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
13	1	NN1218-4131	-2 Res Log Likelihood	-649.7
14	1	NN1218-4131	AIC (Smaller is Better)	-647.7
15	1	NN1218-4131	AICC (Smaller is Better)	-647.7
16	1	NN1218-4131	BIC (Smaller is Better)	-642.8

Parameter Code=LDL_SU Parameter=LDL cholesterol (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
17	1	NN1218-4131	-2 Res Log Likelihood	-268.7
18	1	NN1218-4131	AIC (Smaller is Better)	-266.7
19	1	NN1218-4131	AICC (Smaller is Better)	-266.7
20	1	NN1218-4131	BIC (Smaller is Better)	-261.7

Parameter Code=T_CHOL_U Parameter=Total cholesterol (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
21	1	NN1218-4131	-2 Res Log Likelihood	-1063.1
22	1	NN1218-4131	AIC (Smaller is Better)	-1061.1
23	1	NN1218-4131	AICC (Smaller is Better)	-1061.1
24	1	NN1218-4131	BIC (Smaller is Better)	-1056.1

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The Mixed procedure
Solution for Fixed Effects

Parameter Code=C105586S Parameter=Total cholesterol (mmol/L)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
1	1	NN1218-4131	TRTPN	2				
2	1	NN1218-4131	TRTPN	3				
3	1	NN1218-4131	TRTPN	4				
4	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
5	1	NN1218-4131	REGION1	—	EUROPE			
6	1	NN1218-4131	REGION1	—	JAPAN			
7	1	NN1218-4131	REGION1	—	NORTH AMERICA			
8	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
9	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
10	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	0.3997	0.03483	1017	11.48	<.0001	0.05	0.3314	0.4681
2	0.4247	0.03488	1017	12.18	<.0001	0.05	0.3563	0.4932
3	0.4160	0.03494	1017	11.91	<.0001	0.05	0.3474	0.4846
4	-0.04173	0.01605	1017	-2.60	0.0094	0.05	-0.07321	-0.01024
5	0.02922	0.01132	1017	2.58	0.0100	0.05	0.007000	0.05143
6	0.07831	0.01287	1017	6.08	<.0001	0.05	0.05306	0.1036
7	0
8	0.01113	0.009849	1017	1.13	0.2589	0.05	-0.00820	0.03045
9	0
10	-0.2845	0.02260	1017	-12.59	<.0001	0.05	-0.3289	-0.2402

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The Mixed procedure
Solution for Fixed Effects

Parameter Code=C105587S Parameter=HDL cholesterol (mmol/L)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
11	1	NN1218-4131	TRTPN	2				
12	1	NN1218-4131	TRTPN	3				
13	1	NN1218-4131	TRTPN	4				
14	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
15	1	NN1218-4131	REGION1	—	EUROPE			
16	1	NN1218-4131	REGION1	—	JAPAN			
17	1	NN1218-4131	REGION1	—	NORTH AMERICA			
18	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
19	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
20	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
11	0.03635	0.01513	1017	2.40	0.0165	0.05	0.006652	0.06604
12	0.04901	0.01525	1017	3.21	0.0013	0.05	0.01909	0.07893
13	0.05029	0.01535	1017	3.28	0.0011	0.05	0.02016	0.08041
14	0.02420	0.01970	1017	1.23	0.2195	0.05	-0.01445	0.06285
15	0.02287	0.01384	1017	1.65	0.0987	0.05	-0.00428	0.05003
16	0.1030	0.01605	1017	6.42	<.0001	0.05	0.07156	0.1345
17	0
18	-0.02111	0.01208	1017	-1.75	0.0807	0.05	-0.04482	0.002586
19	0
20	-0.1716	0.01867	1017	-9.19	<.0001	0.05	-0.2082	-0.1350

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The Mixed procedure
Solution for Fixed Effects

Parameter Code=C105588S Parameter=LDL cholesterol (mmol/L)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1			BOLAD1
21	1	NN1218-4131	TRTPN	2				
22	1	NN1218-4131	TRTPN	3				
23	1	NN1218-4131	TRTPN	4				
24	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
25	1	NN1218-4131	REGION1	—	EUROPE			
26	1	NN1218-4131	REGION1	—	JAPAN			
27	1	NN1218-4131	REGION1	—	NORTH AMERICA			
28	1	NN1218-4131	BOLAD1	—				BOLUS INSULIN ALGORITHM (SLIDING SCALE)
29	1	NN1218-4131	BOLAD1	—				CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY
30	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
21	0.3134	0.02409	1017	13.01	<.0001	0.05	0.2662	0.3607
22	0.3407	0.02435	1017	13.99	<.0001	0.05	0.2930	0.3885
23	0.3422	0.02408	1017	14.21	<.0001	0.05	0.2950	0.3895
24	-0.00730	0.02367	1017	-0.31	0.7578	0.05	-0.05376	0.03915
25	0.04916	0.01671	1017	2.94	0.0033	0.05	0.01637	0.08194
26	0.09804	0.01880	1017	5.21	<.0001	0.05	0.06115	0.1349
27	0
28	0.02266	0.01455	1017	1.56	0.1196	0.05	-0.00588	0.05121
29	0
30	-0.3626	0.02049	1017	-17.69	<.0001	0.05	-0.4028	-0.3223

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Solution for Fixed Effects

Parameter Code=HDL_SU Parameter=HDL cholesterol (mg/dL)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
31	1	NN1218-4131	TRTPN	2				
32	1	NN1218-4131	TRTPN	3				
33	1	NN1218-4131	TRTPN	4				
34	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
35	1	NN1218-4131	REGION1	—	EUROPE			
36	1	NN1218-4131	REGION1	—	JAPAN			
37	1	NN1218-4131	REGION1	—	NORTH AMERICA			
38	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
39	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
40	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
31	0.6633	0.07707	1017	8.61	<.0001	0.05	0.5121	0.8145
32	0.6760	0.07704	1017	8.77	<.0001	0.05	0.5248	0.8272
33	0.6772	0.07707	1017	8.79	<.0001	0.05	0.5260	0.8285
34	0.02420	0.01970	1017	1.23	0.2195	0.05	-0.01445	0.06285
35	0.02287	0.01384	1017	1.65	0.0987	0.05	-0.00428	0.05003
36	0.1030	0.01605	1017	6.42	<.0001	0.05	0.07156	0.1345
37	0
38	-0.02111	0.01208	1017	-1.75	0.0807	0.05	-0.04482	0.002586
39	0
40	-0.1716	0.01867	1017	-9.19	<.0001	0.05	-0.2082	-0.1350

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The Mixed procedure
Solution for Fixed Effects

Parameter Code=LDL_SU Parameter=LDL cholesterol (mg/dL)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
41	1	NN1218-4131	TRTPN	2				
42	1	NN1218-4131	TRTPN	3				
43	1	NN1218-4131	TRTPN	4				
44	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
45	1	NN1218-4131	REGION1	—	EUROPE			
46	1	NN1218-4131	REGION1	—	JAPAN			
47	1	NN1218-4131	REGION1	—	NORTH AMERICA			
48	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
49	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
50	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
41	1.6380	0.09448	1017	17.34	<.0001	0.05	1.4527	1.8234
42	1.6653	0.09467	1017	17.59	<.0001	0.05	1.4796	1.8511
43	1.6668	0.09422	1017	17.69	<.0001	0.05	1.4819	1.8517
44	-0.00730	0.02367	1017	-0.31	0.7578	0.05	-0.05376	0.03915
45	0.04916	0.01671	1017	2.94	0.0033	0.05	0.01637	0.08194
46	0.09804	0.01880	1017	5.21	<.0001	0.05	0.06115	0.1349
47	0
48	0.02266	0.01455	1017	1.56	0.1196	0.05	-0.00588	0.05121
49	0
50	-0.3626	0.02049	1017	-17.69	<.0001	0.05	-0.4028	-0.3223

nn1218/nn1218-4131/ctr_20180214_er
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Parameter Code=T_CHOL_U Parameter=Total cholesterol (mg/dL)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1			BOLAD1
51	1	NN1218-4131	TRTPN	2				
52	1	NN1218-4131	TRTPN	3				
53	1	NN1218-4131	TRTPN	4				
54	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
55	1	NN1218-4131	REGION1	—	EUROPE			
56	1	NN1218-4131	REGION1	—	JAPAN			
57	1	NN1218-4131	REGION1	—	NORTH AMERICA			
58	1	NN1218-4131	BOLAD1	—				BOLUS INSULIN ALGORITHM (SLIDING SCALE)
59	1	NN1218-4131	BOLAD1	—				CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY
60	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
51	1.4392	0.1162	1017	12.38	<.0001	0.05	1.2111	1.6673
52	1.4642	0.1163	1017	12.59	<.0001	0.05	1.2361	1.6924
53	1.4555	0.1163	1017	12.51	<.0001	0.05	1.2273	1.6837
54	-0.04173	0.01605	1017	-2.60	0.0094	0.05	-0.07321	-0.01024
55	0.02922	0.01132	1017	2.58	0.0100	0.05	0.007000	0.05143
56	0.07831	0.01287	1017	6.08	<.0001	0.05	0.05306	0.1036
57	0
58	0.01113	0.009849	1017	1.13	0.2589	0.05	-0.00820	0.03045
59	0
60	-0.2845	0.02260	1017	-12.59	<.0001	0.05	-0.3289	-0.2402

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Obs	_Imputation_	PARAMCD	PARAM	STUDYID	Effect	TRTPN
1	1	C105586S	Total cholesterol (mmol/L)	NN1218-4131	TRTPN	2
2	1	C105586S	Total cholesterol (mmol/L)	NN1218-4131	TRTPN	3
3	1	C105586S	Total cholesterol (mmol/L)	NN1218-4131	TRTPN	4
4	1	C105587S	HDL cholesterol (mmol/L)	NN1218-4131	TRTPN	2
5	1	C105587S	HDL cholesterol (mmol/L)	NN1218-4131	TRTPN	3
6	1	C105587S	HDL cholesterol (mmol/L)	NN1218-4131	TRTPN	4
7	1	C105588S	LDL cholesterol (mmol/L)	NN1218-4131	TRTPN	2
8	1	C105588S	LDL cholesterol (mmol/L)	NN1218-4131	TRTPN	3
9	1	C105588S	LDL cholesterol (mmol/L)	NN1218-4131	TRTPN	4
10	1	HDL_SU	HDL cholesterol (mg/dL)	NN1218-4131	TRTPN	2
11	1	HDL_SU	HDL cholesterol (mg/dL)	NN1218-4131	TRTPN	3
12	1	HDL_SU	HDL cholesterol (mg/dL)	NN1218-4131	TRTPN	4
13	1	LDL_SU	LDL cholesterol (mg/dL)	NN1218-4131	TRTPN	2
14	1	LDL_SU	LDL cholesterol (mg/dL)	NN1218-4131	TRTPN	3

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	WORK.IMPUTE	0.003114	0.007612	1017	0.41	0.6826	0.05	-0.01182	0.01805
2	WORK.IMPUTE	0.02814	0.007621	1017	3.69	0.0002	0.05	0.01319	0.04310
3	WORK.IMPUTE	0.01941	0.007609	1017	2.55	0.0109	0.05	0.004478	0.03434
4	WORK.IMPUTE	-0.01605	0.009323	1017	-1.72	0.0855	0.05	-0.03434	0.002248
5	WORK.IMPUTE	-0.00338	0.009335	1017	-0.36	0.7174	0.05	-0.02170	0.01494
6	WORK.IMPUTE	-0.00211	0.009320	1017	-0.23	0.8211	0.05	-0.02040	0.01618
7	WORK.IMPUTE	0.02703	0.01124	1017	2.40	0.0164	0.05	0.004970	0.04910
8	WORK.IMPUTE	0.05433	0.01126	1017	4.83	<.0001	0.05	0.03224	0.07642
9	WORK.IMPUTE	0.05581	0.01124	1017	4.96	<.0001	0.05	0.03375	0.07787
10	WORK.IMPUTE	-0.01605	0.009323	1017	-1.72	0.0855	0.05	-0.03434	0.002248
11	WORK.IMPUTE	-0.00338	0.009335	1017	-0.36	0.7174	0.05	-0.02170	0.01494
12	WORK.IMPUTE	-0.00211	0.009320	1017	-0.23	0.8211	0.05	-0.02040	0.01618
13	WORK.IMPUTE	0.02703	0.01124	1017	2.40	0.0164	0.05	0.004970	0.04910
14	WORK.IMPUTE	0.05433	0.01126	1017	4.83	<.0001	0.05	0.03224	0.07642

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Obs	_Imputation_	PARAMCD	PARAM	STUDYID	Effect	TRTPN
15	1	LDL_SU	LDL cholesterol (mg/dL)	NN1218-4131	TRTPN	4
16	1	T_CHOL_U	Total cholesterol (mg/dL)	NN1218-4131	TRTPN	2
17	1	T_CHOL_U	Total cholesterol (mg/dL)	NN1218-4131	TRTPN	3
18	1	T_CHOL_U	Total cholesterol (mg/dL)	NN1218-4131	TRTPN	4

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
15	WORK.IMPUTE	0.05581	0.01124	1017	4.96	<.0001	0.05	0.03375	0.07787
16	WORK.IMPUTE	0.003114	0.007612	1017	0.41	0.6826	0.05	-0.01182	0.01805
17	WORK.IMPUTE	0.02814	0.007621	1017	3.69	0.0002	0.05	0.01319	0.04310
18	WORK.IMPUTE	0.01941	0.007609	1017	2.55	0.0109	0.05	0.004478	0.03434

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The Mixed procedure
Least Squares Means Estimate

Parameter Code=C105586S Parameter=Total cholesterol (mmol/L)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
1	1	NN1218-4131	1	TRTPN	Faster aspart (meal) / NovoRapid (meal)
2	1	NN1218-4131	2	TRTPN	Faster aspart (post) / NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	WORK.IMPUTE	-0.01630	0.01077	1017	-1.51	0.1306	0.05	-0.03743	0.004837
2	WORK.IMPUTE	0.008732	0.01077	1017	0.81	0.4178	0.05	-0.01241	0.02987

Parameter Code=C105587S Parameter=HDL cholesterol (mmol/L)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
3	1	NN1218-4131	1	TRTPN	Faster aspart (meal) / NovoRapid (meal)
4	1	NN1218-4131	2	TRTPN	Faster aspart (post) / NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
3	WORK.IMPUTE	-0.01394	0.01319	1017	-1.06	0.2909	0.05	-0.03982	0.01195
4	WORK.IMPUTE	-0.00127	0.01320	1017	-0.10	0.9232	0.05	-0.02717	0.02462

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The Mixed procedure
Least Squares Means Estimate

Parameter Code=C105588S Parameter=LDL cholesterol (mmol/L)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
5	1	NN1218-4131	1	TRTPN	Faster aspart (meal) / NovoRapid (meal)
6	1	NN1218-4131	2	TRTPN	Faster aspart (post) / NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
5	WORK.IMPUTE	-0.02878	0.01591	1017	-1.81	0.0708	0.05	-0.06000	0.002446
6	WORK.IMPUTE	-0.00148	0.01592	1017	-0.09	0.9260	0.05	-0.03272	0.02976

Parameter Code=HDL_SU Parameter=HDL cholesterol (mg/dL)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
7	1	NN1218-4131	1	TRTPN	Faster aspart (meal) / NovoRapid (meal)
8	1	NN1218-4131	2	TRTPN	Faster aspart (post) / NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
7	WORK.IMPUTE	-0.01394	0.01319	1017	-1.06	0.2909	0.05	-0.03982	0.01195
8	WORK.IMPUTE	-0.00127	0.01320	1017	-0.10	0.9232	0.05	-0.02717	0.02462

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Parameter Code=LDL_SU Parameter=LDL cholesterol (mg/dL)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
9	1	NN1218-4131	1	TRTPN	Faster aspart (meal) / NovoRapid (meal)
10	1	NN1218-4131	2	TRTPN	Faster aspart (post) / NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
9	WORK.IMPUTE	-0.02878	0.01591	1017	-1.81	0.0708	0.05	-0.06000	0.002446
10	WORK.IMPUTE	-0.00148	0.01592	1017	-0.09	0.9260	0.05	-0.03272	0.02976

Parameter Code=T_CHOL_U Parameter=Total cholesterol (mg/dL)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
11	1	NN1218-4131	1	TRTPN	Faster aspart (meal) / NovoRapid (meal)
12	1	NN1218-4131	2	TRTPN	Faster aspart (post) / NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
11	WORK.IMPUTE	-0.01630	0.01077	1017	-1.51	0.1306	0.05	-0.03743	0.004837
12	WORK.IMPUTE	0.008732	0.01077	1017	0.81	0.4178	0.05	-0.01241	0.02987

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Planned Treatment for Period 30 (N)=2 Parameter Code=C105586S Parameter=Total cholesterol (mmol/L) Study Identifier=NN1218-41

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000001015	0.000058105	0.000059120	3.39E7	0.017464	0.017164	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.001911	0.007689	-0.01316	0.016981	3.39E7	-0.001680	0.005434

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	0.25	0.8038

Lipids 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=C105587S Parameter=HDL cholesterol (mmol/L) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----				Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total	DF			
Estimate	0.000001517	0.000086909	0.000088426	3.4E7	0.017458	0.017158	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits	DF	Minimum	Maximum
Estimate	-0.017481	0.009404	-0.03591 0.000949	3.4E7	-0.021879	-0.013021

Parameter Estimates

Parameter	Theta0	t for H0: Parameter=Theta0	Pr > t
Estimate	0	-1.86	0.0630

Lipids 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=C105588S Parameter=LDL cholesterol (mmol/L) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000001775	0.000127	0.000129	5.26E7	0.013985	0.013792	0.999999

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.025425	0.011346	0.003187	0.047663	5.26E7	0.020631	0.030038

Parameter Estimates

Parameter	t for H0:		
	Theta0	Parameter=Theta0	Pr > t
Estimate	0	2.24	0.0250

Lipids 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=HDL_SU Parameter=HDL cholesterol (mg/dL) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000001517	0.000086909	0.000088426	3.4E7	0.017458	0.017158	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.017481	0.009404	-0.03591	0.000949	3.4E7	-0.021879	-0.013021

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-1.86	0.0630

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Planned Treatment for Period 30 (N)=2 Parameter Code=LDL_SU Parameter=LDL cholesterol (mg/dL) Study Identifier=NN1218-4131

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Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000001775	0.000127	0.000129	5.26E7	0.013985	0.013792	0.999999

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.025425	0.011346	0.003187	0.047663	5.26E7	0.020631	0.030038

Parameter Estimates

Parameter	Theta0	t for H0: Parameter=Theta0	Pr > t
Estimate	0	2.24	0.0250

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Planned Treatment for Period 30 (N)=2 Parameter Code=T_CHOL_U Parameter=Total cholesterol (mg/dL) Study Identifier=NN1218-413

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000001015	0.000058105	0.000059120	3.39E7	0.017464	0.017164	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.001911	0.007689	-0.01316	0.016981	3.39E7	-0.001680	0.005434

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	0.25	0.8038

Lipids 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=C105586S Parameter=Total cholesterol (mmol/L) Study Identifier=NN1218-41

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000001180	0.000058245	0.000059425	2.53E7	0.020268	0.019866	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.028186	0.007709	0.013077	0.043295	2.53E7	0.023970	0.032305

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	3.66	0.0003

Lipids 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=C105587S Parameter=HDL cholesterol (mmol/L) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000001507	0.000087117	0.000088624	3.46E7	0.017301	0.017007	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.003435	0.009414	-0.02189	0.015016	3.46E7	-0.008346	0.001048

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-0.36	0.7152

Lipids 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=C105588S Parameter=LDL cholesterol (mmol/L) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----				Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total	DF			
Estimate	0.000002403	0.000127	0.000130	2.91E7	0.018878	0.018528	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.054470	0.011389	0.032147	0.076792	2.91E7	0.048449	0.060410

Parameter Estimates

Parameter	Theta0	t for H0: Parameter=Theta0	Pr > t
Estimate	0	4.78	<.0001

Lipids 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=HDL_SU Parameter=HDL cholesterol (mg/dL) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000001507	0.000087117	0.000088624	3.46E7	0.017301	0.017007	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.003435	0.009414	-0.02189	0.015016	3.46E7	-0.008346	0.001048

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-0.36	0.7152

Lipids 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=LDL_SU Parameter=LDL cholesterol (mg/dL) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000002403	0.000127	0.000130	2.91E7	0.018878	0.018528	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.054470	0.011389	0.032147	0.076792	2.91E7	0.048449	0.060410

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	4.78	<.0001

Lipids 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=T_CHOL_U Parameter=Total cholesterol (mg/dL) Study Identifier=NN1218-413

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000001180	0.000058245	0.000059425	2.53E7	0.020268	0.019866	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.028186	0.007709	0.013077	0.043295	2.53E7	0.023970	0.032305

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	3.66	0.0003

Lipids 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=C105586S Parameter=Total cholesterol (mmol/L) Study Identifier=NN1218-41

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000001721	0.000058067	0.000059788	1.21E7	0.029646	0.028792	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.019470	0.007732	0.004315	0.034625	1.21E7	0.014330	0.024799

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	2.52	0.0118

Lipids 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=C105587S Parameter=HDL cholesterol (mmol/L) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000002044	0.000086850	0.000088894	1.89E7	0.023534	0.022993	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.002442	0.009428	-0.02092	0.016038	1.89E7	-0.008353	0.002909

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-0.26	0.7957

Lipids 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=C105588S Parameter=LDL cholesterol (mmol/L) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000003656	0.000127	0.000131	1.28E7	0.028799	0.027993	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.055900	0.011428	0.033501	0.078299	1.28E7	0.048455	0.063712

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	4.89	<.0001

Lipids 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=HDL_SU Parameter=HDL cholesterol (mg/dL) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000002044	0.000086850	0.000088894	1.89E7	0.023534	0.022993	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.002442	0.009428	-0.02092	0.016038	1.89E7	-0.008353	0.002909

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-0.26	0.7957

Lipids 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=LDL_SU Parameter=LDL cholesterol (mg/dL) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000003656	0.000127	0.000131	1.28E7	0.028799	0.027993	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.055900	0.011428	0.033501	0.078299	1.28E7	0.048455	0.063712

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	4.89	<.0001

Lipids 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=T_CHOL_U Parameter=Total cholesterol (mg/dL) Study Identifier=NN1218-413

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000001721	0.000058067	0.000059788	1.21E7	0.029646	0.028792	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.019470	0.007732	0.004315	0.034625	1.21E7	0.014330	0.024799

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	2.52	0.0118

Lipids 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=C105586S Label=Faster aspart (meal) / NovoRapid (meal) Parameter=Total cholesterol (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000002734	0.000116	0.000119	1.9E7	0.023503	0.022963	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.017560	0.010911	-0.03895	0.003826	1.9E7	-0.023693	-0.010915

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-1.61	0.1075

Lipids 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=C105586S Label=Faster aspart (post) / NovoRapid (meal) Parameter=Total cholesterol (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000002899	0.000116	0.000119	1.69E7	0.024911	0.024306	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.008716	0.010922	-0.01269	0.030123	1.69E7	0.002246	0.014902

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	0.80	0.4249

Lipids 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=C105587S Label=Faster aspart (meal) / NovoRapid (meal) Parameter=HDL cholesterol (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000003562	0.000174	0.000178	2.48E7	0.020473	0.020062	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.015040	0.013324	-0.04116	0.011076	2.48E7	-0.023570	-0.007156

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-1.13	0.2590

Lipids 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=C105587S Label=Faster aspart (post) / NovoRapid (meal) Parameter=HDL cholesterol (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000003549	0.000174	0.000178	2.5E7	0.020387	0.019980	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.000993	0.013328	-0.02712	0.025130	2.5E7	-0.008775	0.006385

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-0.07	0.9406

Lipids 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=C105588S Label=Faster aspart (meal) / NovoRapid (meal) Parameter=LDL cholesterol (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000005413	0.000254	0.000260	2.3E7	0.021292	0.020848	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.030475	0.016114	-0.06206	0.001109	2.3E7	-0.039148	-0.021252

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-1.89	0.0586

Lipids 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=C105588S Label=Faster aspart (post) / NovoRapid (meal) Parameter=LDL cholesterol (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000006101	0.000255	0.000261	1.82E7	0.023970	0.023409	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.001430	0.016145	-0.03307	0.030213	1.82E7	-0.010824	0.007578

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-0.09	0.9294

Lipids 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=HDL_SU Label=Faster aspart (meal) / NovoRapid (meal) Parameter=HDL cholesterol (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000003562	0.000174	0.000178	2.48E7	0.020473	0.020062	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.015040	0.013324	-0.04116	0.011076	2.48E7	-0.023570	-0.007156

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-1.13	0.2590

Lipids 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=HDL_SU Label=Faster aspart (post) / NovoRapid (meal) Parameter=HDL cholesterol (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000003549	0.000174	0.000178	2.5E7	0.020387	0.019980	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.000993	0.013328	-0.02712	0.025130	2.5E7	-0.008775	0.006385

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-0.07	0.9406

Lipids 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=LDL_SU Label=Faster aspart (meal) / NovoRapid (meal) Parameter=LDL cholesterol (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000005413	0.000254	0.000260	2.3E7	0.021292	0.020848	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.030475	0.016114	-0.06206	0.001109	2.3E7	-0.039148	-0.021252

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-1.89	0.0586

Lipids 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=LDL_SU Label=Faster aspart (post) / NovoRapid (meal) Parameter=LDL cholesterol (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000006101	0.000255	0.000261	1.82E7	0.023970	0.023409	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.001430	0.016145	-0.03307	0.030213	1.82E7	-0.010824	0.007578

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-0.09	0.9294

Lipids 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=T_CHOL_U Label=Faster aspart (meal) / NovoRapid (meal) Parameter=Total cholesterol (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000002734	0.000116	0.000119	1.9E7	0.023503	0.022963	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.017560	0.010911	-0.03895	0.003826	1.9E7	-0.023693	-0.010915

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-1.61	0.1075

Lipids 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Parameter Code=T_CHOL_U Label=Faster aspart (post) / NovoRapid (meal) Parameter=Total cholesterol (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000002899	0.000116	0.000119	1.69E7	0.024911	0.024306	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.008716	0.010922	-0.01269	0.030123	1.69E7	0.002246	0.014902

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	0.80	0.4249

Fast-acting insulin aspart
NN1218-4131

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Lipids 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Model Information

Parameter Code=C105586S Parameter=Total cholesterol (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Data Set	WORK.IMPUTE_ABS
2	1	NN1218-4131	Dependent Variable	eotVisitAbs
3	1	NN1218-4131	Covariance Structure	Diagonal
4	1	NN1218-4131	Estimation Method	REML
5	1	NN1218-4131	Residual Variance Method	Profile
6	1	NN1218-4131	Fixed Effects SE Method	Model-Based
7	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=C105587S Parameter=HDL cholesterol (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
8	1	NN1218-4131	Data Set	WORK.IMPUTE_ABS
9	1	NN1218-4131	Dependent Variable	eotVisitAbs
10	1	NN1218-4131	Covariance Structure	Diagonal
11	1	NN1218-4131	Estimation Method	REML
12	1	NN1218-4131	Residual Variance Method	Profile
13	1	NN1218-4131	Fixed Effects SE Method	Model-Based
14	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=C105588S Parameter=LDL cholesterol (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
15	1	NN1218-4131	Data Set	WORK.IMPUTE_ABS
16	1	NN1218-4131	Dependent Variable	eotVisitAbs
17	1	NN1218-4131	Covariance Structure	Diagonal

nn1218/nn1218-4131/ctr_20180214_er
09FEB2018:20:27:21 - a_stat_ratio.sas/a_lip_stat_in_fas_app.txt

Fast-acting insulin aspart
NN1218-4131

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Statistical document

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Lipids 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Model Information

Parameter Code=C105588S Parameter=LDL cholesterol (mmol/L)

(continued)

Obs	_Imputation_	STUDYID	Descr	Value
18	1	NN1218-4131	Estimation Method	REML
19	1	NN1218-4131	Residual Variance Method	Profile
20	1	NN1218-4131	Fixed Effects SE Method	Model-Based
21	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=HDL_SU Parameter=HDL cholesterol (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
22	1	NN1218-4131	Data Set	WORK.IMPUTE_ABS
23	1	NN1218-4131	Dependent Variable	eotVisitAbs
24	1	NN1218-4131	Covariance Structure	Diagonal
25	1	NN1218-4131	Estimation Method	REML
26	1	NN1218-4131	Residual Variance Method	Profile
27	1	NN1218-4131	Fixed Effects SE Method	Model-Based
28	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=LDL_SU Parameter=LDL cholesterol (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
29	1	NN1218-4131	Data Set	WORK.IMPUTE_ABS
30	1	NN1218-4131	Dependent Variable	eotVisitAbs
31	1	NN1218-4131	Covariance Structure	Diagonal
32	1	NN1218-4131	Estimation Method	REML

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NN1218-4131

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The Mixed procedure
Model Information

Parameter Code=LDL_SU Parameter=LDL cholesterol (mg/dL)

(continued)

Obs	_Imputation_	STUDYID	Descr	Value
33	1	NN1218-4131	Residual Variance Method	Profile
34	1	NN1218-4131	Fixed Effects SE Method	Model-Based
35	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=T_CHOL_U Parameter=Total cholesterol (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
36	1	NN1218-4131	Data Set	WORK.IMPUTE_ABS
37	1	NN1218-4131	Dependent Variable	eotVisitAbs
38	1	NN1218-4131	Covariance Structure	Diagonal
39	1	NN1218-4131	Estimation Method	REML
40	1	NN1218-4131	Residual Variance Method	Profile
41	1	NN1218-4131	Fixed Effects SE Method	Model-Based
42	1	NN1218-4131	Degrees of Freedom Method	Residual

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The Mixed procedure
Class Level Information

Parameter Code=C105586S Parameter=Total cholesterol (mmol/L)

O b s		I m p u t a t i o n s		S T U D I S		C l a s s e s		L e v e l s		V a r i a t i o n s		m i n	
1	1	NN1218-4131	TRTPN	3	2	3	4					5	
2	1	NN1218-4131	REGION1	4	ASIA (EXCLUDING JAPAN)	EUROPE	JAPAN	NORTH AMERICA				49	
3	1	NN1218-4131	BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	CARBOHYDRATE COUNTING (FLEXIBLE)	BOLUS INSULI	85					

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The Mixed procedure
Class Level Information

Parameter Code=C105587S Parameter=HDL cholesterol (mmol/L)

O		I		S		L		V		m	
b		m		T		U		a		i	
s		p		D		C		l		n	
—		u		Y		l		e		l	
		t		I		a		u		e	
		a		D		s		s		g	
		t								t	
		i								h	
		n									
		s									
4	1	NN1218-4131	TRTPN	3	2	3	4				5
5	1	NN1218-4131	REGION1	4	ASIA (EXCLUDING JAPAN)	EUROPE	JAPAN	NORTH AMERICA			49
6	1	NN1218-4131	BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	CARBOHYDRATE COUNTING (FLEXIBLE)	BOLUS	INSULI			85

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The Mixed procedure
Class Level Information

Parameter Code=C105588S Parameter=LDL cholesterol (mmol/L)

O b s	I m p u t a t i o n s	S T U D Y I D	C l a s s	L e v e l s	V a r i a n c e	m i n
7	1	NN1218-4131	TRTPN	3 2 3 4		5
8	1	NN1218-4131	REGION1	4 ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA		49
9	1	NN1218-4131	BOLAD1	2 BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULI		85

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The Mixed procedure
Class Level Information

Parameter Code=HDL_SU Parameter=HDL cholesterol (mg/dL)

O		I		S		L		V		m	
b		n		t		e		a		i	
s		_		D		s		l		n	
10	1	NN1218-4131	TRTPN	3	2	3	4				5
11	1	NN1218-4131	REGION1	4	ASIA (EXCLUDING JAPAN)	EUROPE	JAPAN	NORTH AMERICA			49
12	1	NN1218-4131	BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	CARBOHYDRATE COUNTING (FLEXIBLE)	BOLUS INSULI				85

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The Mixed procedure
Class Level Information

Parameter Code=LDL_SU Parameter=LDL cholesterol (mg/dL)

Obs	Inpution	STUDY ID	Classes	Levels	Values	Unit
13	1	NN1218-4131	TRTPN	3 2 3 4		5
14	1	NN1218-4131	REGION1	4 ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA		49
15	1	NN1218-4131	BOLAD1	2 BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULI		85

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The Mixed procedure
Dimensions

Parameter Code=C105586S Parameter=Total cholesterol (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Covariance Parameters	1
2	1	NN1218-4131	Columns in X	10
3	1	NN1218-4131	Columns in Z	0
4	1	NN1218-4131	Subjects	1
5	1	NN1218-4131	Max Obs per Subject	1025

Parameter Code=C105587S Parameter=HDL cholesterol (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
6	1	NN1218-4131	Covariance Parameters	1
7	1	NN1218-4131	Columns in X	10
8	1	NN1218-4131	Columns in Z	0
9	1	NN1218-4131	Subjects	1
10	1	NN1218-4131	Max Obs per Subject	1025

Parameter Code=C105588S Parameter=LDL cholesterol (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
11	1	NN1218-4131	Covariance Parameters	1
12	1	NN1218-4131	Columns in X	10
13	1	NN1218-4131	Columns in Z	0
14	1	NN1218-4131	Subjects	1
15	1	NN1218-4131	Max Obs per Subject	1025

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The Mixed procedure
Dimensions

Parameter Code=HDL_SU Parameter=HDL cholesterol (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
16	1	NN1218-4131	Covariance Parameters	1
17	1	NN1218-4131	Columns in X	10
18	1	NN1218-4131	Columns in Z	0
19	1	NN1218-4131	Subjects	1
20	1	NN1218-4131	Max Obs per Subject	1025

Parameter Code=LDL_SU Parameter=LDL cholesterol (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
21	1	NN1218-4131	Covariance Parameters	1
22	1	NN1218-4131	Columns in X	10
23	1	NN1218-4131	Columns in Z	0
24	1	NN1218-4131	Subjects	1
25	1	NN1218-4131	Max Obs per Subject	1025

Parameter Code=T_CHOL_U Parameter=Total cholesterol (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
26	1	NN1218-4131	Covariance Parameters	1
27	1	NN1218-4131	Columns in X	10
28	1	NN1218-4131	Columns in Z	0
29	1	NN1218-4131	Subjects	1
30	1	NN1218-4131	Max Obs per Subject	1025

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The Mixed procedure
Number of Observations

Parameter Code=C105586S Parameter=Total cholesterol (mmol/L)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
1	1	NN1218-4131	Number of Observations Read	1025	1025	1025	1025	1025
2	1	NN1218-4131	Number of Observations Used	1025	1025	1025	1025	1025
3	1	NN1218-4131	Number of Observations Not Used	0	1025	1025	1025	1025

Parameter Code=C105587S Parameter=HDL cholesterol (mmol/L)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
4	1	NN1218-4131	Number of Observations Read	1025	1025	1025	1025	1025
5	1	NN1218-4131	Number of Observations Used	1025	1025	1025	1025	1025
6	1	NN1218-4131	Number of Observations Not Used	0	1025	1025	1025	1025

Parameter Code=C105588S Parameter=LDL cholesterol (mmol/L)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
7	1	NN1218-4131	Number of Observations Read	1025	1025	1025	1025	1025
8	1	NN1218-4131	Number of Observations Used	1025	1025	1025	1025	1025
9	1	NN1218-4131	Number of Observations Not Used	0	1025	1025	1025	1025

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The Mixed procedure
Number of Observations

Parameter Code=HDL_SU Parameter=HDL cholesterol (mg/dL)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
10	1	NN1218-4131	Number of Observations Read	1025	1025	1025	1025	1025
11	1	NN1218-4131	Number of Observations Used	1025	1025	1025	1025	1025
12	1	NN1218-4131	Number of Observations Not Used	0	1025	1025	1025	1025

Parameter Code=LDL_SU Parameter=LDL cholesterol (mg/dL)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
13	1	NN1218-4131	Number of Observations Read	1025	1025	1025	1025	1025
14	1	NN1218-4131	Number of Observations Used	1025	1025	1025	1025	1025
15	1	NN1218-4131	Number of Observations Not Used	0	1025	1025	1025	1025

Parameter Code=T_CHOL_U Parameter=Total cholesterol (mg/dL)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
16	1	NN1218-4131	Number of Observations Read	1025	1025	1025	1025	1025
17	1	NN1218-4131	Number of Observations Used	1025	1025	1025	1025	1025
18	1	NN1218-4131	Number of Observations Not Used	0	1025	1025	1025	1025

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The Mixed procedure
Covariance Parameter Estimates

Parameter Code=C105586S Parameter=Total cholesterol (mmol/L)

Obs	_Imputation_	STUDYID	CovParm	Estimate
1	1	NN1218-4131	Residual	0.01976

Parameter Code=C105587S Parameter=HDL cholesterol (mmol/L)

Obs	_Imputation_	STUDYID	CovParm	Estimate
10001	1	NN1218-4131	Residual	0.02965

Parameter Code=C105588S Parameter=LDL cholesterol (mmol/L)

Obs	_Imputation_	STUDYID	CovParm	Estimate
20001	1	NN1218-4131	Residual	0.04312

Parameter Code=HDL_SU Parameter=HDL cholesterol (mg/dL)

Obs	_Imputation_	STUDYID	CovParm	Estimate
30001	1	NN1218-4131	Residual	0.02965

Parameter Code=LDL_SU Parameter=LDL cholesterol (mg/dL)

Obs	_Imputation_	STUDYID	CovParm	Estimate
40001	1	NN1218-4131	Residual	0.04312

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Covariance Parameter Estimates

Parameter Code=T_CHOL_U Parameter=Total cholesterol (mg/dL)

Obs	_Imputation_	STUDYID	CovParm	Estimate
50001	1	NN1218-4131	Residual	0.01976

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The Mixed procedure
Fit Statistics

Parameter Code=C105586S Parameter=Total cholesterol (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	-2 Res Log Likelihood	-1063.1
2	1	NN1218-4131	AIC (Smaller is Better)	-1061.1
3	1	NN1218-4131	AICC (Smaller is Better)	-1061.1
4	1	NN1218-4131	BIC (Smaller is Better)	-1056.1

Parameter Code=C105587S Parameter=HDL cholesterol (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
5	1	NN1218-4131	-2 Res Log Likelihood	-649.7
6	1	NN1218-4131	AIC (Smaller is Better)	-647.7
7	1	NN1218-4131	AICC (Smaller is Better)	-647.7
8	1	NN1218-4131	BIC (Smaller is Better)	-642.8

Parameter Code=C105588S Parameter=LDL cholesterol (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
9	1	NN1218-4131	-2 Res Log Likelihood	-268.7
10	1	NN1218-4131	AIC (Smaller is Better)	-266.7
11	1	NN1218-4131	AICC (Smaller is Better)	-266.7
12	1	NN1218-4131	BIC (Smaller is Better)	-261.7

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The Mixed procedure
Fit Statistics

Parameter Code=HDL_SU Parameter=HDL cholesterol (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
13	1	NN1218-4131	-2 Res Log Likelihood	-649.7
14	1	NN1218-4131	AIC (Smaller is Better)	-647.7
15	1	NN1218-4131	AICC (Smaller is Better)	-647.7
16	1	NN1218-4131	BIC (Smaller is Better)	-642.8

Parameter Code=LDL_SU Parameter=LDL cholesterol (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
17	1	NN1218-4131	-2 Res Log Likelihood	-268.7
18	1	NN1218-4131	AIC (Smaller is Better)	-266.7
19	1	NN1218-4131	AICC (Smaller is Better)	-266.7
20	1	NN1218-4131	BIC (Smaller is Better)	-261.7

Parameter Code=T_CHOL_U Parameter=Total cholesterol (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
21	1	NN1218-4131	-2 Res Log Likelihood	-1063.1
22	1	NN1218-4131	AIC (Smaller is Better)	-1061.1
23	1	NN1218-4131	AICC (Smaller is Better)	-1061.1
24	1	NN1218-4131	BIC (Smaller is Better)	-1056.1

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Solution for Fixed Effects

Parameter Code=C105586S Parameter=Total cholesterol (mmol/L)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1			BOLAD1
1	1	NN1218-4131	TRTPN	2				
2	1	NN1218-4131	TRTPN	3				
3	1	NN1218-4131	TRTPN	4				
4	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
5	1	NN1218-4131	REGION1	—	EUROPE			
6	1	NN1218-4131	REGION1	—	JAPAN			
7	1	NN1218-4131	REGION1	—	NORTH AMERICA			
8	1	NN1218-4131	BOLAD1	—				BOLUS INSULIN ALGORITHM (SLIDING SCALE)
9	1	NN1218-4131	BOLAD1	—				CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY
10	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	0.3997	0.03483	1017	11.48	<.0001	0.05	0.3314	0.4681
2	0.4247	0.03488	1017	12.18	<.0001	0.05	0.3563	0.4932
3	0.4160	0.03494	1017	11.91	<.0001	0.05	0.3474	0.4846
4	-0.04173	0.01605	1017	-2.60	0.0094	0.05	-0.07321	-0.01024
5	0.02922	0.01132	1017	2.58	0.0100	0.05	0.007000	0.05143
6	0.07831	0.01287	1017	6.08	<.0001	0.05	0.05306	0.1036
7	0
8	0.01113	0.009849	1017	1.13	0.2589	0.05	-0.00820	0.03045
9	0
10	0.7155	0.02260	1017	31.65	<.0001	0.05	0.6711	0.7598

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The Mixed procedure
Solution for Fixed Effects

Parameter Code=C105587S Parameter=HDL cholesterol (mmol/L)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
11	1	NN1218-4131	TRTPN	2				
12	1	NN1218-4131	TRTPN	3				
13	1	NN1218-4131	TRTPN	4				
14	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
15	1	NN1218-4131	REGION1	—	EUROPE			
16	1	NN1218-4131	REGION1	—	JAPAN			
17	1	NN1218-4131	REGION1	—	NORTH AMERICA			
18	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
19	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
20	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
11	0.03635	0.01513	1017	2.40	0.0165	0.05	0.006652	0.06604
12	0.04901	0.01525	1017	3.21	0.0013	0.05	0.01909	0.07893
13	0.05029	0.01535	1017	3.28	0.0011	0.05	0.02016	0.08041
14	0.02420	0.01970	1017	1.23	0.2195	0.05	-0.01445	0.06285
15	0.02287	0.01384	1017	1.65	0.0987	0.05	-0.00428	0.05003
16	0.1030	0.01605	1017	6.42	<.0001	0.05	0.07156	0.1345
17	0
18	-0.02111	0.01208	1017	-1.75	0.0807	0.05	-0.04482	0.002586
19	0
20	0.8284	0.01867	1017	44.36	<.0001	0.05	0.7918	0.8650

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The Mixed procedure
Solution for Fixed Effects

Parameter Code=C105588S Parameter=LDL cholesterol (mmol/L)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1			BOLAD1
21	1	NN1218-4131	TRTPN	2				
22	1	NN1218-4131	TRTPN	3				
23	1	NN1218-4131	TRTPN	4				
24	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
25	1	NN1218-4131	REGION1	—	EUROPE			
26	1	NN1218-4131	REGION1	—	JAPAN			
27	1	NN1218-4131	REGION1	—	NORTH AMERICA			
28	1	NN1218-4131	BOLAD1	—				BOLUS INSULIN ALGORITHM (SLIDING SCALE)
29	1	NN1218-4131	BOLAD1	—				CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY
30	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
21	0.3134	0.02409	1017	13.01	<.0001	0.05	0.2662	0.3607
22	0.3407	0.02435	1017	13.99	<.0001	0.05	0.2930	0.3885
23	0.3422	0.02408	1017	14.21	<.0001	0.05	0.2950	0.3895
24	-0.00730	0.02367	1017	-0.31	0.7578	0.05	-0.05376	0.03915
25	0.04916	0.01671	1017	2.94	0.0033	0.05	0.01637	0.08194
26	0.09804	0.01880	1017	5.21	<.0001	0.05	0.06115	0.1349
27	0
28	0.02266	0.01455	1017	1.56	0.1196	0.05	-0.00588	0.05121
29	0
30	0.6374	0.02049	1017	31.10	<.0001	0.05	0.5972	0.6777

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The Mixed procedure
Solution for Fixed Effects

Parameter Code=HDL_SU Parameter=HDL cholesterol (mg/dL)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
31	1	NN1218-4131	TRTPN	2				
32	1	NN1218-4131	TRTPN	3				
33	1	NN1218-4131	TRTPN	4				
34	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
35	1	NN1218-4131	REGION1	—	EUROPE			
36	1	NN1218-4131	REGION1	—	JAPAN			
37	1	NN1218-4131	REGION1	—	NORTH AMERICA			
38	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
39	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
40	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
31	0.6633	0.07707	1017	8.61	<.0001	0.05	0.5121	0.8145
32	0.6760	0.07704	1017	8.77	<.0001	0.05	0.5248	0.8272
33	0.6772	0.07707	1017	8.79	<.0001	0.05	0.5260	0.8285
34	0.02420	0.01970	1017	1.23	0.2195	0.05	-0.01445	0.06285
35	0.02287	0.01384	1017	1.65	0.0987	0.05	-0.00428	0.05003
36	0.1030	0.01605	1017	6.42	<.0001	0.05	0.07156	0.1345
37	0
38	-0.02111	0.01208	1017	-1.75	0.0807	0.05	-0.04482	0.002586
39	0
40	0.8284	0.01867	1017	44.36	<.0001	0.05	0.7918	0.8650

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The Mixed procedure
Solution for Fixed Effects

Parameter Code=LDL_SU Parameter=LDL cholesterol (mg/dL)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
41	1	NN1218-4131	TRTPN	2				
42	1	NN1218-4131	TRTPN	3				
43	1	NN1218-4131	TRTPN	4				
44	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
45	1	NN1218-4131	REGION1	—	EUROPE			
46	1	NN1218-4131	REGION1	—	JAPAN			
47	1	NN1218-4131	REGION1	—	NORTH AMERICA			
48	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
49	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
50	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
41	1.6380	0.09448	1017	17.34	<.0001	0.05	1.4527	1.8234
42	1.6653	0.09467	1017	17.59	<.0001	0.05	1.4796	1.8511
43	1.6668	0.09422	1017	17.69	<.0001	0.05	1.4819	1.8517
44	-0.00730	0.02367	1017	-0.31	0.7578	0.05	-0.05376	0.03915
45	0.04916	0.01671	1017	2.94	0.0033	0.05	0.01637	0.08194
46	0.09804	0.01880	1017	5.21	<.0001	0.05	0.06115	0.1349
47	0
48	0.02266	0.01455	1017	1.56	0.1196	0.05	-0.00588	0.05121
49	0
50	0.6374	0.02049	1017	31.10	<.0001	0.05	0.5972	0.6777

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Lipids 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Solution for Fixed Effects

Parameter Code=T_CHOL_U Parameter=Total cholesterol (mg/dL)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1			BOLAD1
51	1	NN1218-4131	TRTPN	2				
52	1	NN1218-4131	TRTPN	3				
53	1	NN1218-4131	TRTPN	4				
54	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
55	1	NN1218-4131	REGION1	—	EUROPE			
56	1	NN1218-4131	REGION1	—	JAPAN			
57	1	NN1218-4131	REGION1	—	NORTH AMERICA			
58	1	NN1218-4131	BOLAD1	—				BOLUS INSULIN ALGORITHM (SLIDING SCALE)
59	1	NN1218-4131	BOLAD1	—				CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY
60	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
51	1.4392	0.1162	1017	12.38	<.0001	0.05	1.2111	1.6673
52	1.4642	0.1163	1017	12.59	<.0001	0.05	1.2361	1.6924
53	1.4555	0.1163	1017	12.51	<.0001	0.05	1.2273	1.6837
54	-0.04173	0.01605	1017	-2.60	0.0094	0.05	-0.07321	-0.01024
55	0.02922	0.01132	1017	2.58	0.0100	0.05	0.007000	0.05143
56	0.07831	0.01287	1017	6.08	<.0001	0.05	0.05306	0.1036
57	0
58	0.01113	0.009849	1017	1.13	0.2589	0.05	-0.00820	0.03045
59	0
60	0.7155	0.02260	1017	31.65	<.0001	0.05	0.6711	0.7598

Lipids 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Least Squares Means

Obs	_Imputation_	PARAMCD	PARAM	STUDYID	Effect	TRTPN
1	1	C105586S	Total cholesterol (mmol/L)	NN1218-4131	TRTPN	2
10001	1	C105587S	HDL cholesterol (mmol/L)	NN1218-4131	TRTPN	2
20001	1	C105588S	LDL cholesterol (mmol/L)	NN1218-4131	TRTPN	2
30001	1	HDL_SU	HDL cholesterol (mg/dL)	NN1218-4131	TRTPN	2
40001	1	LDL_SU	LDL cholesterol (mg/dL)	NN1218-4131	TRTPN	2
50001	1	T_CHOL_U	Total cholesterol (mg/dL)	NN1218-4131	TRTPN	2
60001	1	C105586S	Total cholesterol (mmol/L)	NN1218-4131	TRTPN	3
70001	1	C105587S	HDL cholesterol (mmol/L)	NN1218-4131	TRTPN	3
80001	1	C105588S	LDL cholesterol (mmol/L)	NN1218-4131	TRTPN	3
90001	1	HDL_SU	HDL cholesterol (mg/dL)	NN1218-4131	TRTPN	3
100001	1	LDL_SU	LDL cholesterol (mg/dL)	NN1218-4131	TRTPN	3
110001	1	T_CHOL_U	Total cholesterol (mg/dL)	NN1218-4131	TRTPN	3
120001	1	C105586S	Total cholesterol (mmol/L)	NN1218-4131	TRTPN	4
130001	1	C105587S	HDL cholesterol (mmol/L)	NN1218-4131	TRTPN	4

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	WORK.IMPUTE	0.003114	0.007612	1017	0.41	0.6826	0.05	-0.01182	0.01805
10001	WORK.IMPUTE	-0.01605	0.009323	1017	-1.72	0.0855	0.05	-0.03434	0.002248
20001	WORK.IMPUTE	0.02703	0.01124	1017	2.40	0.0164	0.05	0.004970	0.04910
30001	WORK.IMPUTE	-0.01605	0.009323	1017	-1.72	0.0855	0.05	-0.03434	0.002248
40001	WORK.IMPUTE	0.02703	0.01124	1017	2.40	0.0164	0.05	0.004970	0.04910
50001	WORK.IMPUTE	0.003114	0.007612	1017	0.41	0.6826	0.05	-0.01182	0.01805
60001	WORK.IMPUTE	0.02814	0.007621	1017	3.69	0.0002	0.05	0.01319	0.04310
70001	WORK.IMPUTE	-0.00338	0.009335	1017	-0.36	0.7174	0.05	-0.02170	0.01494
80001	WORK.IMPUTE	0.05433	0.01126	1017	4.83	<.0001	0.05	0.03224	0.07642
90001	WORK.IMPUTE	-0.00338	0.009335	1017	-0.36	0.7174	0.05	-0.02170	0.01494
100001	WORK.IMPUTE	0.05433	0.01126	1017	4.83	<.0001	0.05	0.03224	0.07642
110001	WORK.IMPUTE	0.02814	0.007621	1017	3.69	0.0002	0.05	0.01319	0.04310
120001	WORK.IMPUTE	0.01941	0.007609	1017	2.55	0.0109	0.05	0.004478	0.03434
130001	WORK.IMPUTE	-0.00211	0.009320	1017	-0.23	0.8211	0.05	-0.02040	0.01618

Lipids 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

The Mixed procedure
Least Squares Means

Obs	_Imputation_	PARAMCD	PARAM	STUDYID	Effect	TRTPN
140001	1	C105588S	LDL cholesterol (mmol/L)	NN1218-4131	TRTPN	4
150001	1	HDL_SU	HDL cholesterol (mg/dL)	NN1218-4131	TRTPN	4
160001	1	LDL_SU	LDL cholesterol (mg/dL)	NN1218-4131	TRTPN	4
170001	1	T_CHOL_U	Total cholesterol (mg/dL)	NN1218-4131	TRTPN	4

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
140001	WORK.IMPUTE	0.05581	0.01124	1017	4.96	<.0001	0.05	0.03375	0.07787
150001	WORK.IMPUTE	-0.00211	0.009320	1017	-0.23	0.8211	0.05	-0.02040	0.01618
160001	WORK.IMPUTE	0.05581	0.01124	1017	4.96	<.0001	0.05	0.03375	0.07787
170001	WORK.IMPUTE	0.01941	0.007609	1017	2.55	0.0109	0.05	0.004478	0.03434

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The Mixed procedure
Least Squares Means Estimate

Parameter Code=C105586S Parameter=Total cholesterol (mmol/L)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
1	1	NN1218-4131	1	TRTPN	Faster aspart (meal) / NovoRapid (meal)
10001	1	NN1218-4131	2	TRTPN	Faster aspart (post) / NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	WORK.IMPUTE	-0.01630	0.01077	1017	-1.51	0.1306	0.05	-0.03743	0.004837
10001	WORK.IMPUTE	0.008732	0.01077	1017	0.81	0.4178	0.05	-0.01241	0.02987

Parameter Code=C105587S Parameter=HDL cholesterol (mmol/L)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
20001	1	NN1218-4131	1	TRTPN	Faster aspart (meal) / NovoRapid (meal)
30001	1	NN1218-4131	2	TRTPN	Faster aspart (post) / NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
20001	WORK.IMPUTE	-0.01394	0.01319	1017	-1.06	0.2909	0.05	-0.03982	0.01195
30001	WORK.IMPUTE	-0.00127	0.01320	1017	-0.10	0.9232	0.05	-0.02717	0.02462

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The Mixed procedure
Least Squares Means Estimate

Parameter Code=C105588S Parameter=LDL cholesterol (mmol/L)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
40001	1	NN1218-4131	1	TRTPN	Faster aspart (meal) / NovoRapid (meal)
50001	1	NN1218-4131	2	TRTPN	Faster aspart (post) / NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
40001	WORK.IMPUTE	-0.02878	0.01591	1017	-1.81	0.0708	0.05	-0.06000	0.002446
50001	WORK.IMPUTE	-0.00148	0.01592	1017	-0.09	0.9260	0.05	-0.03272	0.02976

Parameter Code=HDL_SU Parameter=HDL cholesterol (mg/dL)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
60001	1	NN1218-4131	1	TRTPN	Faster aspart (meal) / NovoRapid (meal)
70001	1	NN1218-4131	2	TRTPN	Faster aspart (post) / NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
60001	WORK.IMPUTE	-0.01394	0.01319	1017	-1.06	0.2909	0.05	-0.03982	0.01195
70001	WORK.IMPUTE	-0.00127	0.01320	1017	-0.10	0.9232	0.05	-0.02717	0.02462

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The Mixed procedure
Least Squares Means Estimate

Parameter Code=LDL_SU Parameter=LDL cholesterol (mg/dL)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
80001	1	NN1218-4131	1	TRTPN	Faster aspart (meal) / NovoRapid (meal)
90001	1	NN1218-4131	2	TRTPN	Faster aspart (post) / NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
80001	WORK.IMPUTE	-0.02878	0.01591	1017	-1.81	0.0708	0.05	-0.06000	0.002446
90001	WORK.IMPUTE	-0.00148	0.01592	1017	-0.09	0.9260	0.05	-0.03272	0.02976

Parameter Code=T_CHOL_U Parameter=Total cholesterol (mg/dL)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
100001	1	NN1218-4131	1	TRTPN	Faster aspart (meal) / NovoRapid (meal)
110001	1	NN1218-4131	2	TRTPN	Faster aspart (post) / NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
100001	WORK.IMPUTE	-0.01630	0.01077	1017	-1.51	0.1306	0.05	-0.03743	0.004837
110001	WORK.IMPUTE	0.008732	0.01077	1017	0.81	0.4178	0.05	-0.01241	0.02987

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Lipids 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=C105586S Parameter=Total cholesterol (mmol/L) Study Identifier=NN1218-41

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000001015	0.000058105	0.000059120	3.39E7	0.017464	0.017164	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	1.499827	0.007689	1.484757	1.514897	3.39E7	1.496236	1.503350

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	195.06	<.0001

Lipids 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=C105587S Parameter=HDL cholesterol (mmol/L) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000001517	0.000086909	0.000088426	3.4E7	0.017458	0.017158	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.423010	0.009404	0.404580	0.441441	3.4E7	0.418613	0.427471

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	44.98	<.0001

Lipids 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=C105588S Parameter=LDL cholesterol (mmol/L) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000001775	0.000127	0.000129	5.26E7	0.013985	0.013792	0.999999

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.959464	0.011346	0.937226	0.981703	5.26E7	0.954670	0.964077

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	84.56	<.0001

Lipids 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=HDL_SU Parameter=HDL cholesterol (mg/dL) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000001517	0.000086909	0.000088426	3.4E7	0.017458	0.017158	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	4.076522	0.009404	4.058091	4.094952	3.4E7	4.072124	4.080982

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	433.51	<.0001

Lipids 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=LDL_SU Parameter=LDL cholesterol (mg/dL) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000001775	0.000127	0.000129	5.26E7	0.013985	0.013792	0.999999

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	4.612976	0.011346	4.590738	4.635214	5.26E7	4.608181	4.617588

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	406.57	<.0001

Lipids 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=T_CHOL_U Parameter=Total cholesterol (mg/dL) Study Identifier=NN1218-413

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000001015	0.000058105	0.000059120	3.39E7	0.017464	0.017164	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	5.153338	0.007689	5.138268	5.168408	3.39E7	5.149748	5.156862

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	670.23	<.0001

Lipids 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=C105586S Parameter=Total cholesterol (mmol/L) Study Identifier=NN1218-41

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000001180	0.000058245	0.000059425	2.53E7	0.020268	0.019866	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	1.526103	0.007709	1.510994	1.541211	2.53E7	1.521886	1.530222

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	197.97	<.0001

Lipids 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=C105587S Parameter=HDL cholesterol (mmol/L) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000001507	0.000087117	0.000088624	3.46E7	0.017301	0.017007	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.437057	0.009414	0.418606	0.455508	3.46E7	0.432145	0.441540

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	46.43	<.0001

Lipids 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=C105588S Parameter=LDL cholesterol (mmol/L) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000002403	0.000127	0.000130	2.91E7	0.018878	0.018528	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits	DF	Minimum	Maximum
Estimate	0.988509	0.011389	0.966186 1.010831	2.91E7	0.982488	0.994449

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	86.79	<.0001

Lipids 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=HDL_SU Parameter=HDL cholesterol (mg/dL) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000001507	0.000087117	0.000088624	3.46E7	0.017301	0.017007	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	4.090568	0.009414	4.072117	4.109019	3.46E7	4.085657	4.095051

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	434.52	<.0001

Lipids 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=LDL_SU Parameter=LDL cholesterol (mg/dL) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000002403	0.000127	0.000130	2.91E7	0.018878	0.018528	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	4.642020	0.011389	4.619698	4.664343	2.91E7	4.635999	4.647961

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	407.58	<.0001

Lipids 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=T_CHOL_U Parameter=Total cholesterol (mg/dL) Study Identifier=NN1218-413

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000001180	0.000058245	0.000059425	2.53E7	0.020268	0.019866	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	5.179614	0.007709	5.164505	5.194723	2.53E7	5.175397	5.183733

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	671.91	<.0001

Lipids 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=C105586S Parameter=Total cholesterol (mmol/L) Study Identifier=NN1218-41

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000001721	0.000058067	0.000059788	1.21E7	0.029646	0.028792	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	1.517387	0.007732	1.502232	1.532542	1.21E7	1.512247	1.522715

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	196.24	<.0001

Lipids 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=C105587S Parameter=HDL cholesterol (mmol/L) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000002044	0.000086850	0.000088894	1.89E7	0.023534	0.022993	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.438050	0.009428	0.419571	0.456529	1.89E7	0.432139	0.443401

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	46.46	<.0001

Lipids 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=C105588S Parameter=LDL cholesterol (mmol/L) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000003656	0.000127	0.000131	1.28E7	0.028799	0.027993	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits	DF	Minimum	Maximum
Estimate	0.989939	0.011428	0.967540 1.012338	1.28E7	0.982494	0.997751

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	86.62	<.0001

Lipids 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=HDL_SU Parameter=HDL cholesterol (mg/dL) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000002044	0.000086850	0.000088894	1.89E7	0.023534	0.022993	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	4.091561	0.009428	4.073082	4.110041	1.89E7	4.085650	4.096912

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	433.96	<.0001

Lipids 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=LDL_SU Parameter=LDL cholesterol (mg/dL) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----				Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total	DF			
Estimate	0.000003656	0.000127	0.000131	1.28E7	0.028799	0.027993	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits	DF	Minimum	Maximum
Estimate	4.643450	0.011428	4.621052 4.665849	1.28E7	4.636005	4.651262

Parameter Estimates

Parameter	Theta0	t for H0: Parameter=Theta0	Pr > t
Estimate	0	406.32	<.0001

Lipids 26 weeks after randomisation - statistical analysis - in-trial - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=T_CHOL_U Parameter=Total cholesterol (mg/dL) Study Identifier=NN1218-413

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000001721	0.000058067	0.000059788	1.21E7	0.029646	0.028792	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	5.170898	0.007732	5.155743	5.186053	1.21E7	5.165758	5.176227

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	668.74	<.0001

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The MI Procedure with MCMC
Model Information

Parameter Code=HDL_SU Planned Treatment for Period 30 (N)=2

Obs	PARAM	Description	Value
1	HDL cholesterol (mg/dL)	Data Set	WORK.ENDPOINT_PARAM
2	HDL cholesterol (mg/dL)	Method	Monotone-data_MCMC
3	HDL cholesterol (mg/dL)	Multiple Imputation Chain	Multiple Chains
4	HDL cholesterol (mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
5	HDL cholesterol (mg/dL)	Start	Starting Value
6	HDL cholesterol (mg/dL)	Prior	Jeffreys
7	HDL cholesterol (mg/dL)	Number of Imputations	10000
8	HDL cholesterol (mg/dL)	Number of Burn-in Iterations	200
9	HDL cholesterol (mg/dL)	Seed for random number generator	144500

Parameter Code=HDL_SU Planned Treatment for Period 30 (N)=3

Obs	PARAM	Description	Value
10	HDL cholesterol (mg/dL)	Data Set	WORK.ENDPOINT_PARAM
11	HDL cholesterol (mg/dL)	Method	Monotone-data_MCMC
12	HDL cholesterol (mg/dL)	Multiple Imputation Chain	Multiple Chains
13	HDL cholesterol (mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
14	HDL cholesterol (mg/dL)	Start	Starting Value
15	HDL cholesterol (mg/dL)	Prior	Jeffreys
16	HDL cholesterol (mg/dL)	Number of Imputations	10000
17	HDL cholesterol (mg/dL)	Number of Burn-in Iterations	200
18	HDL cholesterol (mg/dL)	Seed for random number generator	2064268711

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The MI Procedure with MCMC
Model Information

Parameter Code=HDL_SU Planned Treatment for Period 30 (N)=4

Obs	PARAM	Description	Value
19	HDL cholesterol (mg/dL)	Data Set	WORK.ENDPOINT_PARAM
20	HDL cholesterol (mg/dL)	Method	Monotone-data MCMC
21	HDL cholesterol (mg/dL)	Multiple Imputation Chain	Multiple Chains
22	HDL cholesterol (mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
23	HDL cholesterol (mg/dL)	Start	Starting Value
24	HDL cholesterol (mg/dL)	Prior	Jeffreys
25	HDL cholesterol (mg/dL)	Number of Imputations	10000
26	HDL cholesterol (mg/dL)	Number of Burn-in Iterations	200
27	HDL cholesterol (mg/dL)	Seed for random number generator	1198333808

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10FEB2018:04:32:20 - a_stat_ratio.sas/a_lip_stat_on_fas_app.txt

Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC
Missing data pattern

Parameter Code=HDL_SU Planned Treatment for Period 30 (N)=2

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
1	HDL cholesterol (mg/dL)	1	X	X	X	325	95.03	4.094211	-0.005082	-0.021372
2	HDL cholesterol (mg/dL)	2	X	X	O	9	2.63	3.949756	0.057936	.
3	HDL cholesterol (mg/dL)	3	X	.	X	6	1.75	4.149010	.	0.013531
4	HDL cholesterol (mg/dL)	4	X	O	O	2	0.58	4.051724	.	.

Parameter Code=HDL_SU Planned Treatment for Period 30 (N)=3

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
5	HDL cholesterol (mg/dL)	1	X	X	X	331	97.07	4.097614	0.004443	-0.001242
6	HDL cholesterol (mg/dL)	2	X	X	O	7	2.05	4.200772	-0.015993	.
7	HDL cholesterol (mg/dL)	3	X	.	X	1	0.29	4.110936	.	-0.106768
8	HDL cholesterol (mg/dL)	4	X	O	O	2	0.59	4.142580	.	.

Parameter Code=HDL_SU Planned Treatment for Period 30 (N)=4

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
9	HDL cholesterol (mg/dL)	1	X	X	X	318	92.98	4.092537	0.000965	-0.005623
10	HDL cholesterol (mg/dL)	2	X	X	O	16	4.68	4.120039	0.016848	.
11	HDL cholesterol (mg/dL)	3	X	.	X	6	1.75	3.819294	.	0.098766
12	HDL cholesterol (mg/dL)	4	X	O	O	2	0.58	4.407214	.	.

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The MI Procedure with Monotone Regression
Model Information

Parameter Code=HDL_SU Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM	Description	Value
1	1	HDL cholesterol (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	HDL cholesterol (mg/dL)	Method	Monotone
3	1	HDL cholesterol (mg/dL)	Number of Imputations	1
4	1	HDL cholesterol (mg/dL)	Seed for random number generator	144800

Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=HDL_SU Planned Treatment for Period 30 (N)=2

O b s	I m p u t a t i o n _	P A R A M _	G r o u p	R E G I O N _	B O L _	L _	B _	A _	A _	S _	E _	F r e q	P e r c e n t	B _	v i s i t _	v i s i t _
1	1	HDL cholesterol (mg/dL)	1	X	X	X	X	X	X	X	X	331	96.78	4.095204	-0.004849	-0.020739
2	1	HDL cholesterol (mg/dL)	2	X	X	X	X	X	X	X	X	9	2.63	3.949756	0.057936	.
3	1	HDL cholesterol (mg/dL)	3	X	X	X	X	X	X	X	X	2	0.58	4.051724	.	.

Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=HDL_SU Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2200

O b s _	P A R A M E T E R	E F F E C T	R E G I O N	B O L U S	O b s _	T
1	1	HDL cholesterol (mg/dL)	Intercept		0.03267	0.090139
2	1	HDL cholesterol (mg/dL)	REGION1 ASIA (EXCLUDING JAPAN)		-0.00333	-0.134053
3	1	HDL cholesterol (mg/dL)	REGION1 EUROPE		-0.06222	0.061852
4	1	HDL cholesterol (mg/dL)	REGION1 JAPAN		0.10817	0.198123
5	1	HDL cholesterol (mg/dL)	BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.11757	-0.202820
6	1	HDL cholesterol (mg/dL)	BASE		-0.25686	-0.306126

Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=HDL_SU Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

O b s _	i n s _	P A R A M E T E R	E f f e c t	R E G I O N 1	B O L A D 1	O b s _	T
7	1	HDL cholesterol (mg/dL)	Intercept			0.02504	0.037034
8	1	HDL cholesterol (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)		-0.04947	-0.049280
9	1	HDL cholesterol (mg/dL)	REGION1	EUROPE		-0.02616	0.045630
10	1	HDL cholesterol (mg/dL)	REGION1	JAPAN		0.18340	0.187715
11	1	HDL cholesterol (mg/dL)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.06067	-0.098013
12	1	HDL cholesterol (mg/dL)	BASE			-0.05787	-0.048393
13	1	HDL cholesterol (mg/dL)	visit2200			0.59117	0.561422

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The MI Procedure with Monotone Regression
Model Information

Parameter Code=HDL_SU Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM	Description	Value
1	1	HDL cholesterol (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	HDL cholesterol (mg/dL)	Method	Monotone
3	1	HDL cholesterol (mg/dL)	Number of Imputations	1
4	1	HDL cholesterol (mg/dL)	Seed for random number generator	144801

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10FEB2018:04:32:20 - a_stat_ratio.sas/a_lip_stat_on_fas_app.txt

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nn1218/nn1218-4131/ctr_20180214_er
10FEB2018:04:32:20 - a stat ratio.sas/a lip stat on_fas app.txt
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Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=HDL_SU Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

O b s _	i n s _	P A R M _	E f f e c t	R E G I O N 1	B O L A D 1	O b s _	T
7	1	HDL cholesterol (mg/dL)	Intercept			0.01002	-0.044615
8	1	HDL cholesterol (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)		-0.02087	-0.247301
9	1	HDL cholesterol (mg/dL)	REGION1	EUROPE		-0.07865	0.036536
10	1	HDL cholesterol (mg/dL)	REGION1	JAPAN		0.34435	0.346839
11	1	HDL cholesterol (mg/dL)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.04109	0.056546
12	1	HDL cholesterol (mg/dL)	BASE			-0.18419	-0.199685
13	1	HDL cholesterol (mg/dL)	visit2200			0.44257	0.396468

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The MI Procedure with Monotone Regression
Model Information

Parameter Code=HDL_SU Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM	Description	Value
1	1	HDL cholesterol (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	HDL cholesterol (mg/dL)	Method	Monotone
3	1	HDL cholesterol (mg/dL)	Number of Imputations	1
4	1	HDL cholesterol (mg/dL)	Seed for random number generator	144802

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Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=HDL_SU Planned Treatment for Period 30 (N)=4

Obs	I	mp	ut	at	ion	P	A	R	A	M	G	r	o	u	p	R	E	G	I	O	N	L	B	A	A	S	E	0	0	F	r	e	q	P	e	r	c	e	n	t	B	A	S	E	v	i	s	i	t	2	3	6	0	0	v	i	s	i	t	3	6	0	0	v	i	s	i	t	3	6	0	0	v	i	s	i	t	3	6	0	0	v	i	s	i	t	3	6	0	0	v	i	s	i	t	3	6	0	0	v	i	s	i	t	3	6	0	0	v	i	s	i	t	3	6	0	0	v	i	s	i	t	3	6	0	0	v	i	s	i	t	3	6	0	0	v	i	s	i	t	3	6	0	0	v	i	s	i	t	3	6	0	0	v	i	s	i	t	3	6	0	0	v	i	s	i	t	3	6	0	0	v	i	s	i	t	3	6	0	0	v	i	s	i	t	3	6	0	0	v	i	s	i	t	3	6	0	0	v	i	s	i	t	3	6	0	0	v	i	s	i	t	3	6	0	0	v	i	s	i	t	3	6	0	0	v	i	s	i	t	3	6	0	0	v	i	s	i	t	3	6	0	0	v	i	s	i	t	3	6	0	0	v	i	s	i	t	3	6	0	0	v	i	s	i	t	3	6	0	0	v	i	s	i	t	3	6	0	0	v	i	s	i	t	3	6	0	0	v	i	s	i	t	3	6	0	0	v	i	s	i	t	3	6	0	0	v	i	s	i	t	3	6	0	0	v	i	s	i	t	3	6	0	0	v	i	s	i	t	3	6	0	0	v	i	s	i	t	3	6	0	0	v	i	s	i	t	3	6	0	0	v	i	s	i	t	3	6	0	0	v	i	s	i	t	3	6	0	0	v	i	s	i	t	3	6	0	0	v	i	s	i	t	3	6	0	0	v	i	s	i	t	3	6	0	0	v	i	s	i	t	3	6	0	0	v	i	s	i	t	3	6	0	0	v	i	s	i	t	3	6	0	0	v	i	s	i	t	3	6	0	0	v	i	s	i	t	3	6	0	0	v	i	s	i	t	3	6	0	0	v	i	s	i	t	3	6	0	0	v	i	s	i	t	3	6	0	0	v	i	s	i	t	3	6	0	0	v	i	s	i	t	3	6	0	0	v	i	s	i	t	3	6	0	0	v	i	s	i	t	3	6	0	0	v	i	s	i	t	3	6	0	0	v	i	s	i	t	3	6	0	0	v	i	s	i	t	3	6	0	0	v	i	s	i	t	3	6	0	0	v	i	s	i	t	3	6	0	0	v	i	s	i	t	3	6	0	0	v	i	s	i	t	3	6	0	0	v	i	s	i	t	3	6	0	0	v	i	s	i	t	3	6	0	0	v	i	s	i	t	3	6	0	0	v	i	s	i	t	3	6	0	0	v	i	s	i
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Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=HDL_SU Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

O b s _	P A R A M E T E R S	E F F E C T	R E G I O N	B O L A D	O b s _	T
7	1	HDL cholesterol (mg/dL)	Intercept		0.01175	0.030980
8	1	HDL cholesterol (mg/dL)	REGION1 ASIA (EXCLUDING JAPAN)		-0.06685	-0.002234
9	1	HDL cholesterol (mg/dL)	REGION1 EUROPE		-0.02082	0.052301
10	1	HDL cholesterol (mg/dL)	REGION1 JAPAN		0.23635	0.161940
11	1	HDL cholesterol (mg/dL)	BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.04813	-0.044285
12	1	HDL cholesterol (mg/dL)	BASE		-0.18461	-0.209149
13	1	HDL cholesterol (mg/dL)	visit2200		0.65122	0.637257

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The MI Procedure with MCMC
Model Information

Parameter Code=C105587S Planned Treatment for Period 30 (N)=2

Obs	PARAM	Description	Value
1	HDL cholesterol (mmol/L)	Data Set	WORK.ENDPOINT_PARAM
2	HDL cholesterol (mmol/L)	Method	Monotone-data_MCMC
3	HDL cholesterol (mmol/L)	Multiple Imputation Chain	Multiple Chains
4	HDL cholesterol (mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
5	HDL cholesterol (mmol/L)	Start	Starting Value
6	HDL cholesterol (mmol/L)	Prior	Jeffreys
7	HDL cholesterol (mmol/L)	Number of Imputations	10000
8	HDL cholesterol (mmol/L)	Number of Burn-in Iterations	200
9	HDL cholesterol (mmol/L)	Seed for random number generator	144500

Parameter Code=C105587S Planned Treatment for Period 30 (N)=3

Obs	PARAM	Description	Value
10	HDL cholesterol (mmol/L)	Data Set	WORK.ENDPOINT_PARAM
11	HDL cholesterol (mmol/L)	Method	Monotone-data_MCMC
12	HDL cholesterol (mmol/L)	Multiple Imputation Chain	Multiple Chains
13	HDL cholesterol (mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
14	HDL cholesterol (mmol/L)	Start	Starting Value
15	HDL cholesterol (mmol/L)	Prior	Jeffreys
16	HDL cholesterol (mmol/L)	Number of Imputations	10000
17	HDL cholesterol (mmol/L)	Number of Burn-in Iterations	200
18	HDL cholesterol (mmol/L)	Seed for random number generator	2064268711

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The MI Procedure with MCMC
Model Information

Parameter Code=C105587S Planned Treatment for Period 30 (N)=4

Obs	PARAM	Description	Value
19	HDL cholesterol (mmol/L)	Data Set	WORK.ENDPOINT_PARAM
20	HDL cholesterol (mmol/L)	Method	Monotone-data_MCMC
21	HDL cholesterol (mmol/L)	Multiple Imputation Chain	Multiple Chains
22	HDL cholesterol (mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
23	HDL cholesterol (mmol/L)	Start	Starting Value
24	HDL cholesterol (mmol/L)	Prior	Jeffreys
25	HDL cholesterol (mmol/L)	Number of Imputations	10000
26	HDL cholesterol (mmol/L)	Number of Burn-in Iterations	200
27	HDL cholesterol (mmol/L)	Seed for random number generator	1198333808

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The MI Procedure with MCMC
Missing data pattern

Parameter Code=C105587S Planned Treatment for Period 30 (N)=2

Obs	PARAM	Group	BASE_ Miss_	visit2200_ Miss_	visit3600_ Miss_	Freq	Percent	BASE	visit2200	visit3600
1	HDL cholesterol (mmol/L)	1	X	X	X	325	95.03	0.440699	-0.005082	-0.021372
2	HDL cholesterol (mmol/L)	2	X	X	O	9	2.63	0.296245	0.057936	.
3	HDL cholesterol (mmol/L)	3	X	.	X	6	1.75	0.495499	.	0.013531
4	HDL cholesterol (mmol/L)	4	X	O	O	2	0.58	0.398213	.	.

Parameter Code=C105587S Planned Treatment for Period 30 (N)=3

Obs	PARAM	Group	BASE_ Miss_	visit2200_ Miss_	visit3600_ Miss_	Freq	Percent	BASE	visit2200	visit3600
5	HDL cholesterol (mmol/L)	1	X	X	X	331	97.07	0.444103	0.004443	-0.001242
6	HDL cholesterol (mmol/L)	2	X	X	O	7	2.05	0.547261	-0.015993	.
7	HDL cholesterol (mmol/L)	3	X	.	X	1	0.29	0.457425	.	-0.106768
8	HDL cholesterol (mmol/L)	4	X	O	O	2	0.59	0.489069	.	.

Parameter Code=C105587S Planned Treatment for Period 30 (N)=4

Obs	PARAM	Group	BASE_ Miss_	visit2200_ Miss_	visit3600_ Miss_	Freq	Percent	BASE	visit2200	visit3600
9	HDL cholesterol (mmol/L)	1	X	X	X	318	92.98	0.439025	0.000965	-0.005623
10	HDL cholesterol (mmol/L)	2	X	X	O	16	4.68	0.466528	0.016848	.
11	HDL cholesterol (mmol/L)	3	X	.	X	6	1.75	0.165783	.	0.098766
12	HDL cholesterol (mmol/L)	4	X	O	O	2	0.58	0.753703	.	.

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The MI Procedure with Monotone Regression
Model Information

Parameter Code=C105587S Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM	Description	Value
1	1	HDL cholesterol (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	HDL cholesterol (mmol/L)	Method	Monotone
3	1	HDL cholesterol (mmol/L)	Number of Imputations	1
4	1	HDL cholesterol (mmol/L)	Seed for random number generator	144800

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The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=C105587S Planned Treatment for Period 30 (N)=2

O b s	I m p u t a t i o n	P A R A M E T E R	G r o u p	R E G I O N 1	B O L 1	B L A D E	B L A D E	B L A D E	B L A D E	F r e q	P e r c e n t	B A S E	v i s i t 2 0	v i s i t 3 6 0 0
1	1	HDL cholesterol (mmol/L)	1	X	X	X	X	X	X	331	96.78	0.441693	-0.004849	-0.020739
2	1	HDL cholesterol (mmol/L)	2	X	X	X	X	.	.	9	2.63	0.296245	0.057936	.
3	1	HDL cholesterol (mmol/L)	3	X	X	X	.	.	.	2	0.58	0.398213	.	.

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=C105587S Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	HDL cholesterol (mmol/L)	Intercept	
2	1	HDL cholesterol (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	HDL cholesterol (mmol/L)	REGION1	EUROPE
4	1	HDL cholesterol (mmol/L)	REGION1	JAPAN
5	1	HDL cholesterol (mmol/L)	BOLAD1	
6	1	HDL cholesterol (mmol/L)	BASE	

Obs		BOLAD1	ObsVal	_1
1			0.03267	0.090139
2			-0.00333	-0.134053
3			-0.06222	0.061852
4			0.10817	0.198123
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.11757	-0.202820
6			-0.25686	-0.306126

Parameter Code=C105587S Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	HDL cholesterol (mmol/L)	Intercept			0.02504	0.037034
8	1	HDL cholesterol (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)		-0.04947	-0.049280
9	1	HDL cholesterol (mmol/L)	REGION1	EUROPE		-0.02616	0.045630

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=C105587S Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
10	1	HDL cholesterol (mmol/L)	REGION1	JAPAN		0.18340	0.187715
11	1	HDL cholesterol (mmol/L)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.06067	-0.098013
12	1	HDL cholesterol (mmol/L)	BASE			-0.05787	-0.048393
13	1	HDL cholesterol (mmol/L)	visit2200			0.59117	0.561422

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The MI Procedure with Monotone Regression
Model Information

Parameter Code=C105587S Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM	Description	Value
1	1	HDL cholesterol (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	HDL cholesterol (mmol/L)	Method	Monotone
3	1	HDL cholesterol (mmol/L)	Number of Imputations	1
4	1	HDL cholesterol (mmol/L)	Seed for random number generator	144801

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The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=C105587S Planned Treatment for Period 30 (N)=3

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1	1	HDL cholesterol (mmol/L)	1	X	X	X	X	X	X	332	97.36	0.444143	0.004133	-0.001560
2	1	HDL cholesterol (mmol/L)	2	X	X	X	X	.	.	7	2.05	0.547261	-0.015993	.
3	1	HDL cholesterol (mmol/L)	3	X	X	X	.	.	.	2	0.59	0.489069	.	.

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=C105587S Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	HDL cholesterol (mmol/L)	Intercept	
2	1	HDL cholesterol (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	HDL cholesterol (mmol/L)	REGION1	EUROPE
4	1	HDL cholesterol (mmol/L)	REGION1	JAPAN
5	1	HDL cholesterol (mmol/L)	BOLAD1	
6	1	HDL cholesterol (mmol/L)	BASE	

Obs		BOLAD1	ObsVal	_1
1			-0.01774	-0.011050
2			-0.16303	-0.169112
3			-0.08853	-0.116893
4			0.42219	0.547585
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.04829	0.123943
6			-0.20372	-0.282617

Parameter Code=C105587S Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	HDL cholesterol (mmol/L)	Intercept			0.01002	-0.044615
8	1	HDL cholesterol (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)		-0.02087	-0.247301
9	1	HDL cholesterol (mmol/L)	REGION1	EUROPE		-0.07865	0.036536

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=C105587S Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
10	1	HDL cholesterol (mmol/L)	REGION1	JAPAN		0.34435	0.346839
11	1	HDL cholesterol (mmol/L)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.04109	0.056546
12	1	HDL cholesterol (mmol/L)	BASE			-0.18419	-0.199685
13	1	HDL cholesterol (mmol/L)	visit2200			0.44257	0.396468

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The MI Procedure with Monotone Regression
Model Information

Parameter Code=C105587S Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM	Description	Value
1	1	HDL cholesterol (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	HDL cholesterol (mmol/L)	Method	Monotone
3	1	HDL cholesterol (mmol/L)	Number of Imputations	1
4	1	HDL cholesterol (mmol/L)	Seed for random number generator	144802

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The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=C105587S Planned Treatment for Period 30 (N)=4

O b s	I m p u t a t i o n	P A R A M	G r o u p	R E G I O N 1	B O L 1	B L A D E	B L A D E	B L A D E	B L A D E	F r e q	P e r c e n t	B A S E	v i s i t 2 0	v i s i t 3 6 0 0
1	1	HDL cholesterol (mmol/L)	1	X	X	X	X	X	X	324	94.74	0.433965	0.001846	-0.003690
2	1	HDL cholesterol (mmol/L)	2	X	X	X	X	X	.	16	4.68	0.466528	0.016848	.
3	1	HDL cholesterol (mmol/L)	3	X	X	X	.	.	.	2	0.58	0.753703	.	.

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Novo Nordisk

Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=C105587S Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	HDL cholesterol (mmol/L)	Intercept	
2	1	HDL cholesterol (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	HDL cholesterol (mmol/L)	REGION1	EUROPE
4	1	HDL cholesterol (mmol/L)	REGION1	JAPAN
5	1	HDL cholesterol (mmol/L)	BOLAD1	
6	1	HDL cholesterol (mmol/L)	BASE	

Obs		BOLAD1	ObsVal	_1
1			0.0002126	-0.008017
2			-0.00673	0.127402
3			-0.04401	0.051453
4			0.10323	-0.043225
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.01646	-0.093189
6			-0.29403	-0.270962

Parameter Code=C105587S Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	HDL cholesterol (mmol/L)	Intercept			0.01175	0.030980
8	1	HDL cholesterol (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)		-0.06685	-0.002234
9	1	HDL cholesterol (mmol/L)	REGION1	EUROPE		-0.02082	0.052301

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=C105587S Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
10	1	HDL cholesterol (mmol/L)	REGION1	JAPAN		0.23635	0.161940
11	1	HDL cholesterol (mmol/L)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.04813	-0.044285
12	1	HDL cholesterol (mmol/L)	BASE			-0.18461	-0.209149
13	1	HDL cholesterol (mmol/L)	visit2200			0.65122	0.637257

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Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=LDL_SU Planned Treatment for Period 30 (N)=2

Obs	PARAM	Description	Value
1	LDL cholesterol (mg/dL)	Data Set	WORK.ENDPOINT_PARAM
2	LDL cholesterol (mg/dL)	Method	Monotone-data MCMC
3	LDL cholesterol (mg/dL)	Multiple Imputation Chain	Multiple Chains
4	LDL cholesterol (mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
5	LDL cholesterol (mg/dL)	Start	Starting Value
6	LDL cholesterol (mg/dL)	Prior	Jeffreys
7	LDL cholesterol (mg/dL)	Number of Imputations	10000
8	LDL cholesterol (mg/dL)	Number of Burn-in Iterations	200
9	LDL cholesterol (mg/dL)	Seed for random number generator	144500

Parameter Code=LDL_SU Planned Treatment for Period 30 (N)=3

Obs	PARAM	Description	Value
10	LDL cholesterol (mg/dL)	Data Set	WORK.ENDPOINT_PARAM
11	LDL cholesterol (mg/dL)	Method	Monotone-data MCMC
12	LDL cholesterol (mg/dL)	Multiple Imputation Chain	Multiple Chains
13	LDL cholesterol (mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
14	LDL cholesterol (mg/dL)	Start	Starting Value
15	LDL cholesterol (mg/dL)	Prior	Jeffreys
16	LDL cholesterol (mg/dL)	Number of Imputations	10000
17	LDL cholesterol (mg/dL)	Number of Burn-in Iterations	200
18	LDL cholesterol (mg/dL)	Seed for random number generator	2064268711

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The MI Procedure with MCMC
Model Information

Parameter Code=LDL_SU Planned Treatment for Period 30 (N)=4

Obs	PARAM	Description	Value
19	LDL cholesterol (mg/dL)	Data Set	WORK.ENDPOINT_PARAM
20	LDL cholesterol (mg/dL)	Method	Monotone-data MCMC
21	LDL cholesterol (mg/dL)	Multiple Imputation Chain	Multiple Chains
22	LDL cholesterol (mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
23	LDL cholesterol (mg/dL)	Start	Starting Value
24	LDL cholesterol (mg/dL)	Prior	Jeffreys
25	LDL cholesterol (mg/dL)	Number of Imputations	10000
26	LDL cholesterol (mg/dL)	Number of Burn-in Iterations	200
27	LDL cholesterol (mg/dL)	Seed for random number generator	1198333808

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Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC
Missing data pattern

Parameter Code=LDL_SU Planned Treatment for Period 30 (N)=2

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
1	LDL cholesterol (mg/dL)	1	X	X	X	325	95.03	4.589524	0.033173	0.023370
2	LDL cholesterol (mg/dL)	2	X	X	O	9	2.63	4.512923	0.059173	.
3	LDL cholesterol (mg/dL)	3	X	.	X	6	1.75	4.564432	.	0.055554
4	LDL cholesterol (mg/dL)	4	X	O	O	2	0.58	4.602141	.	.

Parameter Code=LDL_SU Planned Treatment for Period 30 (N)=3

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
5	LDL cholesterol (mg/dL)	1	X	X	X	331	97.07	4.605104	0.039271	0.049490
6	LDL cholesterol (mg/dL)	2	X	X	O	7	2.05	4.374732	0.064987	.
7	LDL cholesterol (mg/dL)	3	X	.	X	1	0.29	4.356609	.	0.014742
8	LDL cholesterol (mg/dL)	4	X	O	O	2	0.59	4.730246	.	.

Parameter Code=LDL_SU Planned Treatment for Period 30 (N)=4

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
9	LDL cholesterol (mg/dL)	1	X	X	X	317	92.69	4.576754	0.043941	0.054152
10	LDL cholesterol (mg/dL)	2	X	X	O	17	4.97	4.620949	-0.010866	.
11	LDL cholesterol (mg/dL)	3	X	.	X	6	1.75	4.338394	.	0.243440
12	LDL cholesterol (mg/dL)	4	X	O	O	2	0.58	4.644701	.	.

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The MI Procedure with Monotone Regression
Model Information

Parameter Code=LDL_SU Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM	Description	Value
1	1	LDL cholesterol (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	LDL cholesterol (mg/dL)	Method	Monotone
3	1	LDL cholesterol (mg/dL)	Number of Imputations	1
4	1	LDL cholesterol (mg/dL)	Seed for random number generator	144800

Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=LDL_SU Planned Treatment for Period 30 (N)=2

O b s	I m p u t a t i o n	P A R A M E T E R	G r o u p	R E G I S T E R E D I T I O N A L	B O L U S I N G	L I P I D S	B O L U S I N G	L I P I D S	F R E Q U E N C Y	P E R C E N T	B O L U S I N G	V A R I A N C E	V A R I A N C E
1	1	LDL cholesterol (mg/dL)	1	X	X	X	X	X	331	96.78	4.589070	0.033489	0.023953
2	1	LDL cholesterol (mg/dL)	2	X	X	X	X	.	9	2.63	4.512923	0.059173	.
3	1	LDL cholesterol (mg/dL)	3	X	X	X	.	.	2	0.58	4.602141	.	.

Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=LDL_SU Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

Imputed		Observed		Observed		Observed		Observed	
a		t		f		e		o	
i		P		A		R		A	
O o		A		R		A		D	
b n		M		c		N		1	
s _				t		1		1	
7	1	LDL cholesterol (mg/dL)	Intercept					-0.03732	-0.025883
8	1	LDL cholesterol (mg/dL)	REGION1 ASIA (EXCLUDING JAPAN)					-0.26604	-0.265779
9	1	LDL cholesterol (mg/dL)	REGION1 EUROPE					0.16912	0.237233
10	1	LDL cholesterol (mg/dL)	REGION1 JAPAN					0.25690	0.262304
11	1	LDL cholesterol (mg/dL)	BOLAD1				BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.03557	0.000003727
12	1	LDL cholesterol (mg/dL)	BASE					-0.21053	-0.203543
13	1	LDL cholesterol (mg/dL)	visit2200					0.52909	0.503163

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The MI Procedure with Monotone Regression
Model Information

Parameter Code=LDL_SU Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM	Description	Value
1	1	LDL cholesterol (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	LDL cholesterol (mg/dL)	Method	Monotone
3	1	LDL cholesterol (mg/dL)	Number of Imputations	1
4	1	LDL cholesterol (mg/dL)	Seed for random number generator	144801

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=LDL_SU Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2200

		Imputed		Region		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		Observed			
		Parameter		Effect		BOLUS		Observed		Mean	
		Parameter		Effect		BOLUS		Observed		Mean	
		Parameter		Effect		BOLUS		Observed		Mean	
		Parameter		Effect		BOLUS		Observed		Mean	
		Parameter		Effect		BOLUS		Observed		Mean	
		Parameter		Effect		BOLUS		Observed		Mean	
		Parameter		Effect		BOLUS		Observed		Mean	
		Parameter		Effect		BOLUS		Observed		Mean	
		Parameter		Effect		BOLUS		Observed		Mean	
		Parameter		Effect		BOLUS		Observed		Mean	
		Parameter		Effect		BOLUS		Observed		Mean	
		Parameter		Effect		BOLUS		Observed		Mean	
		Parameter		Effect		BOLUS		Observed		Mean	
		Parameter		Effect		BOLUS		Observed		Mean	
		Parameter		Effect		BOLUS		Observed		Mean	
		Parameter		Effect		BOLUS		Observed		Mean	
		Parameter		Effect		BOLUS		Observed		Mean	
		Parameter		Effect		BOLUS		Observed		Mean	
		Parameter		Effect		BOLUS		Observed		Mean	
		Parameter		Effect		BOLUS		Observed		Mean	
		Parameter		Effect		BOLUS		Observed		Mean	
		Parameter		Effect		BOLUS		Observed		Mean	
		Parameter		Effect		BOLUS		Observed		Mean	
		Parameter		Effect		BOLUS		Observed		Mean	
		Parameter		Effect		BOLUS		Observed		Mean	
		Parameter		Effect		BOLUS		Observed		Mean	
		Parameter		Effect		BOLUS		Observed		Mean	
		Parameter		Effect		BOLUS		Observed		Mean	
		Parameter		Effect		BOLUS		Observed		Mean	
		Parameter		Effect		BOLUS		Observed		Mean	
		Parameter		Effect		BOLUS		Observed		Mean	
		Parameter		Effect		BOLUS		Observed		Mean	
		Parameter		Effect		BOLUS		Observed		Mean	
		Parameter		Effect		BOLUS		Observed		Mean	
		Parameter		Effect		BOLUS		Observed		Mean	
		Parameter		Effect		BOLUS		Observed		Mean	
		Parameter		Effect		BOLUS		Observed		Mean	
		Parameter		Effect		BOLUS		Observed		Mean	
		Parameter		Effect		BOLUS		Observed		Mean	
		Parameter		Effect		BOLUS		Observed		Mean	
		Parameter		Effect		BOLUS		Observed		Mean	
		Parameter		Effect		BOLUS		Observed		Mean	
		Parameter		Effect		BOLUS		Observed		Mean	
		Parameter		Effect		BOLUS		Observed		Mean	
		Parameter		Effect		BOLUS		Observed		Mean	
		Parameter		Effect		BOLUS		Observed		Mean	
		Parameter		Effect		BOLUS		Observed		Mean	
		Parameter		Effect		BOLUS		Observed		Mean	
		Parameter		Effect		BOLUS		Observed		Mean	
		Parameter		Effect		BOLUS		Observed		Mean	
		Parameter		Effect		BOLUS		Observed		Mean	
		Parameter		Effect		BOLUS		Observed		Mean	
		Parameter		Effect		BOLUS		Observed		Mean	
		Parameter		Effect		BOLUS		Observed		Mean	
		Parameter		Effect		BOLUS		Observed		Mean	
		Parameter		Effect		BOLUS		Observed		Mean	
		Parameter		Effect		BOLUS		Observed		Mean	
		Parameter		Effect		BOLUS		Observed		Mean	
		Parameter		Effect		BOLUS		Observed		Mean	
		Parameter		Effect		BOLUS		Observed		Mean	
		Parameter		Effect		BOLUS		Observed		Mean	
		Parameter		Effect		BOLUS		Observed		Mean	
		Parameter		Effect		BOLUS		Observed		Mean	
		Parameter		Effect		BOLUS		Observed		Mean	
		Parameter		Effect		BOLUS		Observed		Mean	
		Parameter		Effect		BOLUS		Observed		Mean	
		Parameter		Effect		BOLUS		Observed		Mean	
		Parameter		Effect		BOLUS		Observed		Mean	
		Parameter		Effect		BOLUS		Observed		Mean	
		Parameter		Effect		BOLUS		Observed		Mean	
		Parameter		Effect		BOLUS		Observed		Mean	
		Parameter		Effect		BOLUS		Observed		Mean	
		Parameter		Effect		BOLUS		Observed		Mean	
		Parameter		Effect		BOLUS		Observed		Mean	
		Parameter		Effect		BOLUS		Observed		Mean	
		Parameter		Effect		BOLUS		Observed		Mean	
		Parameter		Effect		BOLUS		Observed		Mean	
		Parameter		Effect		BOLUS		Observed		Mean	
		Parameter									

Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression Regression Information

Parameter Code=LDL SU Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

	O b s _	P A R M	E f f e c t	R E G I O N 1	B O L U S D 1	O b s V a l	T
7	1	LDL cholesterol (mg/dL)	Intercept			-0.01778	-0.073564
8	1	LDL cholesterol (mg/dL)	REGION1 ASIA (EXCLUDING JAPAN)			-0.10685	-0.336480
9	1	LDL cholesterol (mg/dL)	REGION1 EUROPE			0.03331	0.152293
10	1	LDL cholesterol (mg/dL)	REGION1 JAPAN			0.15078	0.150950
11	1	LDL cholesterol (mg/dL)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.05073	0.150389
12	1	LDL cholesterol (mg/dL)	BASE			-0.21531	-0.233377
13	1	LDL cholesterol (mg/dL)	visit2200			0.41915	0.369764

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Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=LDL_SU Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM	Description	Value
1	1	LDL cholesterol (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	LDL cholesterol (mg/dL)	Method	Monotone
3	1	LDL cholesterol (mg/dL)	Number of Imputations	1
4	1	LDL cholesterol (mg/dL)	Seed for random number generator	144802

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The MI Procedure with Monotone Regression Regression Information

Parameter Code=LDL_SU Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2200

O b s _		P A R A M		E f f e c t		R E G I O N		B O L U S		O b s _		I	
1	1	LDL	cholesterol	(mg/dL)	Intercept						0.00790		0.001171
2	1	LDL	cholesterol	(mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)					0.06516		0.171793
3	1	LDL	cholesterol	(mg/dL)	REGION1	EUROPE					-0.01854		0.056358
4	1	LDL	cholesterol	(mg/dL)	REGION1	JAPAN					0.03180		-0.074118
5	1	LDL	cholesterol	(mg/dL)	BOLAD1				BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.00875		-0.084876
6	1	LDL	cholesterol	(mg/dL)	BASE						-0.62213		-0.616935

Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=LDL_SU Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

O b s _	i n s _	P A R M _	E f f e c t	R E G I O N _	B O L A D _	O b s _	T
7	1	LDL cholesterol (mg/dL)	Intercept			-0.02034	-0.004533
8	1	LDL cholesterol (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)		-0.08635	-0.034417
9	1	LDL cholesterol (mg/dL)	REGION1	EUROPE		0.05804	0.116748
10	1	LDL cholesterol (mg/dL)	REGION1	JAPAN		0.10900	0.054434
11	1	LDL cholesterol (mg/dL)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.01448	0.015636
12	1	LDL cholesterol (mg/dL)	BASE			-0.16858	-0.212161
13	1	LDL cholesterol (mg/dL)	visit2200			0.69533	0.662971

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The MI Procedure with MCMC
Model Information

Parameter Code=C105588S Planned Treatment for Period 30 (N)=2

Obs	PARAM	Description	Value
1	LDL cholesterol (mmol/L)	Data Set	WORK.ENDPOINT_PARAM
2	LDL cholesterol (mmol/L)	Method	Monotone-data_MCMC
3	LDL cholesterol (mmol/L)	Multiple Imputation Chain	Multiple Chains
4	LDL cholesterol (mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
5	LDL cholesterol (mmol/L)	Start	Starting Value
6	LDL cholesterol (mmol/L)	Prior	Jeffreys
7	LDL cholesterol (mmol/L)	Number of Imputations	10000
8	LDL cholesterol (mmol/L)	Number of Burn-in Iterations	200
9	LDL cholesterol (mmol/L)	Seed for random number generator	144500

Parameter Code=C105588S Planned Treatment for Period 30 (N)=3

Obs	PARAM	Description	Value
10	LDL cholesterol (mmol/L)	Data Set	WORK.ENDPOINT_PARAM
11	LDL cholesterol (mmol/L)	Method	Monotone-data_MCMC
12	LDL cholesterol (mmol/L)	Multiple Imputation Chain	Multiple Chains
13	LDL cholesterol (mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
14	LDL cholesterol (mmol/L)	Start	Starting Value
15	LDL cholesterol (mmol/L)	Prior	Jeffreys
16	LDL cholesterol (mmol/L)	Number of Imputations	10000
17	LDL cholesterol (mmol/L)	Number of Burn-in Iterations	200
18	LDL cholesterol (mmol/L)	Seed for random number generator	2064268711

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The MI Procedure with MCMC
Model Information

Parameter Code=C105588S Planned Treatment for Period 30 (N)=4

Obs	PARAM	Description	Value
19	LDL cholesterol (mmol/L)	Data Set	WORK.ENDPOINT_PARAM
20	LDL cholesterol (mmol/L)	Method	Monotone-data MCMC
21	LDL cholesterol (mmol/L)	Multiple Imputation Chain	Multiple Chains
22	LDL cholesterol (mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
23	LDL cholesterol (mmol/L)	Start	Starting Value
24	LDL cholesterol (mmol/L)	Prior	Jeffreys
25	LDL cholesterol (mmol/L)	Number of Imputations	10000
26	LDL cholesterol (mmol/L)	Number of Burn-in Iterations	200
27	LDL cholesterol (mmol/L)	Seed for random number generator	1198333808

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The MI Procedure with MCMC
Missing data pattern

Parameter Code=C105588S Planned Treatment for Period 30 (N)=2

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
1	LDL cholesterol (mmol/L)	1	X	X	X	325	95.03	0.936013	0.033173	0.023370
2	LDL cholesterol (mmol/L)	2	X	X	O	9	2.63	0.859412	0.059173	.
3	LDL cholesterol (mmol/L)	3	X	.	X	6	1.75	0.910920	.	0.055554
4	LDL cholesterol (mmol/L)	4	X	O	O	2	0.58	0.948630	.	.

Parameter Code=C105588S Planned Treatment for Period 30 (N)=3

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
5	LDL cholesterol (mmol/L)	1	X	X	X	331	97.07	0.951592	0.039271	0.049490
6	LDL cholesterol (mmol/L)	2	X	X	O	7	2.05	0.721220	0.064987	.
7	LDL cholesterol (mmol/L)	3	X	.	X	1	0.29	0.703098	.	0.014742
8	LDL cholesterol (mmol/L)	4	X	O	O	2	0.59	1.076735	.	.

Parameter Code=C105588S Planned Treatment for Period 30 (N)=4

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
9	LDL cholesterol (mmol/L)	1	X	X	X	317	92.69	0.923243	0.043941	0.054152
10	LDL cholesterol (mmol/L)	2	X	X	O	17	4.97	0.967437	-0.010866	.
11	LDL cholesterol (mmol/L)	3	X	.	X	6	1.75	0.684883	.	0.243440
12	LDL cholesterol (mmol/L)	4	X	O	O	2	0.58	0.991190	.	.

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Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=C105588S Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM	Description	Value
1	1	LDL cholesterol (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	LDL cholesterol (mmol/L)	Method	Monotone
3	1	LDL cholesterol (mmol/L)	Number of Imputations	1
4	1	LDL cholesterol (mmol/L)	Seed for random number generator	144800

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Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=C105588S Planned Treatment for Period 30 (N)=2

O b s	I m p u t a t i o n _	P A R A M _	G r o u p	R E G I O N _	B O L _	B L _	B A _	B S _	B E _	F r e q	P e r c e n t	B A S E	v i s i t _	v i s i t _
1	1	LDL cholesterol (mmol/L)	1	X	X	X	X	X	X	331	96.78	0.935558	0.033489	0.023953
2	1	LDL cholesterol (mmol/L)	2	X	X	X	X	.	.	9	2.63	0.859412	0.059173	.
3	1	LDL cholesterol (mmol/L)	3	X	X	X	.	.	.	2	0.58	0.948630	.	.

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Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=C105588S Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	LDL cholesterol (mmol/L)	Intercept	
2	1	LDL cholesterol (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	LDL cholesterol (mmol/L)	REGION1	EUROPE
4	1	LDL cholesterol (mmol/L)	REGION1	JAPAN
5	1	LDL cholesterol (mmol/L)	BOLAD1	
6	1	LDL cholesterol (mmol/L)	BASE	

Obs		BOLAD1	ObsVal	_1
1			-0.01861	0.036878
2			-0.16320	-0.286620
3			0.00937	0.130272
4			0.23284	0.315657
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.05737	-0.024676
6			-0.36050	-0.402218

Parameter Code=C105588S Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	LDL cholesterol (mmol/L)	Intercept			-0.03732	-0.025883
8	1	LDL cholesterol (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)		-0.26604	-0.265779
9	1	LDL cholesterol (mmol/L)	REGION1	EUROPE		0.16912	0.237233

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=C105588S Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
10	1	LDL cholesterol (mmol/L)	REGION1	JAPAN		0.25690	0.262304
11	1	LDL cholesterol (mmol/L)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.03557	0.000003727
12	1	LDL cholesterol (mmol/L)	BASE			-0.21053	-0.203543
13	1	LDL cholesterol (mmol/L)	visit2200			0.52909	0.503163

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Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=C105588S Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM	Description	Value
1	1	LDL cholesterol (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	LDL cholesterol (mmol/L)	Method	Monotone
3	1	LDL cholesterol (mmol/L)	Number of Imputations	1
4	1	LDL cholesterol (mmol/L)	Seed for random number generator	144801

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Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=C105588S Planned Treatment for Period 30 (N)=3

O b s	I m p u t a t i o n	P A R A M E T E R	G r o u p	R E G I O N 1	B O L 1	B L A D E	B L A D E	B L A D E	B L A D E	F r e q	P e r c e n t	B A S E	v i s i t 2 0	v i s i t 3 6 0 0
1	1	LDL cholesterol (mmol/L)	1	X	X	X	X	X	X	332	97.36	0.950844	0.039041	0.049385
2	1	LDL cholesterol (mmol/L)	2	X	X	X	X	.	.	7	2.05	0.721220	0.064987	.
3	1	LDL cholesterol (mmol/L)	3	X	X	X	.	.	.	2	0.59	1.076735	.	.

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Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=C105588S Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	LDL cholesterol (mmol/L)	Intercept	
2	1	LDL cholesterol (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	LDL cholesterol (mmol/L)	REGION1	EUROPE
4	1	LDL cholesterol (mmol/L)	REGION1	JAPAN
5	1	LDL cholesterol (mmol/L)	BOLAD1	
6	1	LDL cholesterol (mmol/L)	BASE	

Obs		BOLAD1	ObsVal	_1
1			-0.01415	-0.007483
2			-0.12840	-0.134399
3			-0.15265	-0.180521
4			0.27414	0.394629
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.06348	0.140156
6			-0.24112	-0.307098

Parameter Code=C105588S Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	LDL cholesterol (mmol/L)	Intercept			-0.01778	-0.073564
8	1	LDL cholesterol (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)		-0.10685	-0.336480
9	1	LDL cholesterol (mmol/L)	REGION1	EUROPE		0.03331	0.152293

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=C105588S Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
10	1	LDL cholesterol (mmol/L)	REGION1	JAPAN		0.15078	0.150950
11	1	LDL cholesterol (mmol/L)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.05073	0.150389
12	1	LDL cholesterol (mmol/L)	BASE			-0.21531	-0.233377
13	1	LDL cholesterol (mmol/L)	visit2200			0.41915	0.369764

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Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=C105588S Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM	Description	Value
1	1	LDL cholesterol (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	LDL cholesterol (mmol/L)	Method	Monotone
3	1	LDL cholesterol (mmol/L)	Number of Imputations	1
4	1	LDL cholesterol (mmol/L)	Seed for random number generator	144802

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The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=C105588S Planned Treatment for Period 30 (N)=4

O b s	I m p u t a t i o n	P A R A M	G r o u p	R E G I O N 1	B O L 1	B L A D E	B L A D E	B L A D E	B L A D E	F r e q	P e r c e n t	B A S E	v i s i t 2 0	v i s i t 3 6 0 0
1	1	LDL cholesterol (mmol/L)	1	X	X	X	X	X	X	323	94.44	0.918815	0.046347	0.057668
2	1	LDL cholesterol (mmol/L)	2	X	X	X	X	.	.	17	4.97	0.967437	-0.010866	.
3	1	LDL cholesterol (mmol/L)	3	X	X	X	.	.	.	2	0.58	0.991190	.	.

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Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=C105588S Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	LDL cholesterol (mmol/L)	Intercept	
2	1	LDL cholesterol (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	LDL cholesterol (mmol/L)	REGION1	EUROPE
4	1	LDL cholesterol (mmol/L)	REGION1	JAPAN
5	1	LDL cholesterol (mmol/L)	BOLAD1	
6	1	LDL cholesterol (mmol/L)	BASE	

Obs		BOLAD1	ObsVal	_1
1			0.00790	0.001171
2			0.06516	0.171793
3			-0.01854	0.056358
4			0.03180	-0.074118
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.00875	-0.084876
6			-0.62213	-0.616935

Parameter Code=C105588S Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	LDL cholesterol (mmol/L)	Intercept			-0.02034	-0.004533
8	1	LDL cholesterol (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)		-0.08635	-0.034417
9	1	LDL cholesterol (mmol/L)	REGION1	EUROPE		0.05804	0.116748

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=C105588S Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
10	1	LDL cholesterol (mmol/L)	REGION1	JAPAN		0.10900	0.054434
11	1	LDL cholesterol (mmol/L)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.01448	0.015636
12	1	LDL cholesterol (mmol/L)	BASE			-0.16858	-0.212161
13	1	LDL cholesterol (mmol/L)	visit2200			0.69533	0.662971

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The MI Procedure with MCMC
Model Information

Parameter Code=T_CHOL_U Planned Treatment for Period 30 (N)=2

Obs	PARAM	Description	Value
1	Total cholesterol (mg/dL)	Data Set	WORK.ENDPOINT_PARAM
2	Total cholesterol (mg/dL)	Method	Monotone-data_MCMC
3	Total cholesterol (mg/dL)	Multiple Imputation Chain	Multiple Chains
4	Total cholesterol (mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
5	Total cholesterol (mg/dL)	Start	Starting Value
6	Total cholesterol (mg/dL)	Prior	Jeffreys
7	Total cholesterol (mg/dL)	Number of Imputations	10000
8	Total cholesterol (mg/dL)	Number of Burn-in Iterations	200
9	Total cholesterol (mg/dL)	Seed for random number generator	144500

Parameter Code=T_CHOL_U Planned Treatment for Period 30 (N)=3

Obs	PARAM	Description	Value
10	Total cholesterol (mg/dL)	Data Set	WORK.ENDPOINT_PARAM
11	Total cholesterol (mg/dL)	Method	Monotone-data_MCMC
12	Total cholesterol (mg/dL)	Multiple Imputation Chain	Multiple Chains
13	Total cholesterol (mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
14	Total cholesterol (mg/dL)	Start	Starting Value
15	Total cholesterol (mg/dL)	Prior	Jeffreys
16	Total cholesterol (mg/dL)	Number of Imputations	10000
17	Total cholesterol (mg/dL)	Number of Burn-in Iterations	200
18	Total cholesterol (mg/dL)	Seed for random number generator	2064268711

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Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=T_CHOL_U Planned Treatment for Period 30 (N)=4

Obs	PARAM	Description	Value
19	Total cholesterol (mg/dL)	Data Set	WORK.ENDPOINT_PARAM
20	Total cholesterol (mg/dL)	Method	Monotone-data_MCMC
21	Total cholesterol (mg/dL)	Multiple Imputation Chain	Multiple Chains
22	Total cholesterol (mg/dL)	Initial Estimates for MCMC	EM Posterior Mode
23	Total cholesterol (mg/dL)	Start	Starting Value
24	Total cholesterol (mg/dL)	Prior	Jeffreys
25	Total cholesterol (mg/dL)	Number of Imputations	10000
26	Total cholesterol (mg/dL)	Number of Burn-in Iterations	200
27	Total cholesterol (mg/dL)	Seed for random number generator	1198333808

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Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with MCMC
Missing data pattern

Parameter Code=T_CHOL_U Planned Treatment for Period 30 (N)=2

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
1	Total cholesterol (mg/dL)	1	X	X	X	325	95.03	5.151295	0.021671	0.000628
2	Total cholesterol (mg/dL)	2	X	X	O	9	2.63	5.077446	0.043255	.
3	Total cholesterol (mg/dL)	3	X	.	X	6	1.75	5.120558	.	0.039451
4	Total cholesterol (mg/dL)	4	X	O	O	2	0.58	5.120275	.	.

Parameter Code=T_CHOL_U Planned Treatment for Period 30 (N)=3

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
5	Total cholesterol (mg/dL)	1	X	X	X	331	97.07	5.155795	0.030425	0.028715
6	Total cholesterol (mg/dL)	2	X	X	O	7	2.05	5.051777	0.044005	.
7	Total cholesterol (mg/dL)	3	X	.	X	1	0.29	5.029755	.	-0.051825
8	Total cholesterol (mg/dL)	4	X	O	O	2	0.59	5.290411	.	.

Parameter Code=T_CHOL_U Planned Treatment for Period 30 (N)=4

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
9	Total cholesterol (mg/dL)	1	X	X	X	317	92.69	5.154092	0.021503	0.013057
10	Total cholesterol (mg/dL)	2	X	X	O	17	4.97	5.184211	0.007922	.
11	Total cholesterol (mg/dL)	3	X	.	X	6	1.75	4.897076	.	0.166369
12	Total cholesterol (mg/dL)	4	X	O	O	2	0.58	5.239676	.	.

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Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=T_CHOL_U Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM	Description	Value
1	1	Total cholesterol (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	Total cholesterol (mg/dL)	Method	Monotone
3	1	Total cholesterol (mg/dL)	Number of Imputations	1
4	1	Total cholesterol (mg/dL)	Seed for random number generator	144800

Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=T_CHOL_U Planned Treatment for Period 30 (N)=2

O b s	I m p u t a t i o n _	P A R A M _	G r o u p	R E G I O N _	B O L _	L _	B _	A _	A _	S _	E _	F r e q	P e r c e n t	B A S E	v i s i t _	v i s i t _
1	1	Total cholesterol (mg/dL)	1	X	X	X	X	X	X	X	X	331	96.78	5.150738	0.022072	0.001332
2	1	Total cholesterol (mg/dL)	2	X	X	X	X	X	.	.	.	9	2.63	5.077446	0.043255	.
3	1	Total cholesterol (mg/dL)	3	X	X	X	2	0.58	5.120275	.	.

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=T_CHOL_U Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	Total cholesterol (mg/dL)	Intercept	
2	1	Total cholesterol (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	Total cholesterol (mg/dL)	REGION1	EUROPE
4	1	Total cholesterol (mg/dL)	REGION1	JAPAN
5	1	Total cholesterol (mg/dL)	BOLAD1	
6	1	Total cholesterol (mg/dL)	BASE	

Obs		BOLAD1	ObsVal	_1
1			-0.04649	0.009403
2			-0.36586	-0.492233
3			0.13561	0.257543
4			0.31215	0.399396
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.01166	-0.072574
6			-0.34133	-0.395911

Parameter Code=T_CHOL_U Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	Total cholesterol (mg/dL)	Intercept			-0.04574	-0.034163
8	1	Total cholesterol (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)		-0.31427	-0.314007
9	1	Total cholesterol (mg/dL)	REGION1	EUROPE		0.14478	0.213705

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=T_CHOL_U Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
10	1	Total cholesterol (mg/dL)	REGION1	JAPAN		0.25522	0.261431
11	1	Total cholesterol (mg/dL)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.03836	0.001855
12	1	Total cholesterol (mg/dL)	BASE			-0.15186	-0.148404
13	1	Total cholesterol (mg/dL)	visit2200			0.55758	0.525596

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The MI Procedure with Monotone Regression
Model Information

Parameter Code=T_CHOL_U Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM	Description	Value
1	1	Total cholesterol (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	Total cholesterol (mg/dL)	Method	Monotone
3	1	Total cholesterol (mg/dL)	Number of Imputations	1
4	1	Total cholesterol (mg/dL)	Seed for random number generator	144801

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Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression Missing Data Pattern

Parameter Code=T_CHOL U Planned Treatment for Period 30 (N)=3

Obs	Imp	Total	cholesterol	(mg/dL)	Group	REGIONS					Frequency	Percent	Bias	Vissit	Vissit
						MG	OL	BA	ES	IS					
1	1	Total	cholesterol	(mg/dL)	1	X	X	X	X	X	332	97.36	5.155415	0.030182	0.028472
2	1	Total	cholesterol	(mg/dL)	2	X	X	X	X	.	7	2.05	5.051777	0.044005	.
3	1	Total	cholesterol	(mg/dL)	3	X	X	X	.	.	2	0.59	5.290411	.	.

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=T_CHOL_U Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	Total cholesterol (mg/dL)	Intercept	
2	1	Total cholesterol (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	Total cholesterol (mg/dL)	REGION1	EUROPE
4	1	Total cholesterol (mg/dL)	REGION1	JAPAN
5	1	Total cholesterol (mg/dL)	BOLAD1	
6	1	Total cholesterol (mg/dL)	BASE	

Obs		BOLAD1	ObsVal	_1
1			-0.06559	-0.058942
2			-0.38706	-0.393073
3			0.07076	0.042823
4			0.37120	0.493510
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.04659	0.122377
6			-0.25623	-0.329420

Parameter Code=T_CHOL_U Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	Total cholesterol (mg/dL)	Intercept			-0.02220	-0.076435
8	1	Total cholesterol (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)		-0.16194	-0.389860
9	1	Total cholesterol (mg/dL)	REGION1	EUROPE		0.00820	0.123612

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=T_CHOL_U Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
10	1	Total cholesterol (mg/dL)	REGION1	JAPAN		0.27902	0.286471
11	1	Total cholesterol (mg/dL)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.03387	0.130542
12	1	Total cholesterol (mg/dL)	BASE			-0.26264	-0.287269
13	1	Total cholesterol (mg/dL)	visit2200			0.42198	0.364673

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The MI Procedure with Monotone Regression
Model Information

Parameter Code=T_CHOL_U Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM	Description	Value
1	1	Total cholesterol (mg/dL)	Data Set	WORK.MONO_SORT_TRT
2	1	Total cholesterol (mg/dL)	Method	Monotone
3	1	Total cholesterol (mg/dL)	Number of Imputations	1
4	1	Total cholesterol (mg/dL)	Seed for random number generator	144802

Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression Missing Data Pattern

Parameter Code=T_CHOL U Planned Treatment for Period 30 (N)=4

Obs	I m p u t a t i o n _	P A R A M	G r o u p	R E G I O N 1					B O L A S E					v i s i t 2		v i s i t 3		P e r c e n t	B A S E	v i s i t 2	v i s i t 3
				M i s s	M i s s	M i s s	M i s s	M i s s	F r e q	F r e q	F r e q	F r e q	F r e q								
1	1	Total cholesterol (mg/dL)	1	X	X	X	X	X	323	94.44	5.149318	0.023232	0.015905								
2	1	Total cholesterol (mg/dL)	2	X	X	X	X	.	17	4.97	5.184211	0.007922	.								
3	1	Total cholesterol (mg/dL)	3	X	X	X	.	.	2	0.58	5.239676	.	.								

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=T_CHOL_U Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	Total cholesterol (mg/dL)	Intercept	
2	1	Total cholesterol (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	Total cholesterol (mg/dL)	REGION1	EUROPE
4	1	Total cholesterol (mg/dL)	REGION1	JAPAN
5	1	Total cholesterol (mg/dL)	BOLAD1	
6	1	Total cholesterol (mg/dL)	BASE	

Obs		BOLAD1	ObsVal	_1
1			-0.0007492	-0.008520
2			-0.17468	-0.050833
3			0.02076	0.107221
4			0.23403	0.109324
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.07200	-0.180061
6			-0.41969	-0.406862

Parameter Code=T_CHOL_U Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	Total cholesterol (mg/dL)	Intercept			-0.02934	-0.008324
8	1	Total cholesterol (mg/dL)	REGION1	ASIA (EXCLUDING JAPAN)		-0.17305	-0.103368
9	1	Total cholesterol (mg/dL)	REGION1	EUROPE		-0.00376	0.074220

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=T_CHOL_U Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
10	1	Total cholesterol (mg/dL)	REGION1	JAPAN		0.16329	0.088625
11	1	Total cholesterol (mg/dL)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.04427	0.046026
12	1	Total cholesterol (mg/dL)	BASE			-0.15038	-0.191624
13	1	Total cholesterol (mg/dL)	visit2200			0.57777	0.558497

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The MI Procedure with MCMC
Model Information

Parameter Code=C105586S Planned Treatment for Period 30 (N)=2

Obs	PARAM	Description	Value
1	Total cholesterol (mmol/L)	Data Set	WORK.ENDPOINT_PARAM
2	Total cholesterol (mmol/L)	Method	Monotone-data_MCMC
3	Total cholesterol (mmol/L)	Multiple Imputation Chain	Multiple Chains
4	Total cholesterol (mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
5	Total cholesterol (mmol/L)	Start	Starting Value
6	Total cholesterol (mmol/L)	Prior	Jeffreys
7	Total cholesterol (mmol/L)	Number of Imputations	10000
8	Total cholesterol (mmol/L)	Number of Burn-in Iterations	200
9	Total cholesterol (mmol/L)	Seed for random number generator	144500

Parameter Code=C105586S Planned Treatment for Period 30 (N)=3

Obs	PARAM	Description	Value
10	Total cholesterol (mmol/L)	Data Set	WORK.ENDPOINT_PARAM
11	Total cholesterol (mmol/L)	Method	Monotone-data_MCMC
12	Total cholesterol (mmol/L)	Multiple Imputation Chain	Multiple Chains
13	Total cholesterol (mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
14	Total cholesterol (mmol/L)	Start	Starting Value
15	Total cholesterol (mmol/L)	Prior	Jeffreys
16	Total cholesterol (mmol/L)	Number of Imputations	10000
17	Total cholesterol (mmol/L)	Number of Burn-in Iterations	200
18	Total cholesterol (mmol/L)	Seed for random number generator	2064268711

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The MI Procedure with MCMC
Model Information

Parameter Code=C105586S Planned Treatment for Period 30 (N)=4

Obs	PARAM	Description	Value
19	Total cholesterol (mmol/L)	Data Set	WORK.ENDPOINT_PARAM
20	Total cholesterol (mmol/L)	Method	Monotone-data_MCMC
21	Total cholesterol (mmol/L)	Multiple Imputation Chain	Multiple Chains
22	Total cholesterol (mmol/L)	Initial Estimates for MCMC	EM Posterior Mode
23	Total cholesterol (mmol/L)	Start	Starting Value
24	Total cholesterol (mmol/L)	Prior	Jeffreys
25	Total cholesterol (mmol/L)	Number of Imputations	10000
26	Total cholesterol (mmol/L)	Number of Burn-in Iterations	200
27	Total cholesterol (mmol/L)	Seed for random number generator	1198333808

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The MI Procedure with MCMC
Missing data pattern

Parameter Code=C105586S Planned Treatment for Period 30 (N)=2

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
1	Total cholesterol (mmol/L)	1	X	X	X	325	95.03	1.497784	0.021671	0.000628
2	Total cholesterol (mmol/L)	2	X	X	O	9	2.63	1.423935	0.043255	.
3	Total cholesterol (mmol/L)	3	X	.	X	6	1.75	1.467046	.	0.039451
4	Total cholesterol (mmol/L)	4	X	O	O	2	0.58	1.466764	.	.

Parameter Code=C105586S Planned Treatment for Period 30 (N)=3

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
5	Total cholesterol (mmol/L)	1	X	X	X	331	97.07	1.502284	0.030425	0.028715
6	Total cholesterol (mmol/L)	2	X	X	O	7	2.05	1.398266	0.044005	.
7	Total cholesterol (mmol/L)	3	X	.	X	1	0.29	1.376244	.	-0.051825
8	Total cholesterol (mmol/L)	4	X	O	O	2	0.59	1.636900	.	.

Parameter Code=C105586S Planned Treatment for Period 30 (N)=4

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
9	Total cholesterol (mmol/L)	1	X	X	X	317	92.69	1.500581	0.021503	0.013057
10	Total cholesterol (mmol/L)	2	X	X	O	17	4.97	1.530700	0.007922	.
11	Total cholesterol (mmol/L)	3	X	.	X	6	1.75	1.243564	.	0.166369
12	Total cholesterol (mmol/L)	4	X	O	O	2	0.58	1.586165	.	.

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The MI Procedure with Monotone Regression
Model Information

Parameter Code=C105586S Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM	Description	Value
1	1	Total cholesterol (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	Total cholesterol (mmol/L)	Method	Monotone
3	1	Total cholesterol (mmol/L)	Number of Imputations	1
4	1	Total cholesterol (mmol/L)	Seed for random number generator	144800

Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=C105586S Planned Treatment for Period 30 (N)=2

O b s	I m p u t a t i o n _	P A R A M _	G r o u p	R E G I O N 1	E B O L 1	B L A D 1	B L A D 1	B L A D 1	B L A D 1	F r e q	P e r c e n t	B A S E	v i s i t 2 0 0	v i s i t 3 6 0 0
1	1	Total cholesterol (mmol/L)	1	X	X	X	X	X	X	331	96.78	1.497226	0.022072	0.001332
2	1	Total cholesterol (mmol/L)	2	X	X	X	X	X	.	9	2.63	1.423935	0.043255	.
3	1	Total cholesterol (mmol/L)	3	X	X	X	.	.	.	2	0.58	1.466764	.	.

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=C105586S Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	Total cholesterol (mmol/L)	Intercept	
2	1	Total cholesterol (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	Total cholesterol (mmol/L)	REGION1	EUROPE
4	1	Total cholesterol (mmol/L)	REGION1	JAPAN
5	1	Total cholesterol (mmol/L)	BOLAD1	
6	1	Total cholesterol (mmol/L)	BASE	

Obs		BOLAD1	ObsVal	_1
1			-0.04649	0.009403
2			-0.36586	-0.492233
3			0.13561	0.257543
4			0.31215	0.399396
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.01166	-0.072574
6			-0.34133	-0.395911

Parameter Code=C105586S Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	Total cholesterol (mmol/L)	Intercept			-0.04574	-0.034163
8	1	Total cholesterol (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)		-0.31427	-0.314007
9	1	Total cholesterol (mmol/L)	REGION1	EUROPE		0.14478	0.213705

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=C105586S Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
10	1	Total cholesterol (mmol/L)	REGION1	JAPAN		0.25522	0.261431
11	1	Total cholesterol (mmol/L)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.03836	0.001855
12	1	Total cholesterol (mmol/L)	BASE			-0.15186	-0.148404
13	1	Total cholesterol (mmol/L)	visit2200			0.55758	0.525596

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The MI Procedure with Monotone Regression
Model Information

Parameter Code=C105586S Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM	Description	Value
1	1	Total cholesterol (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	Total cholesterol (mmol/L)	Method	Monotone
3	1	Total cholesterol (mmol/L)	Number of Imputations	1
4	1	Total cholesterol (mmol/L)	Seed for random number generator	144801

Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=C105586S Planned Treatment for Period 30 (N)=3

O b s	I m p u t a t i o n _	P A R A M _	G r o u p	R E G I O N 1	E B O L A 1	B O L A 1	B O L A 1	B O L A 1	B O L A 1	F r e q	P e r c e n t	B A S E	v i s i t 2 0 0	v i s i t 3 6 0 0
1	1	Total cholesterol (mmol/L)	1	X	X	X	X	X	X	332	97.36	1.501904	0.030182	0.028472
2	1	Total cholesterol (mmol/L)	2	X	X	X	X	X	.	7	2.05	1.398266	0.044005	.
3	1	Total cholesterol (mmol/L)	3	X	X	X	.	.	.	2	0.59	1.636900	.	.

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=C105586S Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	Total cholesterol (mmol/L)	Intercept	
2	1	Total cholesterol (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	Total cholesterol (mmol/L)	REGION1	EUROPE
4	1	Total cholesterol (mmol/L)	REGION1	JAPAN
5	1	Total cholesterol (mmol/L)	BOLAD1	
6	1	Total cholesterol (mmol/L)	BASE	

Obs		BOLAD1	ObsVal	_1
1			-0.06559	-0.058942
2			-0.38706	-0.393073
3			0.07076	0.042823
4			0.37120	0.493510
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.04659	0.122377
6			-0.25623	-0.329420

Parameter Code=C105586S Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	Total cholesterol (mmol/L)	Intercept			-0.02220	-0.076435
8	1	Total cholesterol (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)		-0.16194	-0.389860
9	1	Total cholesterol (mmol/L)	REGION1	EUROPE		0.00820	0.123612

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=C105586S Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
10	1	Total cholesterol (mmol/L)	REGION1	JAPAN		0.27902	0.286471
11	1	Total cholesterol (mmol/L)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.03387	0.130542
12	1	Total cholesterol (mmol/L)	BASE			-0.26264	-0.287269
13	1	Total cholesterol (mmol/L)	visit2200			0.42198	0.364673

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The MI Procedure with Monotone Regression
Model Information

Parameter Code=C105586S Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM	Description	Value
1	1	Total cholesterol (mmol/L)	Data Set	WORK.MONO_SORT_TRT
2	1	Total cholesterol (mmol/L)	Method	Monotone
3	1	Total cholesterol (mmol/L)	Number of Imputations	1
4	1	Total cholesterol (mmol/L)	Seed for random number generator	144802

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The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=C105586S Planned Treatment for Period 30 (N)=4

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1	1	Total cholesterol (mmol/L)	1	X	X	X	X	X	X	323	94.44	1.495806	0.023232	0.015905
2	1	Total cholesterol (mmol/L)	2	X	X	X	X	X	.	17	4.97	1.530700	0.007922	.
3	1	Total cholesterol (mmol/L)	3	X	X	X	.	.	.	2	0.58	1.586165	.	.

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=C105586S Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2200

Obs	_Imputation_	PARAM	Effect	REGION1
1	1	Total cholesterol (mmol/L)	Intercept	
2	1	Total cholesterol (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)
3	1	Total cholesterol (mmol/L)	REGION1	EUROPE
4	1	Total cholesterol (mmol/L)	REGION1	JAPAN
5	1	Total cholesterol (mmol/L)	BOLAD1	
6	1	Total cholesterol (mmol/L)	BASE	

Obs		BOLAD1	ObsVal	_1
1			-0.0007492	-0.008520
2			-0.17468	-0.050833
3			0.02076	0.107221
4			0.23403	0.109324
5	BOLUS INSULIN ALGORITHM (SLIDING SCALE)		-0.07200	-0.180061
6			-0.41969	-0.406862

Parameter Code=C105586S Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
7	1	Total cholesterol (mmol/L)	Intercept			-0.02934	-0.008324
8	1	Total cholesterol (mmol/L)	REGION1	ASIA (EXCLUDING JAPAN)		-0.17305	-0.103368
9	1	Total cholesterol (mmol/L)	REGION1	EUROPE		-0.00376	0.074220

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The MI Procedure with Monotone Regression
Regression Information

Parameter Code=C105586S Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

(continued)

Obs	_Imputation_	PARAM	Effect	REGION1	BOLAD1	ObsVal	_1
10	1	Total cholesterol (mmol/L)	REGION1	JAPAN		0.16329	0.088625
11	1	Total cholesterol (mmol/L)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	0.04427	0.046026
12	1	Total cholesterol (mmol/L)	BASE			-0.15038	-0.191624
13	1	Total cholesterol (mmol/L)	visit2200			0.57777	0.558497

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The Mixed procedure
Model Information

Parameter Code=C105586S Parameter=Total cholesterol (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Data Set	WORK.IMPUTE
2	1	NN1218-4131	Dependent Variable	eotVisit
3	1	NN1218-4131	Covariance Structure	Diagonal
4	1	NN1218-4131	Estimation Method	REML
5	1	NN1218-4131	Residual Variance Method	Profile
6	1	NN1218-4131	Fixed Effects SE Method	Model-Based
7	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=C105587S Parameter=HDL cholesterol (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
8	1	NN1218-4131	Data Set	WORK.IMPUTE
9	1	NN1218-4131	Dependent Variable	eotVisit
10	1	NN1218-4131	Covariance Structure	Diagonal
11	1	NN1218-4131	Estimation Method	REML
12	1	NN1218-4131	Residual Variance Method	Profile
13	1	NN1218-4131	Fixed Effects SE Method	Model-Based
14	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=C105588S Parameter=LDL cholesterol (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
15	1	NN1218-4131	Data Set	WORK.IMPUTE
16	1	NN1218-4131	Dependent Variable	eotVisit
17	1	NN1218-4131	Covariance Structure	Diagonal

nn1218/nn1218-4131/ctr_20180214_er
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The Mixed procedure
Model Information

Parameter Code=C105588S Parameter=LDL cholesterol (mmol/L)

(continued)

Obs	_Imputation_	STUDYID	Descr	Value
18	1	NN1218-4131	Estimation Method	REML
19	1	NN1218-4131	Residual Variance Method	Profile
20	1	NN1218-4131	Fixed Effects SE Method	Model-Based
21	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=HDL_SU Parameter=HDL cholesterol (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
22	1	NN1218-4131	Data Set	WORK.IMPUTE
23	1	NN1218-4131	Dependent Variable	eotVisit
24	1	NN1218-4131	Covariance Structure	Diagonal
25	1	NN1218-4131	Estimation Method	REML
26	1	NN1218-4131	Residual Variance Method	Profile
27	1	NN1218-4131	Fixed Effects SE Method	Model-Based
28	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=LDL_SU Parameter=LDL cholesterol (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
29	1	NN1218-4131	Data Set	WORK.IMPUTE
30	1	NN1218-4131	Dependent Variable	eotVisit
31	1	NN1218-4131	Covariance Structure	Diagonal
32	1	NN1218-4131	Estimation Method	REML

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The Mixed procedure
Model Information

Parameter Code=LDL_SU Parameter=LDL cholesterol (mg/dL)

(continued)

Obs	_Imputation_	STUDYID	Descr	Value
33	1	NN1218-4131	Residual Variance Method	Profile
34	1	NN1218-4131	Fixed Effects SE Method	Model-Based
35	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=T_CHOL_U Parameter=Total cholesterol (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
36	1	NN1218-4131	Data Set	WORK.IMPUTE
37	1	NN1218-4131	Dependent Variable	eotVisit
38	1	NN1218-4131	Covariance Structure	Diagonal
39	1	NN1218-4131	Estimation Method	REML
40	1	NN1218-4131	Residual Variance Method	Profile
41	1	NN1218-4131	Fixed Effects SE Method	Model-Based
42	1	NN1218-4131	Degrees of Freedom Method	Residual

Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Class Level Information

Parameter Code=C105586S Parameter=Total cholesterol (mmol/L)

O b s	I m p u t a t i o n _	S T U D Y I D	C l a s s	L e v e l s	V a l u e s	m i n I e g t h
1	1	NN1218-4131	TRTPN	3	2 3 4	5
2	1	NN1218-4131	REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA	49
3	1	NN1218-4131	BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULI	85

Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Class Level Information

Parameter Code=C105587S Parameter=HDL cholesterol (mmol/L)

O		I		S		L		V		m	
b		m		T		U		a		i	
s		p		D		C		l		n	
_		u		Y		l		e		l	
		t		I		a		u		e	
		a		D		s		s		g	
		t								t	
		i								h	
		n									
		s									
4	1	NN1218-4131	TRTPN	3	2	3	4				5
5	1	NN1218-4131	REGION1	4	ASIA (EXCLUDING JAPAN)	EUROPE	JAPAN	NORTH AMERICA			49
6	1	NN1218-4131	BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	CARBOHYDRATE COUNTING (FLEXIBLE)	BOLUS	INSULI			85

Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Class Level Information

Parameter Code=C105588S Parameter=LDL cholesterol (mmol/L)

Ob- s	Input ID	STUDY	Class	Level	Values	min
7	1	NN1218-4131	TRTPN	3	2 3 4	5
8	1	NN1218-4131	REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA	49
9	1	NN1218-4131	BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULI	85

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The Mixed procedure
Class Level Information

Parameter Code=HDL_SU Parameter=HDL cholesterol (mg/dL)

Obs	Input	STUDY ID	Classes	Levels	Values	Unit
10	1	NN1218-4131	TRTPN	3 2 3 4		5
11	1	NN1218-4131	REGION1	4 ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA		49
12	1	NN1218-4131	BOLAD1	2 BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULI		85

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The Mixed procedure
Class Level Information

Parameter Code=LDL_SU Parameter=LDL cholesterol (mg/dL)

Obs	Inpution	STUDY ID	Classes	Levels	Values	min
13	1	NN1218-4131	TRTPN	3 2 3 4		5
14	1	NN1218-4131	REGION1	4 ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA		49
15	1	NN1218-4131	BOLAD1	2 BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULI		85

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The Mixed procedure
Class Level Information

Parameter Code=T_CHOL U Parameter=Total cholesterol (mg/dL)

Obs	Input	STUDY ID	Classes	Levels	Values	min
16	1	NN1218-4131	TRTPN	3 2 3 4		5
17	1	NN1218-4131	REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA	49
18	1	NN1218-4131	BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULI	85

Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Dimensions

Parameter Code=C105586S Parameter=Total cholesterol (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Covariance Parameters	1
2	1	NN1218-4131	Columns in X	10
3	1	NN1218-4131	Columns in Z	0
4	1	NN1218-4131	Subjects	1
5	1	NN1218-4131	Max Obs per Subject	1025

Parameter Code=C105587S Parameter=HDL cholesterol (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
6	1	NN1218-4131	Covariance Parameters	1
7	1	NN1218-4131	Columns in X	10
8	1	NN1218-4131	Columns in Z	0
9	1	NN1218-4131	Subjects	1
10	1	NN1218-4131	Max Obs per Subject	1025

Parameter Code=C105588S Parameter=LDL cholesterol (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
11	1	NN1218-4131	Covariance Parameters	1
12	1	NN1218-4131	Columns in X	10
13	1	NN1218-4131	Columns in Z	0
14	1	NN1218-4131	Subjects	1
15	1	NN1218-4131	Max Obs per Subject	1025

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The Mixed procedure
Dimensions

Parameter Code=HDL_SU Parameter=HDL cholesterol (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
16	1	NN1218-4131	Covariance Parameters	1
17	1	NN1218-4131	Columns in X	10
18	1	NN1218-4131	Columns in Z	0
19	1	NN1218-4131	Subjects	1
20	1	NN1218-4131	Max Obs per Subject	1025

Parameter Code=LDL_SU Parameter=LDL cholesterol (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
21	1	NN1218-4131	Covariance Parameters	1
22	1	NN1218-4131	Columns in X	10
23	1	NN1218-4131	Columns in Z	0
24	1	NN1218-4131	Subjects	1
25	1	NN1218-4131	Max Obs per Subject	1025

Parameter Code=T_CHOL_U Parameter=Total cholesterol (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
26	1	NN1218-4131	Covariance Parameters	1
27	1	NN1218-4131	Columns in X	10
28	1	NN1218-4131	Columns in Z	0
29	1	NN1218-4131	Subjects	1
30	1	NN1218-4131	Max Obs per Subject	1025

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The Mixed procedure
Number of Observations

Parameter Code=C105586S Parameter=Total cholesterol (mmol/L)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
1	1	NN1218-4131	Number of Observations Read	1025	1025	1025	1025	1025
2	1	NN1218-4131	Number of Observations Used	1025	1025	1025	1025	1025
3	1	NN1218-4131	Number of Observations Not Used	0	1025	1025	1025	1025

Parameter Code=C105587S Parameter=HDL cholesterol (mmol/L)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
4	1	NN1218-4131	Number of Observations Read	1025	1025	1025	1025	1025
5	1	NN1218-4131	Number of Observations Used	1025	1025	1025	1025	1025
6	1	NN1218-4131	Number of Observations Not Used	0	1025	1025	1025	1025

Parameter Code=C105588S Parameter=LDL cholesterol (mmol/L)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
7	1	NN1218-4131	Number of Observations Read	1025	1025	1025	1025	1025
8	1	NN1218-4131	Number of Observations Used	1025	1025	1025	1025	1025
9	1	NN1218-4131	Number of Observations Not Used	0	1025	1025	1025	1025

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The Mixed procedure
Number of Observations

Parameter Code=HDL_SU Parameter=HDL cholesterol (mg/dL)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
10	1	NN1218-4131	Number of Observations Read	1025	1025	1025	1025	1025
11	1	NN1218-4131	Number of Observations Used	1025	1025	1025	1025	1025
12	1	NN1218-4131	Number of Observations Not Used	0	1025	1025	1025	1025

Parameter Code=LDL_SU Parameter=LDL cholesterol (mg/dL)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
13	1	NN1218-4131	Number of Observations Read	1025	1025	1025	1025	1025
14	1	NN1218-4131	Number of Observations Used	1025	1025	1025	1025	1025
15	1	NN1218-4131	Number of Observations Not Used	0	1025	1025	1025	1025

Parameter Code=T_CHOL_U Parameter=Total cholesterol (mg/dL)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
16	1	NN1218-4131	Number of Observations Read	1025	1025	1025	1025	1025
17	1	NN1218-4131	Number of Observations Used	1025	1025	1025	1025	1025
18	1	NN1218-4131	Number of Observations Not Used	0	1025	1025	1025	1025

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The Mixed procedure
Covariance Parameter Estimates

Parameter Code=C105586S Parameter=Total cholesterol (mmol/L)

Obs	_Imputation_	STUDYID	CovParm	Estimate
1	1	NN1218-4131	Residual	0.01968

Parameter Code=C105587S Parameter=HDL cholesterol (mmol/L)

Obs	_Imputation_	STUDYID	CovParm	Estimate
10001	1	NN1218-4131	Residual	0.02982

Parameter Code=C105588S Parameter=LDL cholesterol (mmol/L)

Obs	_Imputation_	STUDYID	CovParm	Estimate
20001	1	NN1218-4131	Residual	0.04379

Parameter Code=HDL_SU Parameter=HDL cholesterol (mg/dL)

Obs	_Imputation_	STUDYID	CovParm	Estimate
30001	1	NN1218-4131	Residual	0.02982

Parameter Code=LDL_SU Parameter=LDL cholesterol (mg/dL)

Obs	_Imputation_	STUDYID	CovParm	Estimate
40001	1	NN1218-4131	Residual	0.04379

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The Mixed procedure
Covariance Parameter Estimates

Parameter Code=T_CHOL_U Parameter=Total cholesterol (mg/dL)

Obs	_Imputation_	STUDYID	CovParm	Estimate
50001	1	NN1218-4131	Residual	0.01968

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The Mixed procedure
Fit Statistics

Parameter Code=C105586S Parameter=Total cholesterol (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	-2 Res Log Likelihood	-1067.5
2	1	NN1218-4131	AIC (Smaller is Better)	-1065.5
3	1	NN1218-4131	AICC (Smaller is Better)	-1065.5
4	1	NN1218-4131	BIC (Smaller is Better)	-1060.5

Parameter Code=C105587S Parameter=HDL cholesterol (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
5	1	NN1218-4131	-2 Res Log Likelihood	-644.1
6	1	NN1218-4131	AIC (Smaller is Better)	-642.1
7	1	NN1218-4131	AICC (Smaller is Better)	-642.1
8	1	NN1218-4131	BIC (Smaller is Better)	-637.1

Parameter Code=C105588S Parameter=LDL cholesterol (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
9	1	NN1218-4131	-2 Res Log Likelihood	-252.9
10	1	NN1218-4131	AIC (Smaller is Better)	-250.9
11	1	NN1218-4131	AICC (Smaller is Better)	-250.9
12	1	NN1218-4131	BIC (Smaller is Better)	-246.0

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The Mixed procedure
Fit Statistics

Parameter Code=HDL_SU Parameter=HDL cholesterol (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
13	1	NN1218-4131	-2 Res Log Likelihood	-644.1
14	1	NN1218-4131	AIC (Smaller is Better)	-642.1
15	1	NN1218-4131	AICC (Smaller is Better)	-642.1
16	1	NN1218-4131	BIC (Smaller is Better)	-637.1

Parameter Code=LDL_SU Parameter=LDL cholesterol (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
17	1	NN1218-4131	-2 Res Log Likelihood	-252.9
18	1	NN1218-4131	AIC (Smaller is Better)	-250.9
19	1	NN1218-4131	AICC (Smaller is Better)	-250.9
20	1	NN1218-4131	BIC (Smaller is Better)	-246.0

Parameter Code=T_CHOL_U Parameter=Total cholesterol (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
21	1	NN1218-4131	-2 Res Log Likelihood	-1067.5
22	1	NN1218-4131	AIC (Smaller is Better)	-1065.5
23	1	NN1218-4131	AICC (Smaller is Better)	-1065.5
24	1	NN1218-4131	BIC (Smaller is Better)	-1060.5

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The Mixed procedure
Solution for Fixed Effects

Parameter Code=C105586S Parameter=Total cholesterol (mmol/L)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1			BOLAD1
1	1	NN1218-4131	TRTPN	2				
2	1	NN1218-4131	TRTPN	3				
3	1	NN1218-4131	TRTPN	4				
4	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
5	1	NN1218-4131	REGION1	—	EUROPE			
6	1	NN1218-4131	REGION1	—	JAPAN			
7	1	NN1218-4131	REGION1	—	NORTH AMERICA			
8	1	NN1218-4131	BOLAD1	—				BOLUS INSULIN ALGORITHM (SLIDING SCALE)
9	1	NN1218-4131	BOLAD1	—				CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY
10	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	0.3963	0.03476	1017	11.40	<.0001	0.05	0.3281	0.4645
2	0.4216	0.03480	1017	12.11	<.0001	0.05	0.3533	0.4899
3	0.4075	0.03487	1017	11.69	<.0001	0.05	0.3391	0.4759
4	-0.03749	0.01601	1017	-2.34	0.0194	0.05	-0.06891	-0.00607
5	0.03054	0.01130	1017	2.70	0.0070	0.05	0.008376	0.05271
6	0.07424	0.01284	1017	5.78	<.0001	0.05	0.04904	0.09945
7	0
8	0.008782	0.009828	1017	0.89	0.3718	0.05	-0.01050	0.02807
9	0
10	-0.2816	0.02256	1017	-12.48	<.0001	0.05	-0.3258	-0.2373

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The Mixed procedure
Solution for Fixed Effects

Parameter Code=C105587S Parameter=HDL cholesterol (mmol/L)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
11	1	NN1218-4131	TRTPN	2				
12	1	NN1218-4131	TRTPN	3				
13	1	NN1218-4131	TRTPN	4				
14	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
15	1	NN1218-4131	REGION1	—	EUROPE			
16	1	NN1218-4131	REGION1	—	JAPAN			
17	1	NN1218-4131	REGION1	—	NORTH AMERICA			
18	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
19	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
20	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
11	0.03865	0.01518	1017	2.55	0.0110	0.05	0.008873	0.06843
12	0.05209	0.01529	1017	3.41	0.0007	0.05	0.02209	0.08210
13	0.04867	0.01539	1017	3.16	0.0016	0.05	0.01847	0.07888
14	0.02516	0.01975	1017	1.27	0.2031	0.05	-0.01360	0.06392
15	0.02534	0.01388	1017	1.83	0.0681	0.05	-0.00189	0.05258
16	0.1039	0.01609	1017	6.46	<.0001	0.05	0.07234	0.1355
17	0
18	-0.02269	0.01211	1017	-1.87	0.0613	0.05	-0.04646	0.001078
19	0
20	-0.1783	0.01873	1017	-9.52	<.0001	0.05	-0.2150	-0.1415

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The Mixed procedure
Solution for Fixed Effects

Parameter Code=C105588S Parameter=LDL cholesterol (mmol/L)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
21	1	NN1218-4131	TRTPN	2				
22	1	NN1218-4131	TRTPN	3				
23	1	NN1218-4131	TRTPN	4				
24	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
25	1	NN1218-4131	REGION1	—	EUROPE			
26	1	NN1218-4131	REGION1	—	JAPAN			
27	1	NN1218-4131	REGION1	—	NORTH AMERICA			
28	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
29	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
30	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
21	0.3115	0.02428	1017	12.83	<.0001	0.05	0.2639	0.3592
22	0.3385	0.02454	1017	13.80	<.0001	0.05	0.2904	0.3867
23	0.3328	0.02426	1017	13.72	<.0001	0.05	0.2852	0.3804
24	-0.00330	0.02386	1017	-0.14	0.8902	0.05	-0.05011	0.04352
25	0.05006	0.01684	1017	2.97	0.0030	0.05	0.01702	0.08310
26	0.09258	0.01895	1017	4.89	<.0001	0.05	0.05540	0.1298
27	0
28	0.01975	0.01466	1017	1.35	0.1783	0.05	-0.00902	0.04851
29	0
30	-0.3585	0.02065	1017	-17.36	<.0001	0.05	-0.3990	-0.3180

nn1218/nn1218-4131/ctr_20180214_er
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The Mixed procedure
Solution for Fixed Effects

Parameter Code=HDL_SU Parameter=HDL cholesterol (mg/dL)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
31	1	NN1218-4131	TRTPN	2				
32	1	NN1218-4131	TRTPN	3				
33	1	NN1218-4131	TRTPN	4				
34	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
35	1	NN1218-4131	REGION1	—	EUROPE			
36	1	NN1218-4131	REGION1	—	JAPAN			
37	1	NN1218-4131	REGION1	—	NORTH AMERICA			
38	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
39	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
40	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
31	0.6900	0.07729	1017	8.93	<.0001	0.05	0.5383	0.8416
32	0.7034	0.07726	1017	9.10	<.0001	0.05	0.5518	0.8550
33	0.7000	0.07728	1017	9.06	<.0001	0.05	0.5483	0.8516
34	0.02516	0.01975	1017	1.27	0.2031	0.05	-0.01360	0.06392
35	0.02534	0.01388	1017	1.83	0.0681	0.05	-0.00189	0.05258
36	0.1039	0.01609	1017	6.46	<.0001	0.05	0.07234	0.1355
37	0
38	-0.02269	0.01211	1017	-1.87	0.0613	0.05	-0.04646	0.001078
39	0
40	-0.1783	0.01873	1017	-9.52	<.0001	0.05	-0.2150	-0.1415

nn1218/nn1218-4131/ctr_20180214_er
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The Mixed procedure
Solution for Fixed Effects

Parameter Code=LDL_SU Parameter=LDL cholesterol (mg/dL)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
41	1	NN1218-4131	TRTPN	2				
42	1	NN1218-4131	TRTPN	3				
43	1	NN1218-4131	TRTPN	4				
44	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
45	1	NN1218-4131	REGION1	—	EUROPE			
46	1	NN1218-4131	REGION1	—	JAPAN			
47	1	NN1218-4131	REGION1	—	NORTH AMERICA			
48	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
49	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
50	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
41	1.6212	0.09521	1017	17.03	<.0001	0.05	1.4344	1.8081
42	1.6483	0.09541	1017	17.28	<.0001	0.05	1.4611	1.8355
43	1.6425	0.09495	1017	17.30	<.0001	0.05	1.4562	1.8288
44	-0.00330	0.02386	1017	-0.14	0.8902	0.05	-0.05011	0.04352
45	0.05006	0.01684	1017	2.97	0.0030	0.05	0.01702	0.08310
46	0.09258	0.01895	1017	4.89	<.0001	0.05	0.05540	0.1298
47	0
48	0.01975	0.01466	1017	1.35	0.1783	0.05	-0.00902	0.04851
49	0
50	-0.3585	0.02065	1017	-17.36	<.0001	0.05	-0.3990	-0.3180

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Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Solution for Fixed Effects

Parameter Code=T_CHOL_U Parameter=Total cholesterol (mg/dL)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1			BOLAD1
51	1	NN1218-4131	TRTPN	2				
52	1	NN1218-4131	TRTPN	3				
53	1	NN1218-4131	TRTPN	4				
54	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
55	1	NN1218-4131	REGION1	—	EUROPE			
56	1	NN1218-4131	REGION1	—	JAPAN			
57	1	NN1218-4131	REGION1	—	NORTH AMERICA			
58	1	NN1218-4131	BOLAD1	—				BOLUS INSULIN ALGORITHM (SLIDING SCALE)
59	1	NN1218-4131	BOLAD1	—				CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY
60	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
51	1.4250	0.1160	1017	12.29	<.0001	0.05	1.1974	1.6527
52	1.4504	0.1160	1017	12.50	<.0001	0.05	1.2227	1.6780
53	1.4363	0.1161	1017	12.38	<.0001	0.05	1.2085	1.6640
54	-0.03749	0.01601	1017	-2.34	0.0194	0.05	-0.06891	-0.00607
55	0.03054	0.01130	1017	2.70	0.0070	0.05	0.008376	0.05271
56	0.07424	0.01284	1017	5.78	<.0001	0.05	0.04904	0.09945
57	0
58	0.008782	0.009828	1017	0.89	0.3718	0.05	-0.01050	0.02807
59	0
60	-0.2816	0.02256	1017	-12.48	<.0001	0.05	-0.3258	-0.2373

Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Least Squares Means

Obs	_Imputation_	PARAMCD	PARAM	STUDYID	Effect	TRTPN
1	1	C105586S	Total cholesterol (mmol/L)	NN1218-4131	TRTPN	2
2	1	C105586S	Total cholesterol (mmol/L)	NN1218-4131	TRTPN	3
3	1	C105586S	Total cholesterol (mmol/L)	NN1218-4131	TRTPN	4
4	1	C105587S	HDL cholesterol (mmol/L)	NN1218-4131	TRTPN	2
5	1	C105587S	HDL cholesterol (mmol/L)	NN1218-4131	TRTPN	3
6	1	C105587S	HDL cholesterol (mmol/L)	NN1218-4131	TRTPN	4
7	1	C105588S	LDL cholesterol (mmol/L)	NN1218-4131	TRTPN	2
8	1	C105588S	LDL cholesterol (mmol/L)	NN1218-4131	TRTPN	3
9	1	C105588S	LDL cholesterol (mmol/L)	NN1218-4131	TRTPN	4
10	1	HDL_SU	HDL cholesterol (mg/dL)	NN1218-4131	TRTPN	2
11	1	HDL_SU	HDL cholesterol (mg/dL)	NN1218-4131	TRTPN	3
12	1	HDL_SU	HDL cholesterol (mg/dL)	NN1218-4131	TRTPN	4
13	1	LDL_SU	LDL cholesterol (mg/dL)	NN1218-4131	TRTPN	2
14	1	LDL_SU	LDL cholesterol (mg/dL)	NN1218-4131	TRTPN	3

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	WORK.IMPUTE	0.002727	0.007595	1017	0.36	0.7196	0.05	-0.01218	0.01763
2	WORK.IMPUTE	0.02808	0.007604	1017	3.69	0.0002	0.05	0.01316	0.04300
3	WORK.IMPUTE	0.01395	0.007593	1017	1.84	0.0665	0.05	-0.00095	0.02885
4	WORK.IMPUTE	-0.01643	0.009349	1017	-1.76	0.0791	0.05	-0.03478	0.001913
5	WORK.IMPUTE	-0.00299	0.009361	1017	-0.32	0.7493	0.05	-0.02136	0.01538
6	WORK.IMPUTE	-0.00641	0.009346	1017	-0.69	0.4930	0.05	-0.02475	0.01193
7	WORK.IMPUTE	0.02673	0.01133	1017	2.36	0.0185	0.05	0.004492	0.04896
8	WORK.IMPUTE	0.05376	0.01135	1017	4.74	<.0001	0.05	0.03149	0.07602
9	WORK.IMPUTE	0.04802	0.01133	1017	4.24	<.0001	0.05	0.02578	0.07025
10	WORK.IMPUTE	-0.01643	0.009349	1017	-1.76	0.0791	0.05	-0.03478	0.001913
11	WORK.IMPUTE	-0.00299	0.009361	1017	-0.32	0.7493	0.05	-0.02136	0.01538
12	WORK.IMPUTE	-0.00641	0.009346	1017	-0.69	0.4930	0.05	-0.02475	0.01193
13	WORK.IMPUTE	0.02673	0.01133	1017	2.36	0.0185	0.05	0.004492	0.04896
14	WORK.IMPUTE	0.05376	0.01135	1017	4.74	<.0001	0.05	0.03149	0.07602

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The Mixed procedure
Least Squares Means

Obs	_Imputation_	PARAMCD	PARAM	STUDYID	Effect	TRTPN
15	1	LDL_SU	LDL cholesterol (mg/dL)	NN1218-4131	TRTPN	4
16	1	T_CHOL_U	Total cholesterol (mg/dL)	NN1218-4131	TRTPN	2
17	1	T_CHOL_U	Total cholesterol (mg/dL)	NN1218-4131	TRTPN	3
18	1	T_CHOL_U	Total cholesterol (mg/dL)	NN1218-4131	TRTPN	4

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
15	WORK.IMPUTE	0.04802	0.01133	1017	4.24	<.0001	0.05	0.02578	0.07025
16	WORK.IMPUTE	0.002727	0.007595	1017	0.36	0.7196	0.05	-0.01218	0.01763
17	WORK.IMPUTE	0.02808	0.007604	1017	3.69	0.0002	0.05	0.01316	0.04300
18	WORK.IMPUTE	0.01395	0.007593	1017	1.84	0.0665	0.05	-0.00095	0.02885

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The Mixed procedure
Least Squares Means Estimate

Parameter Code=C105586S Parameter=Total cholesterol (mmol/L)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
1	1	NN1218-4131	1	TRTPN	Faster aspart (meal) / NovoRapid (meal)
2	1	NN1218-4131	2	TRTPN	Faster aspart (post) / NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	WORK.IMPUTE	-0.01122	0.01075	1017	-1.04	0.2966	0.05	-0.03231	0.009866
2	WORK.IMPUTE	0.01413	0.01075	1017	1.31	0.1890	0.05	-0.00696	0.03523

Parameter Code=C105587S Parameter=HDL cholesterol (mmol/L)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
3	1	NN1218-4131	1	TRTPN	Faster aspart (meal) / NovoRapid (meal)
4	1	NN1218-4131	2	TRTPN	Faster aspart (post) / NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
3	WORK.IMPUTE	-0.01002	0.01323	1017	-0.76	0.4488	0.05	-0.03598	0.01593
4	WORK.IMPUTE	0.003418	0.01323	1017	0.26	0.7963	0.05	-0.02255	0.02938

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The Mixed procedure
Least Squares Means Estimate

Parameter Code=C105588S Parameter=LDL cholesterol (mmol/L)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
5	1	NN1218-4131	1	TRTPN	Faster aspart (meal) / NovoRapid (meal)
6	1	NN1218-4131	2	TRTPN	Faster aspart (post) / NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
5	WORK.IMPUTE	-0.02129	0.01603	1017	-1.33	0.1845	0.05	-0.05276	0.01017
6	WORK.IMPUTE	0.005742	0.01604	1017	0.36	0.7205	0.05	-0.02574	0.03723

Parameter Code=HDL_SU Parameter=HDL cholesterol (mg/dL)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
7	1	NN1218-4131	1	TRTPN	Faster aspart (meal) / NovoRapid (meal)
8	1	NN1218-4131	2	TRTPN	Faster aspart (post) / NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
7	WORK.IMPUTE	-0.01002	0.01323	1017	-0.76	0.4488	0.05	-0.03598	0.01593
8	WORK.IMPUTE	0.003418	0.01323	1017	0.26	0.7963	0.05	-0.02255	0.02938

Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Least Squares Means Estimate

Parameter Code=LDL_SU Parameter=LDL cholesterol (mg/dL)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
9	1	NN1218-4131	1	TRTPN	Faster aspart (meal) / NovoRapid (meal)
10	1	NN1218-4131	2	TRTPN	Faster aspart (post) / NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
9	WORK.IMPUTE	-0.02129	0.01603	1017	-1.33	0.1845	0.05	-0.05276	0.01017
10	WORK.IMPUTE	0.005742	0.01604	1017	0.36	0.7205	0.05	-0.02574	0.03723

Parameter Code=T_CHOL_U Parameter=Total cholesterol (mg/dL)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
11	1	NN1218-4131	1	TRTPN	Faster aspart (meal) / NovoRapid (meal)
12	1	NN1218-4131	2	TRTPN	Faster aspart (post) / NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
11	WORK.IMPUTE	-0.01122	0.01075	1017	-1.04	0.2966	0.05	-0.03231	0.009866
12	WORK.IMPUTE	0.01413	0.01075	1017	1.31	0.1890	0.05	-0.00696	0.03523

Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=C105586S Parameter=Total cholesterol (mmol/L) Study Identifier=NN1218-41

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000001364	0.000057570	0.000058935	1.87E7	0.023703	0.023154	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.001645	0.007677	-0.01340	0.016692	1.87E7	-0.002919	0.006328

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	0.21	0.8303

Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=C105587S Parameter=HDL cholesterol (mmol/L) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000002057	0.000087394	0.000089452	1.89E7	0.023545	0.023003	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.017733	0.009458	-0.03627	0.000805	1.89E7	-0.023494	-0.012048

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-1.87	0.0608

Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=C105588S Parameter=LDL cholesterol (mmol/L) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000002379	0.000128	0.000130	3E7	0.018591	0.018252	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.025282	0.011418	0.002903	0.047660	3E7	0.019249	0.031458

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	2.21	0.0268

Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=HDL_SU Parameter=HDL cholesterol (mg/dL) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000002057	0.000087394	0.000089452	1.89E7	0.023545	0.023003	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.017733	0.009458	-0.03627	0.000805	1.89E7	-0.023494	-0.012048

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-1.87	0.0608

Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=LDL_SU Parameter=LDL cholesterol (mg/dL) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000002379	0.000128	0.000130	3E7	0.018591	0.018252	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.025282	0.011418	0.002903	0.047660	3E7	0.019249	0.031458

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	2.21	0.0268

Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=T_CHOL_U Parameter=Total cholesterol (mg/dL) Study Identifier=NN1218-413

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000001364	0.000057570	0.000058935	1.87E7	0.023703	0.023154	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.001645	0.007677	-0.01340	0.016692	1.87E7	-0.002919	0.006328

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	0.21	0.8303

Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=C105586S Parameter=Total cholesterol (mmol/L) Study Identifier=NN1218-41

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000001358	0.000057708	0.000059066	1.89E7	0.023535	0.022994	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.027631	0.007685	0.012568	0.042694	1.89E7	0.023219	0.032127

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	3.60	0.0003

Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=C105587S Parameter=HDL cholesterol (mmol/L) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000001748	0.000087603	0.000089351	2.61E7	0.019958	0.019568	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.003463	0.009453	-0.02199	0.015064	2.61E7	-0.008600	0.001756

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-0.37	0.7141

Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=C105588S Parameter=LDL cholesterol (mmol/L) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000002798	0.000128	0.000131	2.2E7	0.021802	0.021337	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.053093	0.011452	0.030648	0.075537	2.2E7	0.046715	0.059566

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	4.64	<.0001

Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=HDL_SU Parameter=HDL cholesterol (mg/dL) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000001748	0.000087603	0.000089351	2.61E7	0.019958	0.019568	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.003463	0.009453	-0.02199	0.015064	2.61E7	-0.008600	0.001756

Parameter Estimates

Parameter	t for H0:		
	Theta0	Parameter=Theta0	Pr > t
Estimate	0	-0.37	0.7141

Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=LDL_SU Parameter=LDL cholesterol (mg/dL) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000002798	0.000128	0.000131	2.2E7	0.021802	0.021337	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.053093	0.011452	0.030648	0.075537	2.2E7	0.046715	0.059566

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	4.64	<.0001

Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=T_CHOL_U Parameter=Total cholesterol (mg/dL) Study Identifier=NN1218-413

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000001358	0.000057708	0.000059066	1.89E7	0.023535	0.022994	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.027631	0.007685	0.012568	0.042694	1.89E7	0.023219	0.032127

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	3.60	0.0003

Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=C105586S Parameter=Total cholesterol (mmol/L) Study Identifier=NN1218-41

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000002530	0.000057532	0.000060063	5.63E6	0.043982	0.042130	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.015874	0.007750	0.000684	0.031063	5.63E6	0.007191	0.022156

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	2.05	0.0405

Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=C105587S Parameter=HDL cholesterol (mmol/L) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000003451	0.000087335	0.000090786	6.92E6	0.039514	0.038012	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.004531	0.009528	-0.02321	0.014144	6.92E6	-0.012045	0.002000

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-0.48	0.6344

Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=C105588S Parameter=LDL cholesterol (mmol/L) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000005519	0.000128	0.000133	5.85E6	0.043131	0.041348	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.050736	0.011554	0.028091	0.073382	5.85E6	0.037926	0.059946

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	4.39	<.0001

Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=HDL_SU Parameter=HDL cholesterol (mg/dL) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000003451	0.000087335	0.000090786	6.92E6	0.039514	0.038012	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.004531	0.009528	-0.02321	0.014144	6.92E6	-0.012045	0.002000

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-0.48	0.6344

Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=LDL_SU Parameter=LDL cholesterol (mg/dL) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000005519	0.000128	0.000133	5.85E6	0.043131	0.041348	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.050736	0.011554	0.028091	0.073382	5.85E6	0.037926	0.059946

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	4.39	<.0001

Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=T_CHOL_U Parameter=Total cholesterol (mg/dL) Study Identifier=NN1218-413

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000002530	0.000057532	0.000060063	5.63E6	0.043982	0.042130	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.015874	0.007750	0.000684	0.031063	5.63E6	0.007191	0.022156

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	2.05	0.0405

Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=C105586S Label=Faster aspart (meal) / NovoRapid (meal) Parameter=Total cholesterol (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000003923	0.000115	0.000119	9.23E6	0.034041	0.032921	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.014228	0.010917	-0.03562	0.007168	9.23E6	-0.022435	-0.006423

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-1.30	0.1924

Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=C105586S Label=Faster aspart (post) / NovoRapid (meal) Parameter=Total cholesterol (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000003923	0.000115	0.000119	9.24E6	0.034017	0.032898	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.011757	0.010920	-0.00965	0.033160	9.24E6	0.004278	0.020868

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	1.08	0.2816

Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=C105587S Label=Faster aspart (meal) / NovoRapid (meal) Parameter=HDL cholesterol (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000005616	0.000175	0.000181	1.03E7	0.032102	0.031103	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.013202	0.013438	-0.03954	0.013135	1.03E7	-0.021165	-0.004519

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-0.98	0.3259

Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=C105587S Label=Faster aspart (post) / NovoRapid (meal) Parameter=HDL cholesterol (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000005213	0.000175	0.000180	1.2E7	0.029782	0.028921	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.001068	0.013427	-0.02525	0.027384	1.2E7	-0.010092	0.009986

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	0.08	0.9366

Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=C105588S Label=Faster aspart (meal) / NovoRapid (meal) Parameter=LDL cholesterol (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000007955	0.000256	0.000264	1.1E7	0.031039	0.030104	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.025455	0.016256	-0.05732	0.006407	1.1E7	-0.037337	-0.014378

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-1.57	0.1174

Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=C105588S Label=Faster aspart (post) / NovoRapid (meal) Parameter=LDL cholesterol (mmol/L)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000008450	0.000257	0.000265	9.84E6	0.032931	0.031881	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.002356	0.016281	-0.02955	0.034267	9.84E6	-0.008629	0.015808

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	0.14	0.8849

Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=HDL_SU Label=Faster aspart (meal) / NovoRapid (meal) Parameter=HDL cholesterol (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000005616	0.000175	0.000181	1.03E7	0.032102	0.031103	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.013202	0.013438	-0.03954	0.013135	1.03E7	-0.021165	-0.004519

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-0.98	0.3259

Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=HDL_SU Label=Faster aspart (post) / NovoRapid (meal) Parameter=HDL cholesterol (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000005213	0.000175	0.000180	1.2E7	0.029782	0.028921	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.001068	0.013427	-0.02525	0.027384	1.2E7	-0.010092	0.009986

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	0.08	0.9366

Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=LDL_SU Label=Faster aspart (meal) / NovoRapid (meal) Parameter=LDL cholesterol (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000007955	0.000256	0.000264	1.1E7	0.031039	0.030104	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.025455	0.016256	-0.05732	0.006407	1.1E7	-0.037337	-0.014378

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-1.57	0.1174

Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=LDL_SU Label=Faster aspart (post) / NovoRapid (meal) Parameter=LDL cholesterol (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000008450	0.000257	0.000265	9.84E6	0.032931	0.031881	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.002356	0.016281	-0.02955	0.034267	9.84E6	-0.008629	0.015808

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	0.14	0.8849

Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=T_CHOL_U Label=Faster aspart (meal) / NovoRapid (meal) Parameter=Total cholesterol (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000003923	0.000115	0.000119	9.23E6	0.034041	0.032921	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.014228	0.010917	-0.03562	0.007168	9.23E6	-0.022435	-0.006423

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-1.30	0.1924

Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Parameter Code=T_CHOL_U Label=Faster aspart (post) / NovoRapid (meal) Parameter=Total cholesterol (mg/dL)

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000003923	0.000115	0.000119	9.24E6	0.034017	0.032898	0.999997

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.011757	0.010920	-0.00965	0.033160	9.24E6	0.004278	0.020868

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	1.08	0.2816

Fast-acting insulin aspart
NN1218-4131

Clinical Trial Report
Statistical document

Date:
Version:

14 February 2018
1.0

Status:
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Novo Nordisk

Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Model Information

Parameter Code=C105586S Parameter=Total cholesterol (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Data Set	WORK.IMPUTE_ABS
2	1	NN1218-4131	Dependent Variable	eotVisitAbs
3	1	NN1218-4131	Covariance Structure	Diagonal
4	1	NN1218-4131	Estimation Method	REML
5	1	NN1218-4131	Residual Variance Method	Profile
6	1	NN1218-4131	Fixed Effects SE Method	Model-Based
7	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=C105587S Parameter=HDL cholesterol (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
8	1	NN1218-4131	Data Set	WORK.IMPUTE_ABS
9	1	NN1218-4131	Dependent Variable	eotVisitAbs
10	1	NN1218-4131	Covariance Structure	Diagonal
11	1	NN1218-4131	Estimation Method	REML
12	1	NN1218-4131	Residual Variance Method	Profile
13	1	NN1218-4131	Fixed Effects SE Method	Model-Based
14	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=C105588S Parameter=LDL cholesterol (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
15	1	NN1218-4131	Data Set	WORK.IMPUTE_ABS
16	1	NN1218-4131	Dependent Variable	eotVisitAbs
17	1	NN1218-4131	Covariance Structure	Diagonal

nn1218/nn1218-4131/ctr_20180214_er
10FEB2018:04:32:20 - a_stat_ratio.sas/a_lip_stat_on_fas_app.txt

Fast-acting insulin aspart
NN1218-4131

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The Mixed procedure
Model Information

Parameter Code=C105588S Parameter=LDL cholesterol (mmol/L)

(continued)

Obs	_Imputation_	STUDYID	Descr	Value
18	1	NN1218-4131	Estimation Method	REML
19	1	NN1218-4131	Residual Variance Method	Profile
20	1	NN1218-4131	Fixed Effects SE Method	Model-Based
21	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=HDL_SU Parameter=HDL cholesterol (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
22	1	NN1218-4131	Data Set	WORK.IMPUTE_ABS
23	1	NN1218-4131	Dependent Variable	eotVisitAbs
24	1	NN1218-4131	Covariance Structure	Diagonal
25	1	NN1218-4131	Estimation Method	REML
26	1	NN1218-4131	Residual Variance Method	Profile
27	1	NN1218-4131	Fixed Effects SE Method	Model-Based
28	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=LDL_SU Parameter=LDL cholesterol (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
29	1	NN1218-4131	Data Set	WORK.IMPUTE_ABS
30	1	NN1218-4131	Dependent Variable	eotVisitAbs
31	1	NN1218-4131	Covariance Structure	Diagonal
32	1	NN1218-4131	Estimation Method	REML

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The Mixed procedure
Model Information

Parameter Code=LDL_SU Parameter=LDL cholesterol (mg/dL)

(continued)

Obs	_Imputation_	STUDYID	Descr	Value
33	1	NN1218-4131	Residual Variance Method	Profile
34	1	NN1218-4131	Fixed Effects SE Method	Model-Based
35	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=T_CHOL_U Parameter=Total cholesterol (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
36	1	NN1218-4131	Data Set	WORK.IMPUTE_ABS
37	1	NN1218-4131	Dependent Variable	eotVisitAbs
38	1	NN1218-4131	Covariance Structure	Diagonal
39	1	NN1218-4131	Estimation Method	REML
40	1	NN1218-4131	Residual Variance Method	Profile
41	1	NN1218-4131	Fixed Effects SE Method	Model-Based
42	1	NN1218-4131	Degrees of Freedom Method	Residual

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The Mixed procedure
Class Level Information

Parameter Code=C105586S Parameter=Total cholesterol (mmol/L)

O		I		S		L		V		m	
b		m		p		u		a		i	
s		o		t		a		l		n	
_		n		i		t		e		l	
		Y		U		D		l		e	
		I		D		C		e		g	
		D				l		u		t	
						s		s		h	
1	1	NN1218-4131	TRTPN	3	2	3	4				5
2	1	NN1218-4131	REGION1	4	ASIA (EXCLUDING JAPAN)	EUROPE	JAPAN	NORTH AMERICA			49
3	1	NN1218-4131	BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	CARBOHYDRATE COUNTING (FLEXIBLE)	BOLUS	INSULI			85

Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Class Level Information

Parameter Code=C105587S Parameter=HDL cholesterol (mmol/L)

Ob- s	—	Input ID	STUDY	Class	Level	Values	Unit
4	1	NN1218-4131	TRTPN		3 2 3 4		5
5	1	NN1218-4131	REGION1		4 ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA		49
6	1	NN1218-4131	BOLAD1		2 BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULI		85

Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Class Level Information

Parameter Code=C105588S Parameter=LDL cholesterol (mmol/L)

O b s	I m p u t a t i o n s	S T U D Y I D	C l a s s	L e v e l s	V a r i a n c e	m i n
7	1	NN1218-4131	TRTPN	3 2 3 4		5
8	1	NN1218-4131	REGION1	4 ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA		49
9	1	NN1218-4131	BOLAD1	2 BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULI		85

Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Class Level Information

Parameter Code=HDL_SU Parameter=HDL cholesterol (mg/dL)

Obs	Input	STUDY ID	Classes	Levels	Values	Unit
10	1	NN1218-4131	TRTPN	3 2 3 4		5
11	1	NN1218-4131	REGION1	4 ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA		49
12	1	NN1218-4131	BOLAD1	2 BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULI		85

Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Class Level Information

Parameter Code=LDL_SU Parameter=LDL cholesterol (mg/dL)

Obs	Input	STUDY ID	Class	Level	Values	min
13	1	NN1218-4131	TRTPN	3 2 3 4		5
14	1	NN1218-4131	REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA	49
15	1	NN1218-4131	BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULI	85

Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Class Level Information

Parameter Code=T_CHOL U Parameter=Total cholesterol (mg/dL)

Obs	Input	STUDY ID	Classes	Levels	Values	min
16	1	NN1218-4131	TRTPN	3 2 3 4		5
17	1	NN1218-4131	REGION1	4	ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA	49
18	1	NN1218-4131	BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULI	85

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The Mixed procedure
Dimensions

Parameter Code=C105586S Parameter=Total cholesterol (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Covariance Parameters	1
2	1	NN1218-4131	Columns in X	10
3	1	NN1218-4131	Columns in Z	0
4	1	NN1218-4131	Subjects	1
5	1	NN1218-4131	Max Obs per Subject	1025

Parameter Code=C105587S Parameter=HDL cholesterol (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
6	1	NN1218-4131	Covariance Parameters	1
7	1	NN1218-4131	Columns in X	10
8	1	NN1218-4131	Columns in Z	0
9	1	NN1218-4131	Subjects	1
10	1	NN1218-4131	Max Obs per Subject	1025

Parameter Code=C105588S Parameter=LDL cholesterol (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
11	1	NN1218-4131	Covariance Parameters	1
12	1	NN1218-4131	Columns in X	10
13	1	NN1218-4131	Columns in Z	0
14	1	NN1218-4131	Subjects	1
15	1	NN1218-4131	Max Obs per Subject	1025

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The Mixed procedure
Dimensions

Parameter Code=HDL_SU Parameter=HDL cholesterol (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
16	1	NN1218-4131	Covariance Parameters	1
17	1	NN1218-4131	Columns in X	10
18	1	NN1218-4131	Columns in Z	0
19	1	NN1218-4131	Subjects	1
20	1	NN1218-4131	Max Obs per Subject	1025

Parameter Code=LDL_SU Parameter=LDL cholesterol (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
21	1	NN1218-4131	Covariance Parameters	1
22	1	NN1218-4131	Columns in X	10
23	1	NN1218-4131	Columns in Z	0
24	1	NN1218-4131	Subjects	1
25	1	NN1218-4131	Max Obs per Subject	1025

Parameter Code=T_CHOL_U Parameter=Total cholesterol (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
26	1	NN1218-4131	Covariance Parameters	1
27	1	NN1218-4131	Columns in X	10
28	1	NN1218-4131	Columns in Z	0
29	1	NN1218-4131	Subjects	1
30	1	NN1218-4131	Max Obs per Subject	1025

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The Mixed procedure
Number of Observations

Parameter Code=C105586S Parameter=Total cholesterol (mmol/L)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
1	1	NN1218-4131	Number of Observations Read	1025	1025	1025	1025	1025
2	1	NN1218-4131	Number of Observations Used	1025	1025	1025	1025	1025
3	1	NN1218-4131	Number of Observations Not Used	0	1025	1025	1025	1025

Parameter Code=C105587S Parameter=HDL cholesterol (mmol/L)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
4	1	NN1218-4131	Number of Observations Read	1025	1025	1025	1025	1025
5	1	NN1218-4131	Number of Observations Used	1025	1025	1025	1025	1025
6	1	NN1218-4131	Number of Observations Not Used	0	1025	1025	1025	1025

Parameter Code=C105588S Parameter=LDL cholesterol (mmol/L)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
7	1	NN1218-4131	Number of Observations Read	1025	1025	1025	1025	1025
8	1	NN1218-4131	Number of Observations Used	1025	1025	1025	1025	1025
9	1	NN1218-4131	Number of Observations Not Used	0	1025	1025	1025	1025

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The Mixed procedure
Number of Observations

Parameter Code=HDL_SU Parameter=HDL cholesterol (mg/dL)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
10	1	NN1218-4131	Number of Observations Read	1025	1025	1025	1025	1025
11	1	NN1218-4131	Number of Observations Used	1025	1025	1025	1025	1025
12	1	NN1218-4131	Number of Observations Not Used	0	1025	1025	1025	1025

Parameter Code=LDL_SU Parameter=LDL cholesterol (mg/dL)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
13	1	NN1218-4131	Number of Observations Read	1025	1025	1025	1025	1025
14	1	NN1218-4131	Number of Observations Used	1025	1025	1025	1025	1025
15	1	NN1218-4131	Number of Observations Not Used	0	1025	1025	1025	1025

Parameter Code=T_CHOL_U Parameter=Total cholesterol (mg/dL)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
16	1	NN1218-4131	Number of Observations Read	1025	1025	1025	1025	1025
17	1	NN1218-4131	Number of Observations Used	1025	1025	1025	1025	1025
18	1	NN1218-4131	Number of Observations Not Used	0	1025	1025	1025	1025

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The Mixed procedure
Covariance Parameter Estimates

Parameter Code=C105586S Parameter=Total cholesterol (mmol/L)

Obs	_Imputation_	STUDYID	CovParm	Estimate
1	1	NN1218-4131	Residual	0.01968

Parameter Code=C105587S Parameter=HDL cholesterol (mmol/L)

Obs	_Imputation_	STUDYID	CovParm	Estimate
10001	1	NN1218-4131	Residual	0.02982

Parameter Code=C105588S Parameter=LDL cholesterol (mmol/L)

Obs	_Imputation_	STUDYID	CovParm	Estimate
20001	1	NN1218-4131	Residual	0.04379

Parameter Code=HDL_SU Parameter=HDL cholesterol (mg/dL)

Obs	_Imputation_	STUDYID	CovParm	Estimate
30001	1	NN1218-4131	Residual	0.02982

Parameter Code=LDL_SU Parameter=LDL cholesterol (mg/dL)

Obs	_Imputation_	STUDYID	CovParm	Estimate
40001	1	NN1218-4131	Residual	0.04379

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The Mixed procedure
Covariance Parameter Estimates

Parameter Code=T_CHOL_U Parameter=Total cholesterol (mg/dL)

Obs	_Imputation_	STUDYID	CovParm	Estimate
50001	1	NN1218-4131	Residual	0.01968

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The Mixed procedure
Fit Statistics

Parameter Code=C105586S Parameter=Total cholesterol (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	-2 Res Log Likelihood	-1067.5
2	1	NN1218-4131	AIC (Smaller is Better)	-1065.5
3	1	NN1218-4131	AICC (Smaller is Better)	-1065.5
4	1	NN1218-4131	BIC (Smaller is Better)	-1060.5

Parameter Code=C105587S Parameter=HDL cholesterol (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
5	1	NN1218-4131	-2 Res Log Likelihood	-644.1
6	1	NN1218-4131	AIC (Smaller is Better)	-642.1
7	1	NN1218-4131	AICC (Smaller is Better)	-642.1
8	1	NN1218-4131	BIC (Smaller is Better)	-637.1

Parameter Code=C105588S Parameter=LDL cholesterol (mmol/L)

Obs	_Imputation_	STUDYID	Descr	Value
9	1	NN1218-4131	-2 Res Log Likelihood	-252.9
10	1	NN1218-4131	AIC (Smaller is Better)	-250.9
11	1	NN1218-4131	AICC (Smaller is Better)	-250.9
12	1	NN1218-4131	BIC (Smaller is Better)	-246.0

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The Mixed procedure
Fit Statistics

Parameter Code=HDL_SU Parameter=HDL cholesterol (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
13	1	NN1218-4131	-2 Res Log Likelihood	-644.1
14	1	NN1218-4131	AIC (Smaller is Better)	-642.1
15	1	NN1218-4131	AICC (Smaller is Better)	-642.1
16	1	NN1218-4131	BIC (Smaller is Better)	-637.1

Parameter Code=LDL_SU Parameter=LDL cholesterol (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
17	1	NN1218-4131	-2 Res Log Likelihood	-252.9
18	1	NN1218-4131	AIC (Smaller is Better)	-250.9
19	1	NN1218-4131	AICC (Smaller is Better)	-250.9
20	1	NN1218-4131	BIC (Smaller is Better)	-246.0

Parameter Code=T_CHOL_U Parameter=Total cholesterol (mg/dL)

Obs	_Imputation_	STUDYID	Descr	Value
21	1	NN1218-4131	-2 Res Log Likelihood	-1067.5
22	1	NN1218-4131	AIC (Smaller is Better)	-1065.5
23	1	NN1218-4131	AICC (Smaller is Better)	-1065.5
24	1	NN1218-4131	BIC (Smaller is Better)	-1060.5

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The Mixed procedure
Solution for Fixed Effects

Parameter Code=C105586S Parameter=Total cholesterol (mmol/L)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1			BOLAD1
1	1	NN1218-4131	TRTPN	2				
2	1	NN1218-4131	TRTPN	3				
3	1	NN1218-4131	TRTPN	4				
4	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
5	1	NN1218-4131	REGION1	—	EUROPE			
6	1	NN1218-4131	REGION1	—	JAPAN			
7	1	NN1218-4131	REGION1	—	NORTH AMERICA			
8	1	NN1218-4131	BOLAD1	—				BOLUS INSULIN ALGORITHM (SLIDING SCALE)
9	1	NN1218-4131	BOLAD1	—				CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY
10	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	0.3963	0.03476	1017	11.40	<.0001	0.05	0.3281	0.4645
2	0.4216	0.03480	1017	12.11	<.0001	0.05	0.3533	0.4899
3	0.4075	0.03487	1017	11.69	<.0001	0.05	0.3391	0.4759
4	-0.03749	0.01601	1017	-2.34	0.0194	0.05	-0.06891	-0.00607
5	0.03054	0.01130	1017	2.70	0.0070	0.05	0.008376	0.05271
6	0.07424	0.01284	1017	5.78	<.0001	0.05	0.04904	0.09945
7	0
8	0.008782	0.009828	1017	0.89	0.3718	0.05	-0.01050	0.02807
9	0
10	0.7184	0.02256	1017	31.85	<.0001	0.05	0.6742	0.7627

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The Mixed procedure
Solution for Fixed Effects

Parameter Code=C105587S Parameter=HDL cholesterol (mmol/L)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1			BOLAD1
11	1	NN1218-4131	TRTPN	2				
12	1	NN1218-4131	TRTPN	3				
13	1	NN1218-4131	TRTPN	4				
14	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
15	1	NN1218-4131	REGION1	—	EUROPE			
16	1	NN1218-4131	REGION1	—	JAPAN			
17	1	NN1218-4131	REGION1	—	NORTH AMERICA			
18	1	NN1218-4131	BOLAD1	—				BOLUS INSULIN ALGORITHM (SLIDING SCALE)
19	1	NN1218-4131	BOLAD1	—				CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY
20	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
11	0.03865	0.01518	1017	2.55	0.0110	0.05	0.008873	0.06843
12	0.05209	0.01529	1017	3.41	0.0007	0.05	0.02209	0.08210
13	0.04867	0.01539	1017	3.16	0.0016	0.05	0.01847	0.07888
14	0.02516	0.01975	1017	1.27	0.2031	0.05	-0.01360	0.06392
15	0.02534	0.01388	1017	1.83	0.0681	0.05	-0.00189	0.05258
16	0.1039	0.01609	1017	6.46	<.0001	0.05	0.07234	0.1355
17	0
18	-0.02269	0.01211	1017	-1.87	0.0613	0.05	-0.04646	0.001078
19	0
20	0.8217	0.01873	1017	43.88	<.0001	0.05	0.7850	0.8585

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The Mixed procedure
Solution for Fixed Effects

Parameter Code=C105588S Parameter=LDL cholesterol (mmol/L)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1			BOLAD1
21	1	NN1218-4131	TRTPN	2				
22	1	NN1218-4131	TRTPN	3				
23	1	NN1218-4131	TRTPN	4				
24	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
25	1	NN1218-4131	REGION1	—	EUROPE			
26	1	NN1218-4131	REGION1	—	JAPAN			
27	1	NN1218-4131	REGION1	—	NORTH AMERICA			
28	1	NN1218-4131	BOLAD1	—				BOLUS INSULIN ALGORITHM (SLIDING SCALE)
29	1	NN1218-4131	BOLAD1	—				CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY
30	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
21	0.3115	0.02428	1017	12.83	<.0001	0.05	0.2639	0.3592
22	0.3385	0.02454	1017	13.80	<.0001	0.05	0.2904	0.3867
23	0.3328	0.02426	1017	13.72	<.0001	0.05	0.2852	0.3804
24	-0.00330	0.02386	1017	-0.14	0.8902	0.05	-0.05011	0.04352
25	0.05006	0.01684	1017	2.97	0.0030	0.05	0.01702	0.08310
26	0.09258	0.01895	1017	4.89	<.0001	0.05	0.05540	0.1298
27	0
28	0.01975	0.01466	1017	1.35	0.1783	0.05	-0.00902	0.04851
29	0
30	0.6415	0.02065	1017	31.06	<.0001	0.05	0.6010	0.6820

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The Mixed procedure
Solution for Fixed Effects

Parameter Code=HDL_SU Parameter=HDL cholesterol (mg/dL)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
31	1	NN1218-4131	TRTPN	2				
32	1	NN1218-4131	TRTPN	3				
33	1	NN1218-4131	TRTPN	4				
34	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
35	1	NN1218-4131	REGION1	—	EUROPE			
36	1	NN1218-4131	REGION1	—	JAPAN			
37	1	NN1218-4131	REGION1	—	NORTH AMERICA			
38	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
39	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
40	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
31	0.6900	0.07729	1017	8.93	<.0001	0.05	0.5383	0.8416
32	0.7034	0.07726	1017	9.10	<.0001	0.05	0.5518	0.8550
33	0.7000	0.07728	1017	9.06	<.0001	0.05	0.5483	0.8516
34	0.02516	0.01975	1017	1.27	0.2031	0.05	-0.01360	0.06392
35	0.02534	0.01388	1017	1.83	0.0681	0.05	-0.00189	0.05258
36	0.1039	0.01609	1017	6.46	<.0001	0.05	0.07234	0.1355
37	0
38	-0.02269	0.01211	1017	-1.87	0.0613	0.05	-0.04646	0.001078
39	0
40	0.8217	0.01873	1017	43.88	<.0001	0.05	0.7850	0.8585

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The Mixed procedure
Solution for Fixed Effects

Parameter Code=LDL_SU Parameter=LDL cholesterol (mg/dL)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1			BOLAD1
41	1	NN1218-4131	TRTPN	2				
42	1	NN1218-4131	TRTPN	3				
43	1	NN1218-4131	TRTPN	4				
44	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
45	1	NN1218-4131	REGION1	—	EUROPE			
46	1	NN1218-4131	REGION1	—	JAPAN			
47	1	NN1218-4131	REGION1	—	NORTH AMERICA			
48	1	NN1218-4131	BOLAD1	—				BOLUS INSULIN ALGORITHM (SLIDING SCALE)
49	1	NN1218-4131	BOLAD1	—				CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY
50	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
41	1.6212	0.09521	1017	17.03	<.0001	0.05	1.4344	1.8081
42	1.6483	0.09541	1017	17.28	<.0001	0.05	1.4611	1.8355
43	1.6425	0.09495	1017	17.30	<.0001	0.05	1.4562	1.8288
44	-0.00330	0.02386	1017	-0.14	0.8902	0.05	-0.05011	0.04352
45	0.05006	0.01684	1017	2.97	0.0030	0.05	0.01702	0.08310
46	0.09258	0.01895	1017	4.89	<.0001	0.05	0.05540	0.1298
47	0
48	0.01975	0.01466	1017	1.35	0.1783	0.05	-0.00902	0.04851
49	0
50	0.6415	0.02065	1017	31.06	<.0001	0.05	0.6010	0.6820

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The Mixed procedure
Solution for Fixed Effects

Parameter Code=T_CHOL_U Parameter=Total cholesterol (mg/dL)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1			BOLAD1
51	1	NN1218-4131	TRTPN	2				
52	1	NN1218-4131	TRTPN	3				
53	1	NN1218-4131	TRTPN	4				
54	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
55	1	NN1218-4131	REGION1	—	EUROPE			
56	1	NN1218-4131	REGION1	—	JAPAN			
57	1	NN1218-4131	REGION1	—	NORTH AMERICA			
58	1	NN1218-4131	BOLAD1	—				BOLUS INSULIN ALGORITHM (SLIDING SCALE)
59	1	NN1218-4131	BOLAD1	—				CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY
60	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
51	1.4250	0.1160	1017	12.29	<.0001	0.05	1.1974	1.6527
52	1.4504	0.1160	1017	12.50	<.0001	0.05	1.2227	1.6780
53	1.4363	0.1161	1017	12.38	<.0001	0.05	1.2085	1.6640
54	-0.03749	0.01601	1017	-2.34	0.0194	0.05	-0.06891	-0.00607
55	0.03054	0.01130	1017	2.70	0.0070	0.05	0.008376	0.05271
56	0.07424	0.01284	1017	5.78	<.0001	0.05	0.04904	0.09945
57	0
58	0.008782	0.009828	1017	0.89	0.3718	0.05	-0.01050	0.02807
59	0
60	0.7184	0.02256	1017	31.85	<.0001	0.05	0.6742	0.7627

Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

The Mixed procedure
Least Squares Means

Obs	_Imputation_	PARAMCD	PARAM	STUDYID	Effect	TRTPN
1	1	C105586S	Total cholesterol (mmol/L)	NN1218-4131	TRTPN	2
10001	1	C105587S	HDL cholesterol (mmol/L)	NN1218-4131	TRTPN	2
20001	1	C105588S	LDL cholesterol (mmol/L)	NN1218-4131	TRTPN	2
30001	1	HDL_SU	HDL cholesterol (mg/dL)	NN1218-4131	TRTPN	2
40001	1	LDL_SU	LDL cholesterol (mg/dL)	NN1218-4131	TRTPN	2
50001	1	T_CHOL_U	Total cholesterol (mg/dL)	NN1218-4131	TRTPN	2
60001	1	C105586S	Total cholesterol (mmol/L)	NN1218-4131	TRTPN	3
70001	1	C105587S	HDL cholesterol (mmol/L)	NN1218-4131	TRTPN	3
80001	1	C105588S	LDL cholesterol (mmol/L)	NN1218-4131	TRTPN	3
90001	1	HDL_SU	HDL cholesterol (mg/dL)	NN1218-4131	TRTPN	3
100001	1	LDL_SU	LDL cholesterol (mg/dL)	NN1218-4131	TRTPN	3
110001	1	T_CHOL_U	Total cholesterol (mg/dL)	NN1218-4131	TRTPN	3
120001	1	C105586S	Total cholesterol (mmol/L)	NN1218-4131	TRTPN	4
130001	1	C105587S	HDL cholesterol (mmol/L)	NN1218-4131	TRTPN	4

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	WORK.IMPUTE	0.002727	0.007595	1017	0.36	0.7196	0.05	-0.01218	0.01763
10001	WORK.IMPUTE	-0.01643	0.009349	1017	-1.76	0.0791	0.05	-0.03478	0.001913
20001	WORK.IMPUTE	0.02673	0.01133	1017	2.36	0.0185	0.05	0.004492	0.04896
30001	WORK.IMPUTE	-0.01643	0.009349	1017	-1.76	0.0791	0.05	-0.03478	0.001913
40001	WORK.IMPUTE	0.02673	0.01133	1017	2.36	0.0185	0.05	0.004492	0.04896
50001	WORK.IMPUTE	0.002727	0.007595	1017	0.36	0.7196	0.05	-0.01218	0.01763
60001	WORK.IMPUTE	0.02808	0.007604	1017	3.69	0.0002	0.05	0.01316	0.04300
70001	WORK.IMPUTE	-0.00299	0.009361	1017	-0.32	0.7493	0.05	-0.02136	0.01538
80001	WORK.IMPUTE	0.05376	0.01135	1017	4.74	<.0001	0.05	0.03149	0.07602
90001	WORK.IMPUTE	-0.00299	0.009361	1017	-0.32	0.7493	0.05	-0.02136	0.01538
100001	WORK.IMPUTE	0.05376	0.01135	1017	4.74	<.0001	0.05	0.03149	0.07602
110001	WORK.IMPUTE	0.02808	0.007604	1017	3.69	0.0002	0.05	0.01316	0.04300
120001	WORK.IMPUTE	0.01395	0.007593	1017	1.84	0.0665	0.05	-0.00095	0.02885
130001	WORK.IMPUTE	-0.00641	0.009346	1017	-0.69	0.4930	0.05	-0.02475	0.01193

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Obs	_Imputation_	PARAMCD	PARAM	STUDYID	Effect	TRTPN
140001	1	C105588S	LDL cholesterol (mmol/L)	NN1218-4131	TRTPN	4
150001	1	HDL_SU	HDL cholesterol (mg/dL)	NN1218-4131	TRTPN	4
160001	1	LDL_SU	LDL cholesterol (mg/dL)	NN1218-4131	TRTPN	4
170001	1	T_CHOL_U	Total cholesterol (mg/dL)	NN1218-4131	TRTPN	4

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
140001	WORK.IMPUTE	0.04802	0.01133	1017	4.24	<.0001	0.05	0.02578	0.07025
150001	WORK.IMPUTE	-0.00641	0.009346	1017	-0.69	0.4930	0.05	-0.02475	0.01193
160001	WORK.IMPUTE	0.04802	0.01133	1017	4.24	<.0001	0.05	0.02578	0.07025
170001	WORK.IMPUTE	0.01395	0.007593	1017	1.84	0.0665	0.05	-0.00095	0.02885

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The Mixed procedure
Least Squares Means Estimate

Parameter Code=C105586S Parameter=Total cholesterol (mmol/L)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
1	1	NN1218-4131	1	TRTPN	Faster aspart (meal) / NovoRapid (meal)
10001	1	NN1218-4131	2	TRTPN	Faster aspart (post) / NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	WORK.IMPUTE	-0.01122	0.01075	1017	-1.04	0.2966	0.05	-0.03231	0.009866
10001	WORK.IMPUTE	0.01413	0.01075	1017	1.31	0.1890	0.05	-0.00696	0.03523

Parameter Code=C105587S Parameter=HDL cholesterol (mmol/L)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
20001	1	NN1218-4131	1	TRTPN	Faster aspart (meal) / NovoRapid (meal)
30001	1	NN1218-4131	2	TRTPN	Faster aspart (post) / NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
20001	WORK.IMPUTE	-0.01002	0.01323	1017	-0.76	0.4488	0.05	-0.03598	0.01593
30001	WORK.IMPUTE	0.003418	0.01323	1017	0.26	0.7963	0.05	-0.02255	0.02938

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The Mixed procedure
Least Squares Means Estimate

Parameter Code=C105588S Parameter=LDL cholesterol (mmol/L)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
40001	1	NN1218-4131	1	TRTPN	Faster aspart (meal) / NovoRapid (meal)
50001	1	NN1218-4131	2	TRTPN	Faster aspart (post) / NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
40001	WORK.IMPUTE	-0.02129	0.01603	1017	-1.33	0.1845	0.05	-0.05276	0.01017
50001	WORK.IMPUTE	0.005742	0.01604	1017	0.36	0.7205	0.05	-0.02574	0.03723

Parameter Code=HDL_SU Parameter=HDL cholesterol (mg/dL)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
60001	1	NN1218-4131	1	TRTPN	Faster aspart (meal) / NovoRapid (meal)
70001	1	NN1218-4131	2	TRTPN	Faster aspart (post) / NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
60001	WORK.IMPUTE	-0.01002	0.01323	1017	-0.76	0.4488	0.05	-0.03598	0.01593
70001	WORK.IMPUTE	0.003418	0.01323	1017	0.26	0.7963	0.05	-0.02255	0.02938

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The Mixed procedure
Least Squares Means Estimate

Parameter Code=LDL_SU Parameter=LDL cholesterol (mg/dL)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
80001	1	NN1218-4131	1	TRTPN	Faster aspart (meal) / NovoRapid (meal)
90001	1	NN1218-4131	2	TRTPN	Faster aspart (post) / NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
80001	WORK.IMPUTE	-0.02129	0.01603	1017	-1.33	0.1845	0.05	-0.05276	0.01017
90001	WORK.IMPUTE	0.005742	0.01604	1017	0.36	0.7205	0.05	-0.02574	0.03723

Parameter Code=T_CHOL_U Parameter=Total cholesterol (mg/dL)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
100001	1	NN1218-4131	1	TRTPN	Faster aspart (meal) / NovoRapid (meal)
110001	1	NN1218-4131	2	TRTPN	Faster aspart (post) / NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
100001	WORK.IMPUTE	-0.01122	0.01075	1017	-1.04	0.2966	0.05	-0.03231	0.009866
110001	WORK.IMPUTE	0.01413	0.01075	1017	1.31	0.1890	0.05	-0.00696	0.03523

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Planned Treatment for Period 30 (N)=2 Parameter Code=C105586S Parameter=Total cholesterol (mmol/L) Study Identifier=NN1218-41

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000001364	0.000057570	0.000058935	1.87E7	0.023703	0.023154	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	1.499562	0.007677	1.484515	1.514608	1.87E7	1.494997	1.504244

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	195.33	<.0001

Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=C105587S Parameter=HDL cholesterol (mmol/L) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000002057	0.000087394	0.000089452	1.89E7	0.023545	0.023003	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.422759	0.009458	0.404222	0.441296	1.89E7	0.416998	0.428443

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	44.70	<.0001

Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=C105588S Parameter=LDL cholesterol (mmol/L) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000002379	0.000128	0.000130	3E7	0.018591	0.018252	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.959321	0.011418	0.936942	0.981699	3E7	0.953288	0.965497

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	84.02	<.0001

Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=HDL_SU Parameter=HDL cholesterol (mg/dL) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000002057	0.000087394	0.000089452	1.89E7	0.023545	0.023003	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	4.076270	0.009458	4.057733	4.094808	1.89E7	4.070509	4.081955

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	430.99	<.0001

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Planned Treatment for Period 30 (N)=2 Parameter Code=LDL_SU Parameter=LDL cholesterol (mg/dL) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000002379	0.000128	0.000130	3E7	0.018591	0.018252	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	4.612832	0.011418	4.590453	4.635211	3E7	4.606799	4.619008

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	404.00	<.0001

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Planned Treatment for Period 30 (N)=2 Parameter Code=T_CHOL_U Parameter=Total cholesterol (mg/dL) Study Identifier=NN1218-413

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000001364	0.000057570	0.000058935	1.87E7	0.023703	0.023154	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	5.153073	0.007677	5.138027	5.168119	1.87E7	5.148508	5.157756

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	671.24	<.0001

Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=C105586S Parameter=Total cholesterol (mmol/L) Study Identifier=NN1218-41

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000001358	0.000057708	0.000059066	1.89E7	0.023535	0.022994	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	1.525547	0.007685	1.510484	1.540611	1.89E7	1.521135	1.530044

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	198.50	<.0001

Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=C105587S Parameter=HDL cholesterol (mmol/L) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000001748	0.000087603	0.000089351	2.61E7	0.019958	0.019568	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.437029	0.009453	0.418502	0.455555	2.61E7	0.431891	0.442248

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	46.23	<.0001

Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=C105588S Parameter=LDL cholesterol (mmol/L) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000002798	0.000128	0.000131	2.2E7	0.021802	0.021337	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits	DF	Minimum	Maximum
Estimate	0.987132	0.011452	0.964687 1.009577	2.2E7	0.980754	0.993605

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	86.20	<.0001

Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=HDL_SU Parameter=HDL cholesterol (mg/dL) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000001748	0.000087603	0.000089351	2.61E7	0.019958	0.019568	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	4.090540	0.009453	4.072013	4.109067	2.61E7	4.085403	4.095759

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	432.74	<.0001

Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=LDL_SU Parameter=LDL cholesterol (mg/dL) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000002798	0.000128	0.000131	2.2E7	0.021802	0.021337	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	4.640643	0.011452	4.618198	4.663088	2.2E7	4.634265	4.647117

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	405.24	<.0001

Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=T_CHOL_U Parameter=Total cholesterol (mg/dL) Study Identifier=NN1218-413

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000001358	0.000057708	0.000059066	1.89E7	0.023535	0.022994	0.999998

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	5.179059	0.007685	5.163995	5.194122	1.89E7	5.174646	5.183555

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	673.88	<.0001

Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=C105586S Parameter=Total cholesterol (mmol/L) Study Identifier=NN1218-41

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000002530	0.000057532	0.000060063	5.63E6	0.043982	0.042130	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	1.513790	0.007750	1.498600	1.528980	5.63E6	1.505107	1.520073

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	195.33	<.0001

Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=C105587S Parameter=HDL cholesterol (mmol/L) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000003451	0.000087335	0.000090786	6.92E6	0.039514	0.038012	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.435961	0.009528	0.417286	0.454636	6.92E6	0.428447	0.442491

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	45.76	<.0001

Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=C105588S Parameter=LDL cholesterol (mmol/L) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000005519	0.000128	0.000133	5.85E6	0.043131	0.041348	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits	DF	Minimum	Maximum
Estimate	0.984775	0.011554	0.962130 1.007421	5.85E6	0.971965	0.993985

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	85.23	<.0001

Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=HDL_SU Parameter=HDL cholesterol (mg/dL) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000003451	0.000087335	0.000090786	6.92E6	0.039514	0.038012	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	4.089472	0.009528	4.070797	4.108147	6.92E6	4.081958	4.096003

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	429.20	<.0001

Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=LDL_SU Parameter=LDL cholesterol (mg/dL) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000005519	0.000128	0.000133	5.85E6	0.043131	0.041348	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	4.638287	0.011554	4.615641	4.660932	5.85E6	4.625476	4.647496

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	401.45	<.0001

Lipids 26 weeks after randomisation - statistical analysis - on-treatment - full analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=T_CHOL_U Parameter=Total cholesterol (mg/dL) Study Identifier=NN1218-413

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	10000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000002530	0.000057532	0.000060063	5.63E6	0.043982	0.042130	0.999996

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	5.167301	0.007750	5.152112	5.182491	5.63E6	5.158619	5.173584

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	666.75	<.0001

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The MI Procedure with MCMC
Model Information

Parameter Code=C25208X Planned Treatment for Period 30 (N)=2

Obs	PARAM	Description	Value
1	Body weight (kg)	Data Set	WORK.ENDPOINT_PARAM
2	Body weight (kg)	Method	Monotone-data_MCMC
3	Body weight (kg)	Multiple Imputation Chain	Multiple Chains
4	Body weight (kg)	Initial Estimates for MCMC	EM Posterior Mode
5	Body weight (kg)	Start	Starting Value
6	Body weight (kg)	Prior	Jeffreys
7	Body weight (kg)	Number of Imputations	20000
8	Body weight (kg)	Number of Burn-in Iterations	200
9	Body weight (kg)	Seed for random number generator	1234

Parameter Code=C25208X Planned Treatment for Period 30 (N)=3

Obs	PARAM	Description	Value
10	Body weight (kg)	Data Set	WORK.ENDPOINT_PARAM
11	Body weight (kg)	Method	Monotone-data_MCMC
12	Body weight (kg)	Multiple Imputation Chain	Multiple Chains
13	Body weight (kg)	Initial Estimates for MCMC	EM Posterior Mode
14	Body weight (kg)	Start	Starting Value
15	Body weight (kg)	Prior	Jeffreys
16	Body weight (kg)	Number of Imputations	20000
17	Body weight (kg)	Number of Burn-in Iterations	200
18	Body weight (kg)	Seed for random number generator	1027630576

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Body weight 26 weeks after randomisation - statistical analysis - on-treatment - safety analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=C25208X Planned Treatment for Period 30 (N)=4

Obs	PARAM	Description	Value
19	Body weight (kg)	Data Set	WORK.ENDPOINT_PARAM
20	Body weight (kg)	Method	Monotone-data_MCMC
21	Body weight (kg)	Multiple Imputation Chain	Multiple Chains
22	Body weight (kg)	Initial Estimates for MCMC	EM Posterior Mode
23	Body weight (kg)	Start	Starting Value
24	Body weight (kg)	Prior	Jeffreys
25	Body weight (kg)	Number of Imputations	20000
26	Body weight (kg)	Number of Burn-in Iterations	200
27	Body weight (kg)	Seed for random number generator	2062520436

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09FEB2018:20:29:30 - a_lab_stat_diff.sas/a_bw_stat_on_sas_app.txt

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Body weight 26 weeks after randomisation - statistical analysis - on-treatment - safety analysis set

The MI Procedure with MCMC
Missing data pattern

Parameter Code=C25208X Planned Treatment for Period 30 (N)=2

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
1	Body weight (kg)	1	X	X	X	335	97.95	72.538039	0.857715	1.453712
2	Body weight (kg)	2	X	X	O	3	0.88	84.133333	0.466667	.
3	Body weight (kg)	3	X	.	X	2	0.58	56.287250	.	-0.431437
4	Body weight (kg)	4	X	O	O	2	0.58	79.450000	.	.

Parameter Code=C25208X Planned Treatment for Period 30 (N)=3

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
5	Body weight (kg)	1	X	X	X	335	98.24	71.894305	0.622470	1.135168
6	Body weight (kg)	2	X	X	O	5	1.47	75.384237	1.291557	.
7	Body weight (kg)	3	X	O	O	1	0.29	56.200000	.	.

Parameter Code=C25208X Planned Treatment for Period 30 (N)=4

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
8	Body weight (kg)	1	X	X	X	333	97.37	71.940448	0.782423	1.246789
9	Body weight (kg)	2	X	X	O	7	2.05	69.826211	1.038580	.
10	Body weight (kg)	3	X	O	O	2	0.58	53.650000	.	.

Body weight 26 weeks after randomisation - statistical analysis - on-treatment - safety analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=C25208X Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM	Description	Value
1	1	Body weight (kg)	Data Set	WORK.MONO_SORT_TRT
2	1	Body weight (kg)	Method	Monotone
3	1	Body weight (kg)	Number of Imputations	1
4	1	Body weight (kg)	Seed for random number generator	4321

Body weight 26 weeks after randomisation - statistical analysis - on-treatment - safety analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=C25208X Planned Treatment for Period 30 (N)=2

O b s	I m p u t a t i o n _			P A R A M	G r o u p	R E G I O N 1			B O L A D 1		B A S E	v i s i t 2		v i s i t 3		P e r c e n t	B A S E	v i s i t 2	v i s i t 3
						\bar{M}	\bar{M}	\bar{M}	\bar{M}	\bar{M}		\bar{M}	\bar{M}	\bar{M}	F r e q				
1	1	Body	weight	(kg)	1	X	X	X	X	X	337	98.54	72.441595	0.846881	1.442525				
2	1	Body	weight	(kg)	2	X	X	X	X	.	3	0.88	84.133333	0.466667	.				
3	1	Body	weight	(kg)	3	X	X	X	.	.	2	0.58	79.450000	.	.				

Body weight 26 weeks after randomisation - statistical analysis - on-treatment - safety analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=C25208X Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2200

Imputed		Effect		Regression		Bols		Standard Error	
Obs	N	Parameter	Estimate	Standard Error	95% CI	Estimate	Standard Error	95% CI	Wald Stat
1	1	Body weight (kg)	Intercept			-0.02723	0.011524		
2	1	Body weight (kg)	REGION1 ASIA (EXCLUDING JAPAN)			0.07720	0.118618		
3	1	Body weight (kg)	REGION1 EUROPE			0.04196	-0.105699		
4	1	Body weight (kg)	REGION1 JAPAN			-0.08821	-0.115465		
5	1	Body weight (kg)	BOLAD1			0.19307	0.138871		
6	1	Body weight (kg)	BASE			0.20101	0.150074		

Body weight 26 weeks after randomisation - statistical analysis - on-treatment - safety analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=C25208X Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

Imputed		Effect		Region		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		Observation		Mean	
O	b	P	E	R	B	O	B	s	a		
s	n	A	f	E	O	L	A	V	l		
—	—	M	c	N	D	1	1	1	1		
7	1	Body weight (kg)	Intercept					0.00369		-0.018605	
8	1	Body weight (kg)	REGION1	ASIA (EXCLUDING JAPAN)				0.06777		0.127033	
9	1	Body weight (kg)	REGION1	EUROPE				-0.08967		-0.090693	
10	1	Body weight (kg)	REGION1	JAPAN				0.01475		0.019376	
11	1	Body weight (kg)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)			0.07910		0.126208	
12	1	Body weight (kg)	BASE					0.09179		0.180709	
13	1	Body weight (kg)	visit2200					0.66680		0.639058	

Body weight 26 weeks after randomisation - statistical analysis - on-treatment - safety analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=C25208X Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM	Description	Value
1	1	Body weight (kg)	Data Set	WORK.MONO_SORT_TRT
2	1	Body weight (kg)	Method	Monotone
3	1	Body weight (kg)	Number of Imputations	1
4	1	Body weight (kg)	Seed for random number generator	4322

Body weight 26 weeks after randomisation - statistical analysis - on-treatment - safety analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=C25208X Planned Treatment for Period 30 (N)=3

Obs	Input at i on —	P A R A M E T E R S	G r o u p	R E G I O N 1	B O L A D 1	B A A S E	v i s i t 2	v i s i t 3	F r e q	P e r c e n t	B A S E	v i s i t 2	v i s i t 3
1	1	Body weight (kg)	1	X	X	X	X	X	335	98.24	71.894305	0.622470	1.135168
2	1	Body weight (kg)	2	X	X	X	X	.	5	1.47	75.384237	1.291557	.
3	1	Body weight (kg)	3	X	X	X	.	.	1	0.29	56.200000	.	.

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Body weight 26 weeks after randomisation - statistical analysis - on-treatment - safety analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=C25208X Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2200

Imputed		Observed		Region		Treatment		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		Parameter	
O	b	P	E	R	E	B	O				
s	n	A	f	E	G	O	b				
—	—	R	e	I	I	L	s				
		A	c	O	N	A	V				
		M	t	N	1	D	a				
						1	l				
1	1	Body weight (kg)	Intercept							0.03571	0.149450
2	1	Body weight (kg)	REGION1	ASIA (EXCLUDING JAPAN)						0.15165	0.317635
3	1	Body weight (kg)	REGION1	EUROPE						-0.16829	-0.173143
4	1	Body weight (kg)	REGION1	JAPAN						0.07784	-0.020703
5	1	Body weight (kg)	BOLAD1							0.00600	0.037052
6	1	Body weight (kg)	BASE							0.10753	0.075759

Body weight 26 weeks after randomisation - statistical analysis - on-treatment - safety analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=C25208X Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

		Imputed		Effect		Region		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		Observation		Mean	
O	b	n	s	P	E	R	B	O	B	s	a		
7	1	Body weight (kg)	Intercept										
8	1	Body weight (kg)	REGION1	ASIA (EXCLUDING JAPAN)						-0.00740		0.047074	
9	1	Body weight (kg)	REGION1	EUROPE						-0.05932		0.111106	
10	1	Body weight (kg)	REGION1	JAPAN						0.03866		-0.140196	
11	1	Body weight (kg)	BOLAD1							0.05302		0.189880	
12	1	Body weight (kg)	BASE							-0.00279		-0.098188	
13	1	Body weight (kg)	visit2200							0.08667		0.114042	
										0.55305		0.531880	

Body weight 26 weeks after randomisation - statistical analysis - on-treatment - safety analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=C25208X Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM	Description	Value
1	1	Body weight (kg)	Data Set	WORK.MONO_SORT_TRT
2	1	Body weight (kg)	Method	Monotone
3	1	Body weight (kg)	Number of Imputations	1
4	1	Body weight (kg)	Seed for random number generator	4323

Body weight 26 weeks after randomisation - statistical analysis - on-treatment - safety analysis set

The MI Procedure with Monotone Regression
Missing Data Pattern

Parameter Code=C25208X Planned Treatment for Period 30 (N)=4

O b s	I m p u t a t i o n _				G r o u p	R E G I O N 1			B O L A D 1			B A S E			v i s i t 2		v i s i t 3				v i s i t 2		v i s i t 3			
		P A R A M				\bar{M} i s s	\bar{M} i s s	\bar{M} i s s	\bar{M} i s s	\bar{M} i s s	\bar{M} i s s	F r e q	P e r c e n t	B A S E												
1	1	Body weight (kg)			1	X	X	X	X	X	333	97.37	71.940448	0.782423												
2	1	Body weight (kg)			2	X	X	X	X	.	7	2.05	69.826211	1.038580												
3	1	Body weight (kg)			3	X	X	X	.	.	2	0.58	53.650000	.												

Body weight 26 weeks after randomisation - statistical analysis - on-treatment - safety analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=C25208X Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2200

Imputed		Effect		Regression		Bols		Standard	
Obs		Parameter		Coefficient		Standard Error		t Value	
1	1	Body weight (kg)	Intercept				-0.01648		-0.071139
2	1	Body weight (kg)	REGION1	ASIA (EXCLUDING JAPAN)			-0.06568		-0.006872
3	1	Body weight (kg)	REGION1	EUROPE			-0.21057		-0.344740
4	1	Body weight (kg)	REGION1	JAPAN			0.14089		0.200210
5	1	Body weight (kg)	BOLAD1	BOLUS INSULIN ALGORITHM (SLIDING SCALE)			0.11344		0.116537
6	1	Body weight (kg)	BASE				0.12539		0.064043

Body weight 26 weeks after randomisation - statistical analysis - on-treatment - safety analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=C25208X Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

Imputed		Effect		Region		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		Observation	
O	b	P	E	R	B	O			
s	n	A	f	E	O	b			
—	A	R	e	G	L	s			
	M	c	t	I	A	V			
				N	D	a			
				1	1	l			
7	1	Body weight (kg)	Intercept				0.00245		-0.059130
8	1	Body weight (kg)	REGION1	ASIA (EXCLUDING JAPAN)			-0.01106		-0.099621
9	1	Body weight (kg)	REGION1	EUROPE			-0.09836		-0.034534
10	1	Body weight (kg)	REGION1	JAPAN			0.03065		0.129625
11	1	Body weight (kg)	BOLAD1				0.01601		0.050411
12	1	Body weight (kg)	BASE				0.06408		0.122571
13	1	Body weight (kg)	visit2200				0.50647		0.465121

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Body weight 26 weeks after randomisation - statistical analysis - on-treatment - safety analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=WEIGHTU Planned Treatment for Period 30 (N)=2

Obs	PARAM	Description	Value
1	Body weight (lb)	Data Set	WORK.ENDPOINT_PARAM
2	Body weight (lb)	Method	Monotone-data_MCMC
3	Body weight (lb)	Multiple Imputation Chain	Multiple Chains
4	Body weight (lb)	Initial Estimates for MCMC	EM Posterior Mode
5	Body weight (lb)	Start	Starting Value
6	Body weight (lb)	Prior	Jeffreys
7	Body weight (lb)	Number of Imputations	20000
8	Body weight (lb)	Number of Burn-in Iterations	200
9	Body weight (lb)	Seed for random number generator	1234

Parameter Code=WEIGHTU Planned Treatment for Period 30 (N)=3

Obs	PARAM	Description	Value
10	Body weight (lb)	Data Set	WORK.ENDPOINT_PARAM
11	Body weight (lb)	Method	Monotone-data_MCMC
12	Body weight (lb)	Multiple Imputation Chain	Multiple Chains
13	Body weight (lb)	Initial Estimates for MCMC	EM Posterior Mode
14	Body weight (lb)	Start	Starting Value
15	Body weight (lb)	Prior	Jeffreys
16	Body weight (lb)	Number of Imputations	20000
17	Body weight (lb)	Number of Burn-in Iterations	200
18	Body weight (lb)	Seed for random number generator	1027630576

nn1218/nn1218-4131/ctr_20180214_er
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Body weight 26 weeks after randomisation - statistical analysis - on-treatment - safety analysis set

The MI Procedure with MCMC
Model Information

Parameter Code=WEIGHTU Planned Treatment for Period 30 (N)=4

Obs	PARAM	Description	Value
19	Body weight (lb)	Data Set	WORK.ENDPOINT_PARAM
20	Body weight (lb)	Method	Monotone-data_MCMC
21	Body weight (lb)	Multiple Imputation Chain	Multiple Chains
22	Body weight (lb)	Initial Estimates for MCMC	EM Posterior Mode
23	Body weight (lb)	Start	Starting Value
24	Body weight (lb)	Prior	Jeffreys
25	Body weight (lb)	Number of Imputations	20000
26	Body weight (lb)	Number of Burn-in Iterations	200
27	Body weight (lb)	Seed for random number generator	2062520436

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Body weight 26 weeks after randomisation - statistical analysis - on-treatment - safety analysis set

The MI Procedure with MCMC
Missing data pattern

Parameter Code=WEIGHTU Planned Treatment for Period 30 (N)=2

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
1	Body weight (lb)	1	X	X	X	335	97.95	159.919002	1.890939	3.204887
2	Body weight (lb)	2	X	X	O	3	0.88	185.482250	1.028824	.
3	Body weight (lb)	3	X	.	X	2	0.58	124.092146	.	-0.951156
4	Body weight (lb)	4	X	O	O	2	0.58	175.157267	.	.

Parameter Code=WEIGHTU Planned Treatment for Period 30 (N)=3

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
5	Body weight (lb)	1	X	X	X	335	98.24	158.499812	1.372312	2.502618
6	Body weight (lb)	2	X	X	O	5	1.47	166.193795	2.847396	.
7	Body weight (lb)	3	X	O	O	1	0.29	123.899791	.	.

Parameter Code=WEIGHTU Planned Treatment for Period 30 (N)=4

Obs	PARAM	Group	BASE_ Miss	visit2200_ Miss	visit3600_ Miss	Freq	Percent	BASE	visit2200	visit3600
8	Body weight (lb)	1	X	X	X	333	97.37	158.601538	1.724947	2.748698
9	Body weight (lb)	2	X	X	O	7	2.05	153.940444	2.289677	.
10	Body weight (lb)	3	X	O	O	2	0.58	118.278004	.	.

nn1218/nn1218-4131/ctr_20180214_er
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Body weight 26 weeks after randomisation - statistical analysis - on-treatment - safety analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=WEIGHTU Planned Treatment for Period 30 (N)=2

Obs	_Imputation_	PARAM	Description	Value
1	1	Body weight (lb)	Data Set	WORK.MONO_SORT_TRT
2	1	Body weight (lb)	Method	Monotone
3	1	Body weight (lb)	Number of Imputations	1
4	1	Body weight (lb)	Seed for random number generator	4321

Body weight 26 weeks after randomisation - statistical analysis - on-treatment - safety analysis set

The MI Procedure with Monotone Regression Missing Data Pattern

Parameter Code=WEIGHTU Planned Treatment for Period 30 (N)=2

O b s	I m p u t a t i o n	P A R A M	G r o u p	R E G I O N			B O L A D S		F r e q	P e r c e n t	B A S E	v i s i t 2 0 0	v i s i t 3 6 0 0	v i s i t 2 0 0	v i s i t 3 6 0 0
				M	M	M	M	M							
1	1	Body weight (lb)	1	X	X	X	X	X	337	98.54	159.706379	1.867054	3.180222		
2	1	Body weight (lb)	2	X	X	X	X	.	3	0.88	185.482250	1.028824	.		
3	1	Body weight (lb)	3	X	X	X	.	.	2	0.58	175.157267	.			

Body weight 26 weeks after randomisation - statistical analysis - on-treatment - safety analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=WEIGHTU Planned Treatment for Period 30 (N)=2 Imputed Variable=visit2200

Obs	N	Imputed	P	E	R	B	O	I
1	1	Body weight (lb)	Intercept					
2	1	Body weight (lb)	REGION1	ASIA (EXCLUDING JAPAN)				
3	1	Body weight (lb)	REGION1	EUROPE				
4	1	Body weight (lb)	REGION1	JAPAN				
5	1	Body weight (lb)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)			
6	1	Body weight (lb)	BASE					

Body weight 26 weeks after randomisation - statistical analysis - on-treatment - safety analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=WEIGHTU Planned Treatment for Period 30 (N)=2 Imputed Variable=visit3600

		Imputed		Effect		Region		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		Observation		Mean	
		a		P		E		B		O			
		i		A		f		O		b			
		O		R		e		L		s			
		b		A		c		A		V			
		s		M		t		D		a			
		—						1		1			
7	1	Body weight (lb)	Intercept							0.00369		-0.018605	
8	1	Body weight (lb)	REGION1	ASIA (EXCLUDING JAPAN)						0.06777		0.127033	
9	1	Body weight (lb)	REGION1	EUROPE						-0.08967		-0.090693	
10	1	Body weight (lb)	REGION1	JAPAN						0.01475		0.019376	
11	1	Body weight (lb)	BOLAD1							0.07910		0.126208	
12	1	Body weight (lb)	BASE							0.09179		0.180709	
13	1	Body weight (lb)	visit2200							0.66680		0.639058	

Body weight 26 weeks after randomisation - statistical analysis - on-treatment - safety analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=WEIGHTU Planned Treatment for Period 30 (N)=3

Obs	_Imputation_	PARAM	Description	Value
1	1	Body weight (lb)	Data Set	WORK.MONO_SORT_TRT
2	1	Body weight (lb)	Method	Monotone
3	1	Body weight (lb)	Number of Imputations	1
4	1	Body weight (lb)	Seed for random number generator	4322

Body weight 26 weeks after randomisation - statistical analysis - on-treatment - safety analysis set

The MI Procedure with Monotone Regression Missing Data Pattern

Parameter Code=WEIGHTU Planned Treatment for Period 30 (N)=3

O b s	I m p u t a t i o n	P A R A M	G r o u p	R E G I O N			B O L A D S		B A S E		F r e q	P e r c e n t	B A S E	v i s i t 2 2 0 0	v i s i t 3 6 0 0
				M	M	M	M	M	M	M					
1	1	Body weight (lb)	1	X	X	X	X	X	335	98.24	158.499812	1.372312	2.502618		
2	1	Body weight (lb)	2	X	X	X	X	.	5	1.47	166.193795	2.847396	.		
3	1	Body weight (lb)	3	X	X	X	.	.	1	0.29	123.899791	.	.		

Body weight 26 weeks after randomisation - statistical analysis - on-treatment - safety analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=WEIGHTU Planned Treatment for Period 30 (N)=3 Imputed Variable=visit2200

Imputed		Effect		Region		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		Observations	
O	b	P	E	R	B	O			
s	n	A	f	E	O	b			
—	—	R	e	G	L	s			
		A	c	I	A	V			
		M	t	N	D	a			
				1	1	l			
1	1	Body weight (lb)	Intercept				0.03571	0.149450	
2	1	Body weight (lb)	REGION1	ASIA (EXCLUDING JAPAN)			0.15165	0.317635	
3	1	Body weight (lb)	REGION1	EUROPE			-0.16829	-0.173143	
4	1	Body weight (lb)	REGION1	JAPAN			0.07784	-0.020703	
5	1	Body weight (lb)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		0.00600	0.037052	
6	1	Body weight (lb)	BASE				0.10753	0.075759	

Body weight 26 weeks after randomisation - statistical analysis - on-treatment - safety analysis set

The MI Procedure with Monotone Regression Regression Information

Parameter Code=WEIGHTU Planned Treatment for Period 30 (N)=3 Imputed Variable=visit3600

Obs	Imputation	PARM	Effect	REGION1	BOLD1	ObsV	T
7	1	Body weight (lb)	Intercept			-0.00740	0.047074
8	1	Body weight (lb)	REGION1	ASIA (EXCLUDING JAPAN)		-0.05932	0.111106
9	1	Body weight (lb)	REGION1	EUROPE		0.03866	-0.140196
10	1	Body weight (lb)	REGION1	JAPAN		0.05302	0.189880
11	1	Body weight (lb)	BOLAD1		BOLUS INSULIN ALGORITHM (SLIDING SCALE)	-0.00279	-0.098188
12	1	Body weight (lb)	BASE			0.08667	0.114042
13	1	Body weight (lb)	visit2200			0.55305	0.531880

Body weight 26 weeks after randomisation - statistical analysis - on-treatment - safety analysis set

The MI Procedure with Monotone Regression
Model Information

Parameter Code=WEIGHTU Planned Treatment for Period 30 (N)=4

Obs	_Imputation_	PARAM	Description	Value
1	1	Body weight (lb)	Data Set	WORK.MONO_SORT_TRT
2	1	Body weight (lb)	Method	Monotone
3	1	Body weight (lb)	Number of Imputations	1
4	1	Body weight (lb)	Seed for random number generator	4323

Body weight 26 weeks after randomisation - statistical analysis - on-treatment - safety analysis set

The MI Procedure with Monotone Regression Missing Data Pattern

Parameter Code=WEIGHTU Planned Treatment for Period 30 (N)=4

O b s	I m p u t a t i o n	P A R A M	G r o u p	R E G I O N 1			B O L A D S E			F r e q	P e r c e n t	B A S E	v i s i t 2 0 0	v i s i t 3 6 0 0
				\bar{M} i s s	\bar{M} i s s	\bar{M} i s s	\bar{M} i s s	\bar{M} i s s						
1	1	Body weight (lb)	1	X	X	X	X	X	333	97.37	158.601538	1.724947	2.748698	
2	1	Body weight (lb)	2	X	X	X	X	.	7	2.05	153.940444	2.289677	.	
3	1	Body weight (lb)	3	X	X	X	.	.	2	0.58	118.278004	.	.	

Body weight 26 weeks after randomisation - statistical analysis - on-treatment - safety analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=WEIGHTU Planned Treatment for Period 30 (N)=4 Imputed Variable=visit2200

Obs	N	Imputed	Parameter	Estimate	Standard Error	t Value	Pr > t	Lower 95%	Upper 95%
1	1	Body weight (lb)	Intercept					-0.01648	-0.071139
2	1	Body weight (lb)	REGION1 ASIA (EXCLUDING JAPAN)					-0.06568	-0.006872
3	1	Body weight (lb)	REGION1 EUROPE					-0.21057	-0.344740
4	1	Body weight (lb)	REGION1 JAPAN					0.14089	0.200210
5	1	Body weight (lb)	BOLAD1					0.11344	0.116537
6	1	Body weight (lb)	BASE					0.12539	0.064043

Body weight 26 weeks after randomisation - statistical analysis - on-treatment - safety analysis set

The MI Procedure with Monotone Regression
Regression Information

Parameter Code=WEIGHTU Planned Treatment for Period 30 (N)=4 Imputed Variable=visit3600

		Imputed		Effect		Region		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		Observation			
		a		P		E		B		O			
		i		A		f		O		b			
		O		R		e		L		s			
		b		A		c		A		V			
		s		M		t		D		a			
		—						1		1			
7	1	Body weight (lb)	Intercept							0.00245	-0.059130		
8	1	Body weight (lb)	REGION1	ASIA (EXCLUDING JAPAN)						-0.01106	-0.099621		
9	1	Body weight (lb)	REGION1	EUROPE						-0.09836	-0.034534		
10	1	Body weight (lb)	REGION1	JAPAN						0.03065	0.129625		
11	1	Body weight (lb)	BOLAD1							0.01601	0.050411		
12	1	Body weight (lb)	BASE							0.06408	0.122571		
13	1	Body weight (lb)	visit2200							0.50647	0.465121		

Body weight 26 weeks after randomisation - statistical analysis - on-treatment - safety analysis set

The Mixed procedure
Model Information

Parameter Code=C25208X Parameter=Body weight (kg)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Data Set	WORK.IMPUTE
2	1	NN1218-4131	Dependent Variable	eotVisit
3	1	NN1218-4131	Covariance Structure	Diagonal
4	1	NN1218-4131	Estimation Method	REML
5	1	NN1218-4131	Residual Variance Method	Profile
6	1	NN1218-4131	Fixed Effects SE Method	Model-Based
7	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=WEIGHTU Parameter=Body weight (lb)

Obs	_Imputation_	STUDYID	Descr	Value
8	1	NN1218-4131	Data Set	WORK.IMPUTE
9	1	NN1218-4131	Dependent Variable	eotVisit
10	1	NN1218-4131	Covariance Structure	Diagonal
11	1	NN1218-4131	Estimation Method	REML
12	1	NN1218-4131	Residual Variance Method	Profile
13	1	NN1218-4131	Fixed Effects SE Method	Model-Based
14	1	NN1218-4131	Degrees of Freedom Method	Residual

Body weight 26 weeks after randomisation - statistical analysis - on-treatment - safety analysis set

The Mixed procedure
Class Level Information

Parameter Code=C25208X Parameter=Body weight (kg)

		Input		S		C		L		V		Output	
		O		o		Y		I		a		l	
		b		n		D		s		u		e	
		s		—						s		h	
1	1	NN1218-4131	TRTPN					3	2	3	4		5
2	1	NN1218-4131	REGION1					4	ASIA (EXCLUDING JAPAN)	EUROPE	JAPAN	NORTH AMERICA	49
3	1	NN1218-4131	BOLAD1					2	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	CARBOHYDRATE COUNTING (FLEXIBLE)	BOLUS	INSULI	85

Body weight 26 weeks after randomisation - statistical analysis - on-treatment - safety analysis set

The Mixed procedure
Class Level Information

Parameter Code=WEIGHTU Parameter=Body weight (lb)

Ob- s	—	Input on ID	STUDY ID	Class s	Le- vel s	Val- ues	mi- n le- gt h
4	1	NN1218-4131	TRTPN		3 2 3 4		5
5	1	NN1218-4131	REGION1		4 ASIA (EXCLUDING JAPAN) EUROPE JAPAN NORTH AMERICA		49
6	1	NN1218-4131	BOLAD1		2 BOLUS INSULIN ALGORITHM (SLIDING SCALE) CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULI		85

Body weight 26 weeks after randomisation - statistical analysis - on-treatment - safety analysis set

The Mixed procedure
Dimensions

Parameter Code=C25208X Parameter=Body weight (kg)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Covariance Parameters	1
2	1	NN1218-4131	Columns in X	10
3	1	NN1218-4131	Columns in Z	0
4	1	NN1218-4131	Subjects	1
5	1	NN1218-4131	Max Obs per Subject	1025

Parameter Code=WEIGHTU Parameter=Body weight (lb)

Obs	_Imputation_	STUDYID	Descr	Value
6	1	NN1218-4131	Covariance Parameters	1
7	1	NN1218-4131	Columns in X	10
8	1	NN1218-4131	Columns in Z	0
9	1	NN1218-4131	Subjects	1
10	1	NN1218-4131	Max Obs per Subject	1025

Body weight 26 weeks after randomisation - statistical analysis - on-treatment - safety analysis set

The Mixed procedure
Number of Observations

Parameter Code=C25208X Parameter=Body weight (kg)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
1	1	NN1218-4131	Number of Observations Read	1025	1025	1025	1025	1025
2	1	NN1218-4131	Number of Observations Used	1025	1025	1025	1025	1025
3	1	NN1218-4131	Number of Observations Not Used	0	1025	1025	1025	1025

Parameter Code=WEIGHTU Parameter=Body weight (lb)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
4	1	NN1218-4131	Number of Observations Read	1025	1025	1025	1025	1025
5	1	NN1218-4131	Number of Observations Used	1025	1025	1025	1025	1025
6	1	NN1218-4131	Number of Observations Not Used	0	1025	1025	1025	1025

Body weight 26 weeks after randomisation - statistical analysis - on-treatment - safety analysis set

The Mixed procedure
Covariance Parameter Estimates

Parameter Code=C25208X Parameter=Body weight (kg)

Obs	_Imputation_	STUDYID	CovParm	Estimate
1	1	NN1218-4131	Residual	7.3583

Parameter Code=WEIGHTU Parameter=Body weight (lb)

Obs	_Imputation_	STUDYID	CovParm	Estimate
20001	1	NN1218-4131	Residual	35.7638

Body weight 26 weeks after randomisation - statistical analysis - on-treatment - safety analysis set

The Mixed procedure
Fit Statistics

Parameter Code=C25208X Parameter=Body weight (kg)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	-2 Res Log Likelihood	4966.0
2	1	NN1218-4131	AIC (Smaller is Better)	4968.0
3	1	NN1218-4131	AICC (Smaller is Better)	4968.0
4	1	NN1218-4131	BIC (Smaller is Better)	4972.9

Parameter Code=WEIGHTU Parameter=Body weight (lb)

Obs	_Imputation_	STUDYID	Descr	Value
5	1	NN1218-4131	-2 Res Log Likelihood	6575.5
6	1	NN1218-4131	AIC (Smaller is Better)	6577.5
7	1	NN1218-4131	AICC (Smaller is Better)	6577.5
8	1	NN1218-4131	BIC (Smaller is Better)	6582.5

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Body weight 26 weeks after randomisation - statistical analysis - on-treatment - safety analysis set

The Mixed procedure
Solution for Fixed Effects

Parameter Code=C25208X Parameter=Body weight (kg)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
1	1	NN1218-4131	TRTPN	2				
2	1	NN1218-4131	TRTPN	3				
3	1	NN1218-4131	TRTPN	4				
4	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
5	1	NN1218-4131	REGION1	—	EUROPE			
6	1	NN1218-4131	REGION1	—	JAPAN			
7	1	NN1218-4131	REGION1	—	NORTH AMERICA			
8	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
9	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
10	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	-0.7547	0.5274	1017	-1.43	0.1527	0.05	-1.7896	0.2802
2	-1.0416	0.5295	1017	-1.97	0.0494	0.05	-2.0807	-0.00259
3	-0.9255	0.5315	1017	-1.74	0.0819	0.05	-1.9685	0.1175
4	0.09422	0.3386	1017	0.28	0.7809	0.05	-0.5702	0.7587
5	-0.3521	0.2239	1017	-1.57	0.1161	0.05	-0.7913	0.08724
6	0.1159	0.2720	1017	0.43	0.6702	0.05	-0.4178	0.6496
7	0
8	0.4553	0.1901	1017	2.40	0.0168	0.05	0.08233	0.8283
9	0
10	0.02767	0.005902	1017	4.69	<.0001	0.05	0.01609	0.03926

nn1218/nn1218-4131/ctr_20180214_er
09FEB2018:20:29:30 - a_lab_stat_diff.sas/a_bw_stat_on_sas_app.txt

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Body weight 26 weeks after randomisation - statistical analysis - on-treatment - safety analysis set

The Mixed procedure
Solution for Fixed Effects

Parameter Code=WEIGHTU Parameter=Body weight (lb)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
11	1	NN1218-4131	TRTPN	2				
12	1	NN1218-4131	TRTPN	3				
13	1	NN1218-4131	TRTPN	4				
14	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
15	1	NN1218-4131	REGION1	—	EUROPE			
16	1	NN1218-4131	REGION1	—	JAPAN			
17	1	NN1218-4131	REGION1	—	NORTH AMERICA			
18	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
19	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
20	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
11	-1.6639	1.1627	1017	-1.43	0.1527	0.05	-3.9455	0.6177
12	-2.2964	1.1674	1017	-1.97	0.0494	0.05	-4.5871	-0.00571
13	-2.0403	1.1718	1017	-1.74	0.0819	0.05	-4.3398	0.2591
14	0.2077	0.7465	1017	0.28	0.7809	0.05	-1.2572	1.6726
15	-0.7762	0.4935	1017	-1.57	0.1161	0.05	-1.7446	0.1923
16	0.2554	0.5996	1017	0.43	0.6702	0.05	-0.9212	1.4321
17	0
18	1.0038	0.4191	1017	2.40	0.0168	0.05	0.1815	1.8261
19	0
20	0.02767	0.005902	1017	4.69	<.0001	0.05	0.01609	0.03926

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Fast-acting insulin aspart
NN1218-4131

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Body weight 26 weeks after randomisation - statistical analysis - on-treatment - safety analysis set

The Mixed procedure
Least Squares Means

Obs	_Imputation_	PARAMCD	PARAM	STUDYID	Effect	TRTPN	Margins
1	1	C25208X	Body weight (kg)	NN1218-4131	TRTPN	2	WORK.IMPUTE
2	1	C25208X	Body weight (kg)	NN1218-4131	TRTPN	3	WORK.IMPUTE
3	1	C25208X	Body weight (kg)	NN1218-4131	TRTPN	4	WORK.IMPUTE
4	1	WEIGHTU	Body weight (lb)	NN1218-4131	TRTPN	2	WORK.IMPUTE
5	1	WEIGHTU	Body weight (lb)	NN1218-4131	TRTPN	3	WORK.IMPUTE
6	1	WEIGHTU	Body weight (lb)	NN1218-4131	TRTPN	4	WORK.IMPUTE

Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	1.4270	0.1469	1017	9.72	<.0001	0.05	1.1388	1.7153
2	1.1401	0.1471	1017	7.75	<.0001	0.05	0.8516	1.4287
3	1.2563	0.1468	1017	8.56	<.0001	0.05	0.9681	1.5444
4	3.1461	0.3238	1017	9.72	<.0001	0.05	2.5107	3.7815
5	2.5136	0.3242	1017	7.75	<.0001	0.05	1.8774	3.1497
6	2.7696	0.3237	1017	8.56	<.0001	0.05	2.1344	3.4048

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Body weight 26 weeks after randomisation - statistical analysis - on-treatment - safety analysis set

The Mixed procedure
Least Squares Means Estimate

Parameter Code=C25208X Parameter=Body weight (kg)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
1	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
2	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	WORK.IMPUTE	0.1708	0.2078	1017	0.82	0.4115	0.05	-0.2371	0.5786
2	WORK.IMPUTE	-0.1161	0.2079	1017	-0.56	0.5765	0.05	-0.5241	0.2918

Parameter Code=WEIGHTU Parameter=Body weight (lb)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
3	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
4	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
3	WORK.IMPUTE	0.3765	0.4582	1017	0.82	0.4115	0.05	-0.5226	1.2756
4	WORK.IMPUTE	-0.2561	0.4583	1017	-0.56	0.5765	0.05	-1.1554	0.6433

Body weight 26 weeks after randomisation - statistical analysis - on-treatment - safety analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=C25208X Parameter=Body weight (kg) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000213	0.021618	0.021831	2.1E8	0.009844	0.009748	1.000000

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	1.433861	0.147753	1.144271	1.723452	2.1E8	1.377144	1.491344

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	9.70	<.0001

Body weight 26 weeks after randomisation - statistical analysis - on-treatment - safety analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=WEIGHTU Parameter=Body weight (lb) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.001034	0.105072	0.106106	2.1E8	0.009844	0.009748	1.000000

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	3.161123	0.325740	2.522685	3.799561	2.1E8	3.036083	3.287851

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	9.70	<.0001

Body weight 26 weeks after randomisation - statistical analysis - on-treatment - safety analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=C25208X Parameter=Body weight (kg) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000345	0.021668	0.022013	8.15E7	0.015917	0.015668	0.999999

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	1.160345	0.148369	0.869547	1.451143	8.15E7	1.084641	1.235671

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	7.82	<.0001

Body weight 26 weeks after randomisation - statistical analysis - on-treatment - safety analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=WEIGHTU Parameter=Body weight (lb) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.001676	0.105317	0.106993	8.15E7	0.015917	0.015668	0.999999

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	2.558123	0.327098	1.917023	3.199224	8.15E7	2.391225	2.724187

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	7.82	<.0001

Body weight 26 weeks after randomisation - statistical analysis - on-treatment - safety analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=C25208X Parameter=Body weight (kg) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000434	0.021604	0.022038	5.16E7	0.020076	0.019681	0.999999

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	1.243653	0.148451	0.952695	1.534611	5.16E7	1.159334	1.325970

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	8.38	<.0001

Body weight 26 weeks after randomisation - statistical analysis - on-treatment - safety analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=WEIGHTU Parameter=Body weight (lb) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.002108	0.105003	0.107111	5.16E7	0.020076	0.019681	0.999999

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	2.741786	0.327278	2.100334	3.383239	5.16E7	2.555895	2.923264

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	8.38	<.0001

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Body weight 26 weeks after randomisation - statistical analysis - on-treatment - safety analysis set

Parameter Code=C25208X Label=Faster aspart (meal) - NovoRapid (meal) Parameter=Body weight (kg) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000639	0.043280	0.043919	9.46E7	0.014756	0.014542	0.999999

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.190208	0.209568	-0.22054	0.600953	9.46E7	0.088662	0.287095

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	0.91	0.3641

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Body weight 26 weeks after randomisation - statistical analysis - on-treatment - safety analysis set

Parameter Code=C25208X Label=Faster aspart (post) - NovoRapid (meal) Parameter=Body weight (kg) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000776	0.043304	0.044081	6.45E7	0.017931	0.017615	0.999999

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.083308	0.209954	-0.49481	0.328194	6.45E7	-0.205551	0.027195

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-0.40	0.6915

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Body weight 26 weeks after randomisation - statistical analysis - on-treatment - safety analysis set

Parameter Code=WEIGHTU Label=Faster aspart (meal) - NovoRapid (meal) Parameter=Body weight (lb) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.003104	0.210356	0.213460	9.46E7	0.014756	0.014542	0.999999

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.419337	0.462018	-0.48620	1.324875	9.46E7	0.195467	0.632936

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	0.91	0.3641

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Body weight 26 weeks after randomisation - statistical analysis - on-treatment - safety analysis set

Parameter Code=WEIGHTU Label=Faster aspart (post) - NovoRapid (meal) Parameter=Body weight (lb) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_ESTIMATE
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.003774	0.210474	0.214248	6.45E7	0.017931	0.017615	0.999999

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.183663	0.462869	-1.09087	0.723543	6.45E7	-0.453163	0.059955

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-0.40	0.6915

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Body weight 26 weeks after randomisation - statistical analysis - on-treatment - safety analysis set

The Mixed procedure
Model Information

Parameter Code=C25208X Parameter=Body weight (kg)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Data Set	WORK.IMPUTE_ABS
2	1	NN1218-4131	Dependent Variable	eotVisitAbs
3	1	NN1218-4131	Covariance Structure	Diagonal
4	1	NN1218-4131	Estimation Method	REML
5	1	NN1218-4131	Residual Variance Method	Profile
6	1	NN1218-4131	Fixed Effects SE Method	Model-Based
7	1	NN1218-4131	Degrees of Freedom Method	Residual

Parameter Code=WEIGHTU Parameter=Body weight (lb)

Obs	_Imputation_	STUDYID	Descr	Value
8	1	NN1218-4131	Data Set	WORK.IMPUTE_ABS
9	1	NN1218-4131	Dependent Variable	eotVisitAbs
10	1	NN1218-4131	Covariance Structure	Diagonal
11	1	NN1218-4131	Estimation Method	REML
12	1	NN1218-4131	Residual Variance Method	Profile
13	1	NN1218-4131	Fixed Effects SE Method	Model-Based
14	1	NN1218-4131	Degrees of Freedom Method	Residual

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Body weight 26 weeks after randomisation - statistical analysis - on-treatment - safety analysis set

The Mixed procedure
Class Level Information

Parameter Code=C25208X Parameter=Body weight (kg)

		Input		S		C		L		V		Output	
		O		o		Y		I		u		e	
		b		n		I		s		e		t	
		s		—		D		s		s		h	
1	1	NN1218-4131	TRTPN					3	2	3	4		5
2	1	NN1218-4131	REGION1					4	ASIA (EXCLUDING JAPAN)	EUROPE	JAPAN	NORTH AMERICA	49
3	1	NN1218-4131	BOLAD1					2	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	CARBOHYDRATE COUNTING (FLEXIBLE)	BOLUS INSULI	85	

Body weight 26 weeks after randomisation - statistical analysis - on-treatment - safety analysis set

The Mixed procedure
Class Level Information

Parameter Code=WEIGHTU Parameter=Body weight (lb)

		Input		S		T		U		D		Y		I		D		C		l		a		s		s		L		e		v		V		a		l		u		e		s				m		i		n				l		e		g		t		h	
O	b	s	—	4	1	NN1218-4131	TRTPN	3	2	3	4	5	1	NN1218-4131	REGION1	4	ASIA (EXCLUDING JAPAN)	EUROPE	JAPAN	NORTH AMERICA	49	6	1	NN1218-4131	BOLAD1	2	BOLUS INSULIN ALGORITHM (SLIDING SCALE)	CARBOHYDRATE COUNTING (FLEXIBLE)	BOLUS	INSULI	85																																		

Body weight 26 weeks after randomisation - statistical analysis - on-treatment - safety analysis set

The Mixed procedure
Dimensions

Parameter Code=C25208X Parameter=Body weight (kg)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	Covariance Parameters	1
2	1	NN1218-4131	Columns in X	10
3	1	NN1218-4131	Columns in Z	0
4	1	NN1218-4131	Subjects	1
5	1	NN1218-4131	Max Obs per Subject	1025

Parameter Code=WEIGHTU Parameter=Body weight (lb)

Obs	_Imputation_	STUDYID	Descr	Value
6	1	NN1218-4131	Covariance Parameters	1
7	1	NN1218-4131	Columns in X	10
8	1	NN1218-4131	Columns in Z	0
9	1	NN1218-4131	Subjects	1
10	1	NN1218-4131	Max Obs per Subject	1025

Body weight 26 weeks after randomisation - statistical analysis - on-treatment - safety analysis set

The Mixed procedure
Number of Observations

Parameter Code=C25208X Parameter=Body weight (kg)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
1	1	NN1218-4131	Number of Observations Read	1025	1025	1025	1025	1025
2	1	NN1218-4131	Number of Observations Used	1025	1025	1025	1025	1025
3	1	NN1218-4131	Number of Observations Not Used	0	1025	1025	1025	1025

Parameter Code=WEIGHTU Parameter=Body weight (lb)

Obs	_Imputation_	STUDYID	Label	N	NObs Read	NObs Used	Sum Freqs Read	Sum Freqs Used
4	1	NN1218-4131	Number of Observations Read	1025	1025	1025	1025	1025
5	1	NN1218-4131	Number of Observations Used	1025	1025	1025	1025	1025
6	1	NN1218-4131	Number of Observations Not Used	0	1025	1025	1025	1025

Body weight 26 weeks after randomisation - statistical analysis - on-treatment - safety analysis set

The Mixed procedure
Covariance Parameter Estimates

Parameter Code=C25208X Parameter=Body weight (kg)

Obs	_Imputation_	STUDYID	CovParm	Estimate
1	1	NN1218-4131	Residual	7.3583

Parameter Code=WEIGHTU Parameter=Body weight (lb)

Obs	_Imputation_	STUDYID	CovParm	Estimate
20001	1	NN1218-4131	Residual	35.7638

Body weight 26 weeks after randomisation - statistical analysis - on-treatment - safety analysis set

The Mixed procedure
Fit Statistics

Parameter Code=C25208X Parameter=Body weight (kg)

Obs	_Imputation_	STUDYID	Descr	Value
1	1	NN1218-4131	-2 Res Log Likelihood	4966.0
2	1	NN1218-4131	AIC (Smaller is Better)	4968.0
3	1	NN1218-4131	AICC (Smaller is Better)	4968.0
4	1	NN1218-4131	BIC (Smaller is Better)	4972.9

Parameter Code=WEIGHTU Parameter=Body weight (lb)

Obs	_Imputation_	STUDYID	Descr	Value
5	1	NN1218-4131	-2 Res Log Likelihood	6575.5
6	1	NN1218-4131	AIC (Smaller is Better)	6577.5
7	1	NN1218-4131	AICC (Smaller is Better)	6577.5
8	1	NN1218-4131	BIC (Smaller is Better)	6582.5

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Body weight 26 weeks after randomisation - statistical analysis - on-treatment - safety analysis set

The Mixed procedure
Solution for Fixed Effects

Parameter Code=C25208X Parameter=Body weight (kg)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
1	1	NN1218-4131	TRTPN	2				
2	1	NN1218-4131	TRTPN	3				
3	1	NN1218-4131	TRTPN	4				
4	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
5	1	NN1218-4131	REGION1	—	EUROPE			
6	1	NN1218-4131	REGION1	—	JAPAN			
7	1	NN1218-4131	REGION1	—	NORTH AMERICA			
8	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
9	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
10	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	-0.7547	0.5274	1017	-1.43	0.1527	0.05	-1.7896	0.2802
2	-1.0416	0.5295	1017	-1.97	0.0494	0.05	-2.0807	-0.00259
3	-0.9255	0.5315	1017	-1.74	0.0819	0.05	-1.9685	0.1175
4	0.09422	0.3386	1017	0.28	0.7809	0.05	-0.5702	0.7587
5	-0.3521	0.2239	1017	-1.57	0.1161	0.05	-0.7913	0.08724
6	0.1159	0.2720	1017	0.43	0.6702	0.05	-0.4178	0.6496
7	0
8	0.4553	0.1901	1017	2.40	0.0168	0.05	0.08233	0.8283
9	0
10	1.0277	0.005902	1017	174.11	<.0001	0.05	1.0161	1.0393

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Body weight 26 weeks after randomisation - statistical analysis - on-treatment - safety analysis set

The Mixed procedure
Solution for Fixed Effects

Parameter Code=WEIGHTU Parameter=Body weight (lb)

Obs	_Imputation_	STUDYID	Effect	TRTPN	REGION1	BOLAD1		
11	1	NN1218-4131	TRTPN	2				
12	1	NN1218-4131	TRTPN	3				
13	1	NN1218-4131	TRTPN	4				
14	1	NN1218-4131	REGION1	—	ASIA (EXCLUDING JAPAN)			
15	1	NN1218-4131	REGION1	—	EUROPE			
16	1	NN1218-4131	REGION1	—	JAPAN			
17	1	NN1218-4131	REGION1	—	NORTH AMERICA			
18	1	NN1218-4131	BOLAD1	—		BOLUS INSULIN ALGORITHM (SLIDING SCALE)		
19	1	NN1218-4131	BOLAD1	—		CARBOHYDRATE COUNTING (FLEXIBLE) BOLUS INSULIN THERAPY		
20	1	NN1218-4131	BASE	—				
Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
11	-1.6639	1.1627	1017	-1.43	0.1527	0.05	-3.9455	0.6177
12	-2.2964	1.1674	1017	-1.97	0.0494	0.05	-4.5871	-0.00571
13	-2.0403	1.1718	1017	-1.74	0.0819	0.05	-4.3398	0.2591
14	0.2077	0.7465	1017	0.28	0.7809	0.05	-1.2572	1.6726
15	-0.7762	0.4935	1017	-1.57	0.1161	0.05	-1.7446	0.1923
16	0.2554	0.5996	1017	0.43	0.6702	0.05	-0.9212	1.4321
17	0
18	1.0038	0.4191	1017	2.40	0.0168	0.05	0.1815	1.8261
19	0
20	1.0277	0.005902	1017	174.11	<.0001	0.05	1.0161	1.0393

nn1218/nn1218-4131/ctr_20180214_er
09FEB2018:20:29:30 - a_lab_stat_diff.sas/a_bw_stat_on_sas_app.txt

Fast-acting insulin aspart
NN1218-4131

Clinical Trial Report
Statistical document

Date:
Version:

14 February 2018
1.0

Status:
Page:

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Novo Nordisk

Body weight 26 weeks after randomisation - statistical analysis - on-treatment - safety analysis set

The Mixed procedure
Least Squares Means

Obs	_Imputation_	PARAMCD	PARAM	STUDYID	Effect	TRTPN	Margins
1	1	C25208X	Body weight (kg)	NN1218-4131	TRTPN	2	WORK.IMPUTE
20001	1	WEIGHTU	Body weight (lb)	NN1218-4131	TRTPN	2	WORK.IMPUTE
40001	1	C25208X	Body weight (kg)	NN1218-4131	TRTPN	3	WORK.IMPUTE
60001	1	WEIGHTU	Body weight (lb)	NN1218-4131	TRTPN	3	WORK.IMPUTE
80001	1	C25208X	Body weight (kg)	NN1218-4131	TRTPN	4	WORK.IMPUTE
100001	1	WEIGHTU	Body weight (lb)	NN1218-4131	TRTPN	4	WORK.IMPUTE

Obs	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	1.4270	0.1469	1017	9.72	<.0001	0.05	1.1388	1.7153
20001	3.1461	0.3238	1017	9.72	<.0001	0.05	2.5107	3.7815
40001	1.1401	0.1471	1017	7.75	<.0001	0.05	0.8516	1.4287
60001	2.5136	0.3242	1017	7.75	<.0001	0.05	1.8774	3.1497
80001	1.2563	0.1468	1017	8.56	<.0001	0.05	0.9681	1.5444
100001	2.7696	0.3237	1017	8.56	<.0001	0.05	2.1344	3.4048

nn1218/nn1218-4131/ctr_20180214_er
09FEB2018:20:29:30 - a_lab_stat_diff.sas/a_bw_stat_on_sas_app.txt

Body weight 26 weeks after randomisation - statistical analysis - on-treatment - safety analysis set

The Mixed procedure
Least Squares Means Estimate

Parameter Code=C25208X Parameter=Body weight (kg)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
1	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
20001	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
1	WORK.IMPUTE	0.1708	0.2078	1017	0.82	0.4115	0.05	-0.2371	0.5786
20001	WORK.IMPUTE	-0.1161	0.2079	1017	-0.56	0.5765	0.05	-0.5241	0.2918

Parameter Code=WEIGHTU Parameter=Body weight (lb)

Obs	_Imputation_	STUDYID	Stmt No	Effect	Label
40001	1	NN1218-4131	1	TRTPN	Faster aspart (meal) - NovoRapid (meal)
60001	1	NN1218-4131	2	TRTPN	Faster aspart (post) - NovoRapid (meal)

Obs	Margins	Estimate	StdErr	DF	tValue	Probt	Alpha	Lower	Upper
40001	WORK.IMPUTE	0.3765	0.4582	1017	0.82	0.4115	0.05	-0.5226	1.2756
60001	WORK.IMPUTE	-0.2561	0.4583	1017	-0.56	0.5765	0.05	-1.1554	0.6433

Body weight 26 weeks after randomisation - statistical analysis - on-treatment - safety analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=C25208X Parameter=Body weight (kg) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000213	0.021618	0.021831	2.1E8	0.009844	0.009748	1.000000

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	73.525650	0.147753	73.23606	73.81524	2.1E8	73.468933	73.583133

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	497.63	<.0001

Body weight 26 weeks after randomisation - statistical analysis - on-treatment - safety analysis set

Planned Treatment for Period 30 (N)=2 Parameter Code=WEIGHTU Parameter=Body weight (lb) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.001034	0.105072	0.106106	2.1E8	0.009844	0.009748	1.000000

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	162.096312	0.325740	161.4579	162.7347	2.1E8	161.971271	162.223039

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	497.63	<.0001

Body weight 26 weeks after randomisation - statistical analysis - on-treatment - safety analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=C25208X Parameter=Body weight (kg) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000345	0.021668	0.022013	8.15E7	0.015917	0.015668	0.999999

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	73.252134	0.148369	72.96134	73.54293	8.15E7	73.176430	73.327459

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	493.72	<.0001

Body weight 26 weeks after randomisation - statistical analysis - on-treatment - safety analysis set

Planned Treatment for Period 30 (N)=3 Parameter Code=WEIGHTU Parameter=Body weight (lb) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.001676	0.105317	0.106993	8.15E7	0.015917	0.015668	0.999999

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	161.493312	0.327098	160.8522	162.1344	8.15E7	161.326413	161.659376

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	493.72	<.0001

Body weight 26 weeks after randomisation - statistical analysis - on-treatment - safety analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=C25208X Parameter=Body weight (kg) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.000434	0.021604	0.022038	5.16E7	0.020076	0.019681	0.999999

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	73.335442	0.148451	73.04448	73.62640	5.16E7	73.251123	73.417759

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	494.01	<.0001

Body weight 26 weeks after randomisation - statistical analysis - on-treatment - safety analysis set

Planned Treatment for Period 30 (N)=4 Parameter Code=WEIGHTU Parameter=Body weight (lb) Study Identifier=NN1218-4131

The MIANALYZE Procedure

Model Information

Data Set	WORK.MI_MEANS_ABS
Number of Imputations	20000

Variance Information

Parameter	-----Variance-----			DF	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
	Between	Within	Total				
Estimate	0.002108	0.105003	0.107111	5.16E7	0.020076	0.019681	0.999999

Parameter Estimates

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	161.676975	0.327278	161.0355	162.3184	5.16E7	161.491083	161.858453

Parameter Estimates

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	494.01	<.0001