Statistical Analysis Plan

Zealand Pharma A/S

ZP4207-21052

A Phase 3, single-administration open-label trial to assess the efficacy, safety, pharmacokinetics, and pharmacodynamics of dasiglucagon when administered as a rescue therapy for severe hypoglycemia in pediatric patients below 6 years of age with Type 1 Diabetes (T1D)

Protocol Version: Final 6.0, 12 Jul 2024

Sponsor: Zealand Pharma A/S
CVR No. DK 2004
5078 Sydmarken 11
DK-2860 Søborg
Denmark

Prepared by: [redacted] Syneos Health
Albrechtstr.14, 80636 Munich, Germany

Version	Date
V0.1	24 JUN 2022
V0.2	08 JUL 2022
V0.3	30 AUG 2022
V1.0	31 AUG 2022
V1.1	28 APR 2023
V1.2	09AUG2023
V1.3	18AUG2023
V1.4	22AUG2023
V.2.0	25AUG2023
V.2.1	12SEP2024
V.2.2	17DEC2024
V.3.0	02JAN2025 Final

Approval

Upon review of this document, including the table, listing, and figure shells, the undersigned approves the statistical analysis plan. The analysis methods and data presentation are acceptable.

Signature	Date
[redacted] Syneos Health	
[redacted] MSc, Principal Statistician, [redacted] Zealand Pharma A/S	
[redacted] MD, [redacted] Zealand Pharma A/S	
[redacted] Zealand Pharma A/S	

Revision History

Version	Change
Version 2.0	Statistical Analysis Plan updated to Protocol, version 4.0, 09 Mar 2023.
Version 3.0	Statistical Analysis Plan updated to Protocol, version 6.0, 12 Jul 2024. Update of some shells based on dry-run comments. Addition of plots for plasma Glucose concentrations. Addition of a sensitivity analysis using the nominal pre-dose time point as baseline.

TABLE OF CONTENTS

LIST OF ABBREVIATIONS AND DEFINITIONS OF TERMS

Abbreviation	Definition
ADA	anti-drug antibody
AE	adverse event
AESI	adverse event of special interest
ATC	anatomical therapeutic chemical
BMI	body mass index
CI	confidence interval
CSR	clinical study report
CGM	continuous glucose monitoring
CV	coefficient of variation
ECG	electrocardiogram
eCRF	electronic case report form
FAS	full analysis set
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
IMP	investigational medicinal product
IV	intravenous
BLOQ	below the limit of quantification
MDI	multiple daily injections
MedDRA	Medical Dictionary for Regulatory Activities
PAS	PK analysis set
PD	pharmacodynamic(s)
PK	pharmacokinetic(s)
PT	preferred term
QTc	corrected QT interval
QTcF	corrected QT interval according to Fridericia's formula
SAE	serious adverse event
SAF	safety analysis set
SAP	statistical analysis plan
SC	subcutaneous
SD	standard deviation
SOC	system organ class
TEAE	treatment-emergent adverse event
TLFs	tables, listings, and figures
WHO	World Health Organization

1. INTRODUCTION

This document outlines the statistical methods to be implemented during the analyses of data collected within the scope of Study ZP4207-21052, entitled "A Phase 3, single-administration open-label trial to assess the efficacy, safety, pharmacokinetics, and pharmacodynamics of dasiglucagon when administered as a rescue therapy for severe hypoglycemia in pediatric patients below 6 years of age with Type 1 Diabetes (T1D)". The purpose of this SAP is to provide specific guidelines for the statistical analyses. Any deviations from this plan will be documented in the CSR.

2. STUDY DOCUMENTS

The following study documents are used for the preparation of the SAP:

- Protocol, version 6.0, 12 Jul 2024
- Annotated electronic case report form (eCRF), version 6, 14Aug 2024
- Data management plan, version 3, 22 May 2024

3. STUDY OBJECTIVES

The primary study objective is:

- To assess the efficacy of dasiglucagon injection in children < 6 years of age with T1D

Other study objectives are as follows:

- To assess PK of dasiglucagon in children with T1D
- To assess the safety profile of dasiglucagon in children with T1D

4. STUDY DESIGN AND PLAN

This trial will use a single-administration, open-label trial design to assess the ability of a single SC injection of dasiglucagon to increase plasma glucose in pediatric children with T1D with hypoglycemia. A total of 8 children will be included; 4 children receiving a dose of 0.3 mg and 4 children receiving a dose of 0.6 mg. Of the 4 children receiving 0.3 mg, at least 2 children must be below 2 years at screening. The remaining 2 children aged 2 years or above receiving 0.3 mg should preferably be below 4 years at screening. For children receiving the 0.6 mg dose, all must be above 2 years at screening. Before an eligible child is dosed, the dose level (0.6 mg or 0.3 mg) must be confirmed by the sponsor. Each child will be dosed after the safety assessment of the preceding child has been completed and assessed by the Trial Safety Group.

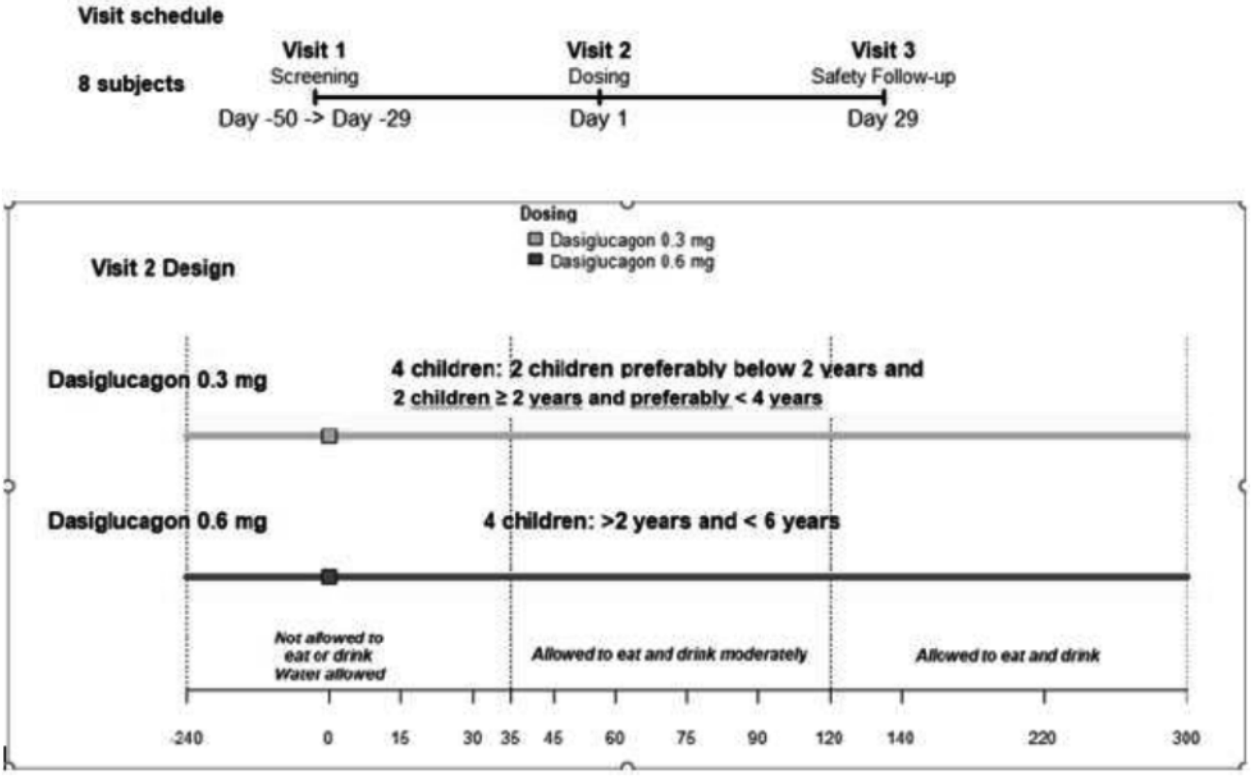
The trial will include the following visits (as illustrated in Figure 4-1).

- A screening visit (Visit 1, pre-treatment visit) in the period from Day -50 to Day -29
- A dosing visit (Visit 2), Day 1 (day of single dosing with IMP)
- A Safety follow-up visit (Visit 3) at Day 29 +5 days (the end-of-trial visit)

The primary endpoint of the trial is plasma glucose change from baseline at 30 minutes after IMP injection or at the time of rescue by IV glucose. Pharmacodynamics (PD) i.e., plasma glucose

will be assessed at baseline and 15 and 30 minutes after dosing, while the glucose levels will be monitored by CGM and by a plasma glucose analyzer during the dosing visit (Visit 2). PK will be assessed throughout a 300-minute period at the dosing visit (Visit 2). Safety will be assessed prior to dosing and throughout a 300-minute period after dosing and again at the follow-up visit. All data must be logged in the electronic case report form (eCRF).

Figure 4-1 Trial Design, taken from study protocol.



The schedule of assessments and trial procedures is available in the protocol.

The end of the trial is defined as the date of the last visit of the last patient in the trial. A patient is considered to have completed the trial if he/she has completed all phases of the trial including the last follow-up visit (Visit 3).

5. DETERMINATION OF SAMPLE SIZE

Eight children will be treated in this trial. The number of children is not based on a formal sample size calculation, evaluating the power of the trial, however some considerations have been made with respect to the precision of the estimate of the primary endpoint. In a previous pediatric trial with dasiglucagon (Trial ZP4207-17086), the mean plasma glucose change from baseline at 30 minutes after IMP injection was 96 mg/dL with a standard deviation (SD) of 20 mg/dL in children aged 6 to 11 years. Assuming the variation is the same in children < 6 years

of age, a 95% confidence interval will have a width of ± 25 mg/dL around the mean plasma glucose change with 95% probability, when 8 children are treated.

The power procedure in SAS with the onesamplemeans statement have been applied for the sample size consideration.

6. GENERAL ANALYSIS CONSIDERATIONS

The statistical analyses will be reported using TLFs. The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) numbering convention will be used for all TLFs.

Continuous variables will be summarized by presenting the number of observations, means, SDs, medians, minimums, and maximums. In addition, 95% confidence intervals (based on a *t* distribution if not otherwise stated) will be calculated if appropriate and detailed in the table shells. For logarithm-transformed data (relevant for selected PK summaries), the geometric mean and coefficient of variation % will also be provided.

Categorical variables will be summarized by presenting counts and percentages of subjects in corresponding categories. All possible categories as defined in the CRF should be populated, even if they have zero counts. Percentages for missing values are omitted and do not account for the percent calculation of other categories. Percentages are based on the total category count excluding the missing category if not otherwise mentioned. In certain tables (eg, AEs), the total number of subjects is used as the denominator. Footnotes will specify the percent basis in those cases.

All data collected in this trial and documented in the eCRFs will be presented in data listings. In case of termination of the trial, all data collected up to that time point will be included in the analysis.

All summary tables will be presented for the two treatment groups and total.

Individual subject data obtained from the eCRFs, external vendors, central clinical laboratory, central ECG laboratory, PK data, and any derived data will be presented by subject in data listings.

The analyses described in this plan are considered a priori, in that they have been defined before first patient dosed in the study. Any analyses performed after first patient dosed will be considered post hoc and exploratory. Post hoc analyses will be labeled as such on the output and identified in the CSR.

All analyses and tabulations will be performed using SAS® statistical software, version 9.4 or higher (SAS Institute Inc., Cary, North Carolina, USA). PK and PD analyses will be performed using Phoenix® WinNonlin®, version 8.3.4 or higher (Certara USA, Inc., Princeton, New Jersey, USA). This software was validated by Syneos Health in compliance with US 21 CFR Part 11 Regulation.

All statistical analysis will be performed as per Syneos SOPs.

7. NOTATION OF TREATMENT GROUPS AND VISITS

Notation of Treatment Groups

The following notation of treatment groups will be used throughout the report:

Full notation (as used in the study protocol)	Notation used throughout all tables, listings, and figures
dasiglucagon, 0.6 mg/0.6 mL SC injection	dasiglucagon 0.6mg
dasiglucagon, 0.3 mg/0.3mL SC injection	dasiglucagon 0.3mg

Visit Terminology

Visit	Notation used throughout all tables, listings, and figures
Screening VISIT 1	Screening
Visit 2 (DOSING)	Dosing
Visit 3 (FOLLOW-UP)	Follow-up

Study Days

Study days corresponding to measurements are calculated as:

- Assessment date – date of exposure to treatment + 1 (if assessment date is on or after the date of exposure to treatment).
- Assessment date – date of exposure to treatment (if assessment date is before the date of exposure to treatment).

8. ANALYSIS SETS

For the purposes of analysis, the following analysis sets are defined:

- Safety analysis set (SAF): All patients who were enrolled and received at least 1 dose of IMP.
- Full analysis set (FAS): All patients of the SAF.
- PK analysis set (PAS): All patients with at least one quantifiable plasma concentration.

Note: "Enrolled" requires parent's/legal guardian's agreement for the child to participate in a clinical trial following completion of the informed consent process and further that the child is screened and found eligible for the trial.

"Screened" requires a patient completed the informed consent process, regardless of whether the patient is eligible or not.

Data from these patients will be listed.

9. STUDY POPULATION

9.1 Patient Disposition

Patient disposition information will be summarized for all patients. Summaries will include the number of patients screened, enrolled, in each analysis set, completing/discontinuing the study and the primary reason for discontinuation.

9.2 Protocol Deviations

Protocol deviations are collected according to the protocol deviation management plan. Major protocol deviations that could potentially affect the efficacy or safety conclusions of the study will be identified before database lock.

The final determination of major protocol deviations will be made during the data review meeting.

All protocol deviations, including the deviation designation (major or minor), and category will be presented in a data listing. Tables will be created for the SAF for all protocol deviations, summarized by the number of subjects in each deviation designation (major or minor) and category.

Due to the COVID-19 pandemic, the following additional analyses will be necessary. If a protocol deviation occurs, it will be documented if there is a relation to the COVID-19 pandemic. These COVID-19-related protocol deviations will be separately presented in tables as described above. In addition, the COVID-19-related protocol deviations will be listed.

9.3 Eligibility

A listing of subjects not fulfilling at least one eligibility criteria will be created.

9.4 Demographic and Baseline Characteristics

Demographic variables include age on consent date, sex, ethnicity, and race.

Other baseline characteristics include height, weight and BMI.

Descriptive statistics will be presented for age, age group (< 2 years, 2 to < 4years, 4 to < 6 years), height, weight, weight group (<15kg, >= 15kg) and BMI. Frequency counts and percentages will be presented for sex, ethnicity and race. Demographic and baseline characteristics will be summarized for the SAF.

Time since diagnosis of diabetes (date of informed consent – date of diabetes diagnosis + 1) in months will also be included in this summary, using descriptive statistics. If the day of diabetes diagnosis is not available, the calculation of duration will be based on month and year only, imputing the start day to 1. In case only the year is available, the start day will be imputed to be 1 and the start month will be imputed to be January.

A demographic and baseline characteristics listing will also be provided for the SAF.

9.5 Medical History

The verbatim term of the medical history condition/event will be coded using the Medical Dictionary for Regulatory Activities (MedDRA), version 24.1.

A summary table will be prepared, summarizing the counts for each SOC and PT, ordered by descending order of incidence of SOC and PT.

A listing will be provided for the SAF.

9.6 Prior and Concomitant Medications and Current Diabetes Treatment

Prior and concomitant medication and current diabetes treatment verbatim terms in the eCRFs will be mapped to the WHO Anatomical Therapeutic Chemical (ATC) classification and preferred names using the WHODrug dictionary, Global B3 format, Sep.1.2021 release.

The distinction between prior and concomitant medications is as follows:

- Prior medication are all medications which stopped before the first IMP administration during the study, regardless of start date.
- Concomitant medication is all medication that started prior to the first IMP administration and is still ongoing or stopped at the date of first study drug intake - or medication that started on or after the date of the first IMP administration.
- If the start or stop date is incomplete and the allocation to prior or concomitant is unclear, the medication will be considered concomitant.

Partial dates will be imputed. For details on imputation rules, refer to Appendix A: Presentation of Data and Programming Specifications. Imputed dates are only used for classification of a medication as a prior or concomitant medication; no other calculation, such as durations, will be done.

Prior and concomitant medications and current diabetes treatment will be summarized by WHO ATC class (level 2) and preferred name. These summaries will present the number and percentage of patients using each medication. Patients may have more than 1 medication per ATC class and preferred name. At each level of patient summarization, a patient is counted once if they reported 1 or more medications at that level. Each summary will be ordered by descending order of incidence of ATC class and preferred name.

A listing will be created, listing all prior and concomitant medications as documented on the eCRF. A flag will be included in this listing, identifying which medications are prior and which are concomitant. An additional listing will be produced, listing all data collected on current diabetes treatment, as documented on the eCRF.

10. EFFICACY ANALYSES

The primary efficacy analysis will be based on the FAS.

10.1 Efficacy Variables

The primary efficacy variable is:

- Plasma glucose concentration change from baseline at 30 minutes after IMP injection or at the time of rescue by IV glucose, if before 30 minutes.

The secondary efficacy variable is:

- Plasma glucose concentration change from baseline at 15 minutes after IMP injection or at the time of rescue by IV glucose, if before 15 minutes.

10.2 Baseline Values

Unless otherwise noted, baseline is defined as the last non-missing value recorded prior to the first dose of study drug. Unscheduled visits will be used in the determination of baseline values, when applicable.

10.3 Adjustments for Covariates

No adjustments for covariates will be made.

10.4 Handling of Dropouts or Missing Data

No imputations will be made for missing values. Summaries will be based on observed data only. For handling of PK concentrations and results BLOQ, please refer to section 0

10.5 Interim Analysis and Data Monitoring

No interim analysis is planned for this study.

Data monitoring will be completed by the Trial Safety Group. New patients will only be dosed after safety assessment of the dosing visit for the preceding patient is completed and assessed by the Trial Safety Group. Thus, except for the first patient being dosed in the trial, investigators need written permission (eg, via an email) from the TSG chair to dose a patient in the trial.

More information on the TSG is available in the protocol.

10.6 Examination of Subgroups

No subgroup analysis is planned for this study.

10.7 Multiple Comparison/Multiplicity

No adjustments for multiplicity will be made in this study.

10.8 Multicenter Studies

This is a multicenter study with 8 subjects to be treated.

The expected low number of subjects per centers does not allow to do subgroup analysis within each site or to stratify by center.

11. METHODS OF EFFICACY ANALYSIS

11.1 Primary Efficacy Analyses

The primary efficacy endpoint, plasma glucose change from baseline at 30 minutes after trial product injection or at the time of rescue by IV glucose if before 30 minutes, will be summarized using descriptive statistics and 95% confidence intervals (based on a *t* distribution).

11.2 Secondary Efficacy Analyses

The secondary efficacy endpoint, plasma glucose change from baseline at 15 minutes after IMP injection or at the time of rescue by IV glucose if before 15 minutes, will be summarized using descriptive statistics.

11.3 Further Efficacy Analyses

Untransformed and change from baseline plasma glucose at all timepoints , will be summarized using descriptive statistics.

A plot of mean glucose concentrations (untransformed) versus each time point will be provide and presented with error bars representing the Standard error of means (SEM).

A overlay plot of individual glucose concentrations (untransformed) versus each time point will be created.

A sensitivity analysis will be performed using the nominal pre-dose time point as baseline instead of the last valid measurement prior dosing.

12. PPHARMACOKINETIC ANALYSES

The pharmacokinetic analysis will be based on the PAS set.

12.1 Pharmacokinetic Variables

The following PK parameters for the dasiglucagon plasma concentrations will be estimated by non-compartmental analysis (NCA):

PK parameter abbreviation	PK parameter	Calculation
$AUC_{0\text{-}30min}$	Area under the plasma concentration versus time curve (AUC) from 0 to 30 minutes post-dose	Linear trapezoidal rule for the ascending part of the concentration-time curve, logarithmic trapezoidal rule for the descending part.

PK parameter abbreviation	PK parameter	Calculation
$AUC_{0\text{-}300min}$	AUC from 0 to 300 minutes post-dose	Linear trapezoidal rule for the ascending part of the concentration-time curve, logarithmic trapezoidal rule for the descending part.
AUC0-t	AUC from 0 to the last time point with a measured concentration	Linear trapezoidal rule for the ascending part of the concentration-time curve, logarithmic trapezoidal rule for the descending part.
$AUC_{0\text{-}inf}$	AUC from 0 to infinity post-dose	(AUClast + $Clast_{obs}$)/ λ_z, where $Clast_{obs}$ is the concentration corresponding to Tlast (time of last measurable (positive) concentration).
C_{max}	Maximum observed concentration	Taken directly from analytical data, selected from individual concentration data. The time when the first occurrence of Cmax is taken as Tmax.
T_{max}	Time to C_{max}	Taken directly from analytical data, selected from individual concentration data
λz	Terminal elimination rate constant of plasma dasiglucagon	Calculated by linear regression of the terminal linear portion of the log concentration vs. time curve. At least 3 concentrations in the terminal elimination phase will be required to calculate λz.
$t_{½}$	Terminal plasma elimination half-life of dasiglucagon	Ln(2)/ λ_z
CL/f	Total body clearance of plasma dasiglucagon	Dose/ $AUC_{0\text{-}inf}$
Vz/f	Volume of distribution of plasma dasiglucagon	Dose/ (λ_z * $AUC_{0\text{-}inf}$) or CL/f/ λ_z
MRT	Mean residence time of plasma dasiglucagon	AUMCinf/ $AUC_{0\text{-}inf}$ where AUMCinf is the area under the first moment curve as estimated by WinNonlin.

12.2 Data Handling

Refer to **Table 12-1** for details on which PD and PK samples to be collected based on body weight at Visit 1 and Visit 2.

Table 12-1 PD (for efficacy) and PK Sampling Based on Body Weight

Body weight at Visit 2	Visit 2	
	PD samples to draw	**PK samples to draw**
BW> 10.0 kg	pre-dose 15 min 30 min	pre-dose 10 min 20 min 30 min 40 min 60 min 90 min 140 min 220 min 300 min
10.0 ≥ BW > 9.0 kg	pre-dose 15 min 30 min	pre-dose 10 min 20 min 30 min 40 min 60 min 90 min 140 min 300 min
9.0 ≥ BW > 8.0 kg	pre-dose 30 min	pre-dose 10 min 20 min 30 min 40 min 60 min 90 min 140 min 300 min

Abbreviations: BW=body weight; PD=pharmacodynamics; PK=pharmacokinetics

The raw plasma concentration data will be handled as follows:

For summary tables and figures for plasma concentrations:

i.) For all pre-dose samples, the sampling time will be set to zero.

ii.) For post-dose samples, the planned sampling time will be used in summary tables, and the actual sampling times will be used for all figures of individual concentrations.

iii.) All concentration values below the Limit of Quantification (BLOQ) will be set to zero.

iv.) Missing post-dose values will not be replaced.

For determination of PK metrics:

i.) For all pre-dose samples, the sampling time will be set to zero.

ii.) For post-dose samples, the actual sampling time will be used.

iii.) All pre-dose concentration values will be set to zero.

iv.) Post-dose concentration values BLOQ after T_{max} will be set to missing.

v.) Missing post-dose values will not be replaced.

vi.) A concentration that is BLOQ is assigned a value of zero if it occurs in a profile after dosing at time zero and before the first measurable concentration.

vii.) If a BLOQ value occurs after a measurable concentration in a profile and is followed by a value above the lower limit of quantification, then the BLOQ is treated as missing data, and the time point is ignored in the computations.

viii.) If a BLOQ value occurs at the end of the collection interval (after the last quantifiable concentration) it is treated as missing data.

ix.) If two BLOQ values occur in succession after Cmax, the profile is deemed to have terminated at the first BLOQ value and any subsequent concentrations and time points are omitted from pharmacokinetic calculations.

12.3 Presentation of Plasma Concentrations

Individual plasma concentration results:

A raw data listing will be provided displaying the dasiglucagon concentration as reported and nominal and actual sampling times relative to the start dose of study drug. Results will be displayed using 3 significant digits.

Summary statistics of plasma concentrations:

The dasiglucagon plasma concentrations will be summarized using descriptive statistics (n, arithmetic mean, SD, coefficient of variation (CV) % of arithmetic mean, median, minimum, maximum, geometric mean, and CV % for the geometric mean).

Results will be displayed using 3 significant digits.

The CV % for the geometric mean will be calculated using the following formula:

$$CV\ (\%) = 100 * \sqrt{e^{SD^2} - 1}$$

Where SD is of the natural-log transformed data.

Figures:

Individual and mean concentration-time profiles will be provided on linear and semilogarithmic scales. For individual concentration-time profiles, the actual sampling times will be used.

Mean concentration-time profiles will be provided on linear and semilogarithmic scales and may be presented with error bars representing the Standard error of means (SEM).

12.4 Determination and Analysis of Pharmacokinetic Parameters

Full precision concentration data and actual sample times will be used for the determination of all PK parameters.

Raw plasma concentrations for the derivation of PK parameters will be handled as described in Section 12.1.

The PK parameters as listed in Section 12.1 will be estimated.

Reporting of missing PK parameters:

The percentage of extrapolated AUC should not exceed 20% of AUC_{inf} for each individual profile. If the percentage of extrapolated AUC is more than 20%, the individual AUC_{inf} result and parameters depending on AUC_{inf} will be listed but flagged as not reliably calculated. They will generally not be included in descriptive statistics and statistical testing procedures.

The terminal half-life regression analysis should contain data from at least 3 different time points after C_{max} in the terminal phase and as many data points as possible (always including the last quantifiable concentration but excluding the concentration at T_{max}), consistent with the assessment of a straight line on the log-transformed scale. The coefficient of regression (r^2) should be larger than or equal to 0.80. If at least one of these conditions is not fulfilled, the terminal half-life and parameters depending on $t_{1/2}$ will be listed but flagged as not reliably calculated. They will generally be excluded from descriptive statistics and statistical testing procedures. However, if the reliability of the estimated terminal half-life is judged to be reasonable by the pharmacokineticist who oversees the PK analysis, the $t_{1/2}$ and related parameters would not be excluded.

Individual PK parameters:

A raw data listing will be provided displaying the individual PK parameters. Results will be displayed using 3 significant digits.

Summary statistics of PK parameters:

Pharmacokinetic parameters will be summarized using descriptive statistics (n, arithmetic mean, SD, CV% for the arithmetic mean, median, minimum, maximum, geometric mean, and CV% for the geometric mean). The geometric mean and CV% for the geometric mean will not be calculated for T_{max}. Results will be displayed using 3 significant digits.

13. PHARMACODYNAMIC ENDPOINTS

Pharmacodynamic endpoints coincide with the primary and secondary efficacy endpoints. The plasma glucose profile for assessment of the primary and secondary clinical efficacy endpoints will be assessed based on plasma glucose concentration data from samples collected at the dosing visit (Visit 2).

Plasma glucose is determined at pre-dose and at 15 and 30 minutes after dosing. The actual time of blood sampling should not deviate from the nominal time by more than ± 1 minute for the collection time points. Pre-dose is defined as within 2 minutes prior to dosing.

14. SAFETY ANALYSES

All safety analyses will be based on the SAF.

14.1 Extent of Exposure

14.1.1 Diabetes Treatment prior hypoglycemia induction

A summary table will be prepared showing the number (percentage) of patients who used any of the following:

- MDI
- Insulin pump

All details related to the diabetes treatment prior hypoglycemia induction will be provided in a listing.

14.1.2 Hypoglycemia Induction Procedure

A summary table will be prepared summarizing the data collected for the hypoglycemia induction procedure. Frequency counts and percentages will be presented for the number of patients where the hypoglycemia induction procedure was performed and for the number of patients where glucose was administered intravenously prior to dosing.

The duration in minutes between stop of insulin pump (respectively for multiple daily injections (MDI) users, last basal dose before the Hypoglycaemia procedure) and time when Hypoglycaemia procedure was initiated will be calculated and summarized.

Descriptive statistics will be given for the total amount of insulin administered to induce hypoglycemia and the total amount of glucose administered during the induction procedure.

All details related to the hypoglycemia induction procedure will be provided in a listing.

14.1.3 Study Drug Administration

All data related to study drug administration will be provided in a data listing.

14.2 Local Tolerability

Local tolerability assessments at 30, 120, and 300 minutes after IMP administration will be performed to assess the following:

- Spontaneous pain
- Pain on palpation
- Itching
- Redness
- Edema
- Induration/infiltration
- Other reaction

Injection site reactions and any findings will be reported as AEs.

The analysis of local tolerability will include a summary table displaying the counts and percentages of patients experiencing local symptoms by time point, symptom and severity. Additionally, all details collected from the local tolerability assessments will be provided in a data listing. Any "other types of reaction" will be summarized under the umbrella term "Other".

14.3 Adverse Events

Unless otherwise stated, all AE summary tables will be restricted to TEAEs, which are defined as those AEs that occurred after dosing and those existing AEs that worsened during the study. Partial dates will be imputed. For details on imputation rules, refer to Appendix A: Presentation of Data and Programming Specifications. Imputed dates are only used to determine if an AE is a TEAE: no other calculation, such as durations, will be done. If it cannot be determined whether the AE is treatment-emergent due to a partial onset date, then it will be counted as treatment-emergent. Verbatim terms in the eCRFs will be mapped to SOCs and PTs using MedDRA, version 24.1.

TEAE summaries that are displayed by SOC and PT, will be ordered by descending patient count, by SOC and PT.

Causal relationships

Causal relationship between the occurrence of an AE and the administration of the study drug is assessed by the investigator according to classification scheme: 0=not related, 1=unlikely, 2=possible and 3=probable. Probable and possible relationships will be included under the category related. All AEs must have a causal relationship assigned. In case of a missing relationship, a query will be raised in order to obtain causality assessment. In case no clarification of relationship via query is possible the missing relationship will be set to related for the analysis.

Severity

Severity grading will differ between 1=mild, 2=moderate and 3=severe. For AEs having a missing severity, the severity will not be imputed and kept as missing.

14.3.1 Summary of Adverse Events

A summary table of all AEs will be prepared, summarizing the number and percentage of patients with at least 1 AE and the total number of AEs in the following categories:

1. AEs that occurred during screening
2. TEAEs
3. TEAEs occurring within 12 hours after dosing
4. TEAEs, which are AESIs
5. TEAEs, which are an other important event
6. TEAEs, which are injection site reactions based on investigator assessment on the eCRF
7. IMP related TEAEs
8. TEAEs, which are SAEs
9. IMP related TEAEs, which are SAEs
10. Deaths

14.3.2 Adverse Events by SOC and PT Terms

The analysis of AEs will include summary tables displaying the counts and percentages of patients experiencing AEs by SOC and PT. If a patient has more than 1 AE which codes to the same PT, the patient will be counted only once for that PT. The total number of events documented per SOC and PT will also be displayed. Summaries will be ordered by descending order of incidence of SOC and PT, within each SOC based on the frequency (proportion of patients) in the dasiglucagon group.

Frequency tables will be prepared by MedDRA terms (SOC and PT) summarizing the categories 1 to 9 as listed in Section 14.3.1.

All details relating to adverse events will also be provided in a data listing. Additional listings will be produced to display: AEs for screening failures, any AESIs, AEs leading to discontinuation of IMP, SAEs and any AEs leading to death.

14.4 Clinical Laboratory Evaluation

Laboratory parameters (clinical chemistry, hematology, coagulation) for continuous results will be summarized using descriptive statistics at baseline and at each post-baseline time point. Changes from baseline will also be summarized.

The numbers in each category (above/below/within the relevant reference ranges) will be counted and percentages presented for each laboratory test result at each scheduled visit.

Three separate listings will be produced, which will include all data related to clinical chemistry, hematology, and coagulation laboratory tests.

14.5 Vital Signs

Vital signs will be summarized using descriptive statistics at baseline and at each scheduled post-baseline visit and time point. Changes from baseline will also be summarized.

Categorical results for interpretation (normal/abnormal) will be summarized using frequency counts at baseline and at each scheduled post-baseline visit and time point.

All data related to vital signs will also be included in a data listing.

14.6 Physical Examination

Physical examination results will be included in data listings only.

14.7 Electrocardiogram

The following 12-lead ECG parameters will be summarized using descriptive statistics at screening.

- Heart Rate (beats/min)
- PR Interval (msec)
- QRS Interval (msec)
- QT Interval (msec)
- QTc Interval (msec)
- QTcF Interval (msec) [QTc calculated using Fredericia's formula]

Additionally, the number of patients with an ECG interpretation of normal/abnormal clinically significant/abnormal not clinically significant will be summarized at screening.

All ECG data will also be provided in a data listing.

14.8 Food and Drink Intake

Data collected on the food and drink intake of patients at Visit 2 (pre-dose and post-dose) will be provided in a data listing only.

14.9 Continuous Glucose Monitoring

CGM data will be presented graphically as individual plots (per patient) of glucose measurements over time, from the time of stopping the participant's insulin pump to 300 minutes after dasiglucagon administration.

A secondary y-axis will be displayed to show Glucose measurements in mmol/L additionally to mg/dl. Results are converted into the unit 'mmol/L' by using the conversion factor 0.0555 (i.e. Glucose [mmol/L]=Glucose [mg/dl] *0.0555).

All CGM data will also be included in a data listing.

14.10 Glucose Analyzer Data

Glucose Analyzer data will be summarized by time point and included in a data listing.

In addition, individual time-concentration curves will be created using the time of first dosing of IMP as relative starting point.

14.11 Immunogenicity

Occurrence of ADA will be analyzed descriptively. ADA and results from associated characterization assays will be presented descriptively.

ADA will be derived from the number of patients having an ADA-positive sample during the trial.

Positive anti-dasiglucagon antibody samples from treatment-induced or treatment-boosted (titer increase above 4-fold) is defined as ADA-positive.

15. CHANGES TO PROTOCOL-SPECIFIED ANALYSES

No changes were made to the protocol-specified analysis.

16. REFERENCES

International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). ICH Harmonised Tripartite Guideline. The clinical evaluation of QT/QTc interval prolongation and proarrhythmic potential for non-antiarrhythmic drugs E14. November 2005.

17. APPENDICES

APPENDIX A: PRESENTATION OF DATA AND PROGRAMMING SPECIFICATIONS

General

- Specialized text styles, such as bold, italics, borders, shading, and superscripted and subscripted text will not be used in tables, figures, and data listings (TFLs) unless they add significant value to the TFL.
- Only standard keyboard characters are to be used in tables and data listings.
- Special characters, such as nonprintable control characters and printer- or font-specific characters, will not be used in a TFL.
- Hexadecimal character representations are allowed (eg, μ, α, and ß).
- All footnotes will be left justified and at the bottom of a page. Footnotes must be used sparingly and add value to the TFL.

Tables

- Means and medians will be presented to 1 decimal place more than the raw data. Standard deviations will be presented to 2 decimal places more than the raw data. Minimums and maximums will be reported with the same number of decimal places as the raw data.
- Percentages will be presented to the tenths place.
- For frequency counts of categorical variables, categories whose counts are zero will be displayed for the sake of completeness. For example, if none of the subjects discontinue due to "lost to follow-up," this reason will be included in the table with a count of 0. Categories with zero counts will not have zero percentages displayed.
- Lower and upper CI values must be presented to 1 decimal place more than the raw/derived data (ie, to the same number of decimal places as the mean).
- Percentiles (eg, 25% and 75%) must be presented to 1 decimal place more than the raw/derived data.
- For all inferential analyses, *P* values will be rounded to 4 decimal places (or at the highest level of precision) with a leading zero (0.0001). *P* values less than 0.0001 will be presented as "<0.0001."
- The last footnotes will be:
  - "Source: xxx", where xxx indicates the source table number(s), if applicable (in case aggregated results, such as the mean or median, are plotted), source listing(s) (in case individual responses are plotted), and/or source dataset(s) (eg, ADaM).
  - "PROGRAM SOURCE:...\\xx.sas, DATA CUT-OFF DATE: DD Mmm YYYY, RUN DATE: DD Mmm YYYY hh:mm".

Figures

- Legends will be used for all figures with more than 1 variable or item displayed.
- Figures will be in black and white but can be in color to add value to the clarity and readability of a figure. Lines must be wide enough to see the line after being copied.
- The last footnotes will be:
  - "Source: xxx", where xxx indicates the source listing number(s) and/or source dataset(s) (eg, ADaM).
  - "PROGRAM SOURCE:...\\xx.sas, DATA CUT-OFF DATE: DD Mmm YYYY, RUN DATE: DD Mmm YYYY hh:mm".

Listings

- If not otherwise specified, all data listings will be sorted by center, subject number, visit, and date/time, as appropriate.
- All date values will be presented in a SAS® statistical software, version 9.4 or higher (SAS Institute Inc) date format (eg, 29AUG2001).
- All observed time values will be presented using a 24-hour clock format (HH:MM:SS) (eg, 01:35:45 or 11:26). Seconds will only be reported if they were measured as part of the study.
- The last footnote will be "PROGRAM SOURCE:...\\xx.sas, DATA CUT-OFF DATE: DD Mmm YYYY, RUN DATE: DD Mmm YYYY hh:mm".

Missing or Incomplete Dates (ie, Adverse Events and Concomitant Medications)

The most conservative approach will be systematically considered. If the adverse event (AE) onset date is missing/incomplete, it is assumed to have occurred during the study treatment phase (ie, considered a treatment-emergent AE) except if the partial onset date or other data, such as the stop date, indicates differently. Similarly, a medication with partial start and stop dates could be considered as both a prior and concomitant medication.

The following algorithms will be applied to missing and incomplete start and stop dates:

Start Dates

- If the day portion of the start date is missing, then the start date will be estimated to be equal to the date of the first dose of study drug, provided the start month and year are the same as the date of the first dose of study drug and stop date is either after the date of the first dose of study drug or completely missing. Otherwise, the missing day portion will be estimated as "01."
- If both the day and month portions of the start date are missing, then the start date will be estimated to be equal to the date of the first dose of study drug, provided the start year is the same as the date of the first dose of study drug and stop date is either after the date of

the first dose of study drug or completely missing. Otherwise, the event will be assumed to start on the first day of the given year (eg,??-???-2013 is estimated as 01-JAN-2013).

- If the start date is completely missing and stop date is either after the date of the first dose of study drug or completely missing, then the start date will be estimated to be equal to the date of the first dose of study drug. Otherwise, the start date will be estimated to be the first day of the same year as the stop date. All other non-AE and non-concomitant medication day calculations where only partial dates are available will be handled as follows: the first day of the month will be used in the calculations if the day part of a start date is missing, and January 1 will be used if both the month and day parts of a start date are missing.

Stop Dates

- If only the day of resolution is unknown, the day of resolution of the event will be assumed to be the last day of the month (eg,??-JAN-2013 will be treated as 31-JAN-2013).
- If both the day and month of resolution are unknown, the day of resolution of the event will be assumed to be the last day of the year (eg,??-???-2013 will be treated as 31-DEC-2013).
- If the stop date of the event is completely missing or event is continuing, the event resolution will be assumed to be after the first dose of study drug, and the stop date will be imputed using the last known date on the study.

Standard Calculations

Variables requiring calculation will be derived using the following formulas:

- Days: A duration expressed in days between 1 date (date1) and another later date (date2) is calculated using the following formula: duration in days = date2 – date1 + 1
- Months: A duration expressed in months is calculated using the INTCK function of SAS using the following formula: months = intck('month', 'date1'd, date2'd, 'continuous')
- Years: A duration expressed in years between 1 date (date1) and another later date (date2) is calculated using the following formula: duration in years = intck('year', 'date1'd, 'date2'd, 'continuous')

- Body Mass Index (BMI): BMI is calculated using height and weight using and is calculated using the following formula: BMI (kg/m^2) = weight (kg) / [[height (cm) / 100]^2]

- Change from baseline: Change from baseline will be calculated using the following formula: change = analysis value (including the baseline value) – baseline value

- Percent change from baseline: Percent change from baseline will be calculated using the following formula: percent change from baseline = (analysis value (including the baseline value) – baseline value)/baseline value × 1

APPENDIX B: LIST OF TABLES, LISTINGS, AND FIGURES

The following proposal for Sections 14 and 16.2 is completed according to ICH E3 guidelines The heading numbers and description are in **bold**. Minor changes from this planned index do not need to be amended in the SAP.

Index of Section 14

Table/Figure number	Table/Figure title	Analysis Set	Comment
14	**Tables and Figures Referred to but not Included in the Text**		
14.1	**Demographic Data**		
14.1.1	Patient Disposition	All Patients	
14.1.2	Patient Number by Country and Center	Safety Analysis Set	
14.1.3	Protocol Deviations	Safety Analysis Set	
14.1.4	COVID-19 Related Protocol Deviations	Safety Analysis Set	
14.1.5	Demographic and Baseline Characteristics	Safety Analysis Set	
14.1.6	Medical History	Safety Analysis Set	
14.1.7	Prior Medications	Safety Analysis Set	
14.1.8	Concomitant Medications	Safety Analysis Set	
14.1.9	Current Diabetes Treatment	Safety Analysis Set	
14.2	**Efficacy Data**		
14.2.1	**Primary Efficacy Endpoint**		
14.2.1.1	Plasma Glucose Change from Baseline at 30 minutes after IMP Injection	Full Analysis Set	
14.2.2	**Secondary Efficacy Endpoint**		
14.2.2.1	Plasma Glucose Change from Baseline at 15 minutes after IMP Injection	Full Analysis Set	
14.2.3	**Exploratory Analysis**		
14.2.3.1	Plasma Glucose Change from Baseline at 30 minutes after IMP Injection in Subjects Without Rescue IV Glucose	Full Analysis Set	
14.2.3.2	Plasma Glucose Change from Baseline at 15 minutes after IMP Injection in Subjects Without Rescue IV Glucose	Full Analysis Set	
14.2.3.3	Plasma Glucose - untransformed and change from baseline at each time point	Full Analysis Set	

14.2.3.4	Mean glucose concentrations versus time - original scale	Full Analysis Set	Figure
14.2.3.5	Individual glucose concentrations versus time - original scale	Full Analysis Set	Figure
14.2.3.6	Plasma Glucose Change from Baseline at 30 minutes after IMP Injection – Sensitivity Analysis	Full Analysis Set	
14.2.3.7	Plasma Glucose Change from Baseline at 15 minutes after IMP Injection – Sensitivity Analysis	Full Analysis Set	
14.2.3.8	Plasma Glucose - untransformed and change from baseline at each time point– Sensitivity Analysis	Full Analysis Set	
14.2.4	**Pharmacokinetic Data**		
14.2.4.1	Descriptive Statistics for dasiglucagon Plasma Concentration	PK Analysis Set	
14.2.4.2	Mean dasiglucagon Concentration-time Profile – linear scale	PK Analysis Set	Figure
14.2.4.3	Mean dasiglucagon Concentration-time Profile – semi-log scale	PK Analysis Set	Figure
14.2.4.4	Individual dasiglucagon Concentration-time Profiles – linear scale	PK Analysis Set	Figure
14.2.4.5	Individual dasiglucagon Concentration-time Profiles – Semi-log scale	PK Analysis Set	Figure
14.2.4.6	Descriptive Statistics for PK Parameters	PK Analysis Set	
14.3	**Safety Data**		
14.3.1	**Adverse Events**		
14.3.1.1	Overall Summary of Adverse Events	Safety Analysis Set	
14.3.1.2	Treatment-Emergent Adverse Events by System Organ Class and Preferred Term	Safety Analysis Set	
14.3.1.3	Treatment-Emergent Adverse Events occurring within 12 hours after dosing by System Organ Class and Preferred Term	Safety Analysis Set	
14.3.1.4	Adverse Events that occurred during Screening, by System Organ Class and Preferred Term	Safety Analysis Set	
14.3.1.5	Treatment-Emergent Adverse Events of Special Interest, by System Organ Class and Preferred Term	Safety Analysis Set	
14.3.1.6	Treatment-Emergent Adverse Events that are Other Important Events, by System Organ Class and Preferred Term	Safety Analysis Set	
14.3.1.7	Treatment-Emergent Adverse Events that are Injection Site Reactions, by System Organ Class and Preferred Term	Safety Analysis Set	
14.3.1.8	Treatment-Emergent Adverse Events that are IMP Related, by System Organ Class and Preferred Term	Safety Analysis Set	

14.3.1.9	Serious Treatment-Emergent Adverse Events, by System Organ Class and Preferred Term	Safety Analysis Set	
14.3.1.10	Serious Treatment-Emergent Adverse Events that are IMP Related, by System Organ Class and Preferred Term	Safety Analysis Set	
14.3.1.11	Local Tolerability Assessment	Safety Analysis Set	
14.3.2	**Listings of Deaths, Other Serious and Significant Adverse Events**		
14.3.2.1	Serious Adverse Events	Safety Analysis Set	
14.3.2.2	Adverse Events Leading to Premature Discontinuation of Study Drug	Safety Analysis Set	
14.3.2.3	Adverse Events Leading to Death	Safety Analysis Set	
14.3.3	**Narratives of Deaths, Other Serious and Certain Other Significant Adverse Events**		This is a cross-reference to section 12.3.2 of the CSR
14.3.4	**Abnormal Laboratory Value Listing (Each Patient)**		
14.3.4.1	Abnormal Laboratory Values	Safety Analysis Set	
14.3.5	**Extent of Exposure**		
14.3.5.1	Diabetes Treatment Prior Hypoglycemia	Safety Analysis Set	
14.3.5.2	Hypoglycemia Induction Procedure	Safety Analysis Set	
14.3.6	**Other Safety Data**		
14.3.6.1	Continuous Glucose Monitoring - Individual Glucose Concentration-time Profiles	PK Analysis Set	Figure
14.3.6.2	Glucose Analyzer Data	Safety Analysis Set	
14.3.6.2	**Laboratory Data**		
14.3.6.2.1	Hematology Results	Safety Analysis Set	
14.3.6.2.2	Hematology Results – Reference Range Analysis	Safety Analysis Set	
14.3.6.2.3	Chemistry Results	Safety Analysis Set	
14.3.6.2.4	Chemistry Results – Reference Range Analysis	Safety Analysis Set	
14.3.6.2.5	Coagulation Results	Safety Analysis Set	
14.3.6.2.6	Coagulation Results – Reference Range Analysis	Safety Analysis Set	

14.3.6.2.7	Immunogenicity	Safety Analysis Set	
14.3.6.3	Vital Signs	Safety Analysis Set	
14.3.6.4.	ECG Data	Safety Analysis Set	

Abbreviations: ECG=electrocardiogram; ICH=International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use.

Index of Sections 16.1.2

ICH listing number	Listing title	Analysis Set	Comments
16.2	**Patient Data Listings**		
16.2.1	**Discontinued Patients**		
16.2.1.1	Patient Disposition	All Patients	
16.2.2	**Protocol Deviations**		
16.2.2.1	Protocol Deviations	Safety Analysis Set	
16.2.2.2	COVID-19 Related Protocol Deviations	Safety Analysis Set	
16.2.2.3	Patients not Fulfilling at least one Inclusion/Exclusion Criteria	All Screened Patients	
16.2.3	**Patients Excluded from the Analysis**		
16.2.3.1	Patients Excluded from Analysis	All Enrolled Patients	
16.2.4	**Demographic Data**		
16.2.4.1	Demographic and Baseline Characteristics	Safety Analysis Set	
16.2.4.2	Medical History	Safety Analysis Set	
16.2.4.3	Prior and Concomitant Medications	Safety Analysis Set	
16.2.4.4	Current Diabetes Treatment	Safety Analysis Set	
16.2.5	**Compliance and/or Drug Concentration Data**		
16.2.5.1	Study Drug Administration	Safety Analysis Set	
16.2.5.2	Diabetes treatment prior hypoglycemia induction - MDI user	Safety Analysis Set	
16.2.5.3	Diabetes treatment prior hypoglycemia induction - meal-time/ bolus insulins	Safety Analysis Set	
16.2.5.4	Diabetes treatment prior hypoglycemia induction - pump user	Safety Analysis Set	
16.2.5.5	Hypoglycemia Induction Procedure	Safety Analysis Set	
16.2.5.6	dasiglucagon Plasma Concentrations	Safety Analysis Set	
16.2.5.7	dasiglucagon PK Parameters	Safety Analysis Set	
16.2.5.8	Continuous Glucose Monitoring	Safety Analysis Set	
16.2.6	**Individual Efficacy Response Data**		
16.2.6.1	Plasma Glucose Concentrations	Safety Analysis Set	

16.2.7	**Adverse Events Listings**		
16.2.7.1	Adverse Events	Safety Analysis Set	
16.2.7.2	Adverse Events of Special Interest	Safety Analysis Set	
16.2.7.3	Hemodynamic Changes During Adverse Events of Special Interest	Safety Analysis Set	
16.2.7.4	Other Important Events	Safety Analysis Set	
16.2.7.5	Details of Other Important Events	Safety Analysis Set	
16.2.7.6	Local Tolerability Assessment	Safety Analysis Set	
16.2.7.7	Death details	Safety Analysis Set	
16.2.7.8	Adverse Events for Screening Failures	Screening Failures	
16.2.8	Listing **of Individual Laboratory Measurements by Subject, When Required by Regulatory Authorities**		
16.2.8.1	Hematology	Safety Analysis Set	
16.2.8.2	Chemistry	Safety Analysis Set	
16.2.8.3	Coagulation	Safety Analysis Set	
16.2.9	**Other Data**		
16.2.9.1	Vital Signs	Safety Analysis Set	
16.2.9.2	Physical Examination	Safety Analysis Set	
16.2.9.3	Electrocardiogram	Safety Analysis Set	
16.2.9.4	Hospitalization	Safety Analysis Set	
16.2.9.5	Immunogenicity	Safety Analysis Set	
16.2.9.6	Food and Drink Intake	Safety Analysis Set	
16.2.9.7	Technical Complaints	Safety Analysis Set	

Abbreviations: ICH=International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use.

APPENDIX C: TABLE, FIGURE, LISTING LAYOUTS

Table, Figure and Listing layouts (shells) are provided in a separate document.

Appendix C1: Study-Specific Shells for Section 14

14.1 Demographic Data

Table 14.1.1 Patient Disposition
All Patients

	dasiglucagon 0.3mg	dasiglucagon 0.6mg	Total
Number of patients screened			xx
Number of patients enrolled[a]	xx	xx	xx
Number of patients in the Safety Analysis Set[b]	xx (100.0%)	xx (100.0%)	xx (100.0%)
Number of patients in the Full Analysis Set[c]	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of patients in the PK Analysis Set[d]	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Completed Study (based on Safety Analysis Set)			
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Primary reason for study discontinuation			
Adverse Event	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Death	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Disease Relapse	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure to Meet Randomization criteria	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Lack of Efficacy	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Lost to Follow-up	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Non-Compliance with Study Drug	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Physician Decision	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Progressive Disease	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Protocol Deviation	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Recovery	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Screen Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Site Terminated by Sponsor	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Study Terminated by Sponsor	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Technical Problems	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Withdrawal by Parent/Guardian	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Other	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Percentages are based on the total number of patients enrolled.
[a] Requires parent's/legal guardian's agreement for the child to participate in a clinical trial following completion of the informed consent process and further that the child is screened and found eligible for the trial.
[b] All patients who were enrolled and received at least 1 dose of study drug.
[c] All patients of the safety analysis set.
[d] All patients with at least one quantifiable plasma concentration.

Source: xxx
PROGRAM SOURCE: xxx.sas, DATA CUT-OFF DATE: DDMMMYYYY RUN DATE: DDMMMYYYY hh:mm

Programming Notes:
1) Include all discontinuation reasons (even if no subjects discontinued for that reason). Sort in order as on CRF.

Table 14.1.2 Patient Number by Country and Center
Safety Analysis Set

Country	Center Number	dasiglucagon 0.3mg (N=XX)	dasiglucagon 0.6mg (N=XX)	Total (N=XX)
xxxxxxx	XXXX	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	XXXX	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
xxxxxxx	XXXX	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	XXXX	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	XXXX	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
... ...	... ...	... ...	... ...	... ...

Percentages are based on the total number of patients in the safety analysis set.

Source: xxx
PROGRAM SOURCE: xxx.sas, DATA CUT-OFF DATE: DDMMMYYYY RUN DATE: DDMMMYYYY hh:mm

Table 14.1.3 Protocol Deviations
Safety Analysis Set

Protocol Deviations [n (%) m]	dasiglucagon 0.3mg (N=XX)	dasiglucagon 0.6mg (N=XX)	Total (N=XX)
Any Protocol Deviations[a]	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Deviation #1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Deviation #2	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Deviation #3	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
etc.	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Any Major Protocol Deviations[a]	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Deviation #1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Deviation #2	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Deviation #3	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
etc.	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx

n = Number of patients; m = Number of deviations
[a] Patients may be included in more than 1 protocol deviation category.
Percentages are based on the total number of patients in the safety analysis set.
This table includes all study protocol deviations that are not COVID-19 related.

Source: xxx
PROGRAM SOURCE: xxx.sas, DATA CUT-OFF DATE: DDMMMYYYY RUN DATE: DDMMMYYYY hh:mm

Programming Note:
1) *Only include protocol deviations that are not COVID-19 related.*
2) *Percentages are based on total number of patients in the safety set.*
3) *Include all non COVID-19 related protocol deviations in 'Any Protocol Deviations' section of the table. Include only Major non COVID-19 related protocol deviations in 'Any Major Protocol Deviations' section of the table.*

Table 14.1.4 COVID-19 Related Protocol Deviations
Safety Analysis Set

COVID-19 Related Protocol Deviations [n (%) m]	dasiglucagon 0.3mg (N=XX)	dasiglucagon 0.6mg (N=XX)	Total (N=XX)
Any COVID-19 Related Protocol Deviations[a]	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Deviation #1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Deviation #2	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Deviation #3	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
etc.	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Any Major COVID-19 Related Protocol Deviations[a]	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Deviation #1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Deviation #2	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Deviation #3	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
etc.	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx

n = Number of patients; m = Number of deviations
[a] Patients may be included in more than 1 protocol deviation category.
Percentages are based on the total number of patients in the safety analysis set.
This table includes all study protocol deviations that are COVID-19 related.

Source: xxx
PROGRAM SOURCE: xxx.sas, DATA CUT-OFF DATE: DDMMMYYYY RUN DATE: DDMMMYYYY hh:mm

Programming Note:
1) *Only include protocol deviations that are COVID-19 related.*
2) *Percentages are based on total number of patients in the safety set.*
3) *Include all COVID-19 related protocol deviations in 'Any COVID-19 Related Protocol Deviations' section of the table. Include only Major COVID-19 related protocol deviations in 'Any Major COVID-19 Related Protocol Deviations' section of the table.*

Table 14.1.5 Demographic and Baseline Characteristics
Safety Analysis Set

	dasiglucagon 0.3mg (N=XX)	dasiglucagon 0.6mg (N=XX)	Total (N=XX)
Age[a] (years)			
n	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
Age groups			
< 2 years	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 to < 4 years	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 to < 6 years	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Sex			
Male	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Female	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Unknown	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Undifferentiated	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Race			
American Indian or Alaska Native	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Asian	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Black or African American	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Native Hawaiian or Other Pacific Islander	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
White	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Not reported	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Not Allowed to Ask per Local Regulation	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Other	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Multiple Races Checked	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Ethnicity			
Hispanic or Latino	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Not Hispanic or Latino	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Not reported	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Not Allowed to Ask per Local Regulation	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Height (cm)			
n	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx

	dasiglucagon 0.3mg (N=XX)	dasiglucagon 0.6mg (N=XX)	Total (N=XX)
Weight (kg)			
n	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
Weight groups			
< 15kg	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
>=15kg	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
BMI (kg/m²)			
n	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
Time Since Diabetes Diagnosis[b] (months)			
n	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx

[a] Age on consent date
[b] Date of informed consent - date of diabetes diagnosis + 1
Percentages are based on the total number of patients in the safety analysis set.
Height, weight and BMI obtained at Screening visit.

Source: xxx
PROGRAM SOURCE: xxx.sas, DATA CUT-OFF DATE: DDMMMYYYY RUN DATE: DDMMMYYYY hh:mm

Programming Note:
1) This shell continues over two pages
2) Percentages are based on total number of patients in the safety set.

Table 14.1.6 Medical History
Safety Analysis Set

System Organ Class Preferred term [n (%) m]	dasiglucagon 0.3mg (N=XX)	dasiglucagon 0.6mg (N=XX)	Total (N=XX)
Any medical history	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
SOC class 1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT Term 1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT Term 2	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
...	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
SOC class 2	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT Term 1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT Term 2	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
...	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx

n = Number of patients; m = Number of events
Diabetes history not included.
Medical History terms are coded using MedDRA version 24.1. At each level of summation (SOC class, preferred name), patients reporting more than 1 event are counted only once for the patient count.
Table is sorted by descending patient count, by system organ class and preferred term.
Percentages are based on the total number of patients in the safety analysis set.

Source: xxx
PROGRAM SOURCE: xxx.sas, DATA CUT-OFF DATE: DDMMMYYYY RUN DATE: DDMMMYYYY hh:mm

Programming Note:
1) *Percentages are based on total number of patients in the safety set.*
2) *Sort by decreasing frequency of the total column by SOC and preferred term on the total column.*
3) *Any uncoded terms to be displayed under a SOC 'Uncoded' and then the verbatim term for the PT (in all capital letters) and to be sorted to appear at the bottom of the table.*
4) *Please exclude any diabetes history defined as MedDDRA Preferred term =' TYPE 1 DIABETES MELLITUS'*

Table 14.1.7 Prior Medications
Safety Analysis Set

ATC Class (level 2) Preferred name [n (%) m]	dasiglucagon 0.3mg (N=XX)	dasiglucagon 0.6mg (N=XX)	Total (N=XX)
Any prior medications	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
ATC Class 1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Preferred Name 1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Preferred Name 2	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
...	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
ATC Class 2	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Preferred Name 1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Preferred Name 2	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
...	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx

n = Number of patients; m = Number of occurrences
Prior medications are those that stopped before the date/time of start of study drug administration.
At each level of summation (overall, ATC class, preferred name), patients reporting more than 1 medication are counted only once for the patient count.
Table is sorted by descending patient count, by ATC level and preferred name.
Percentages are based on the total number of patients in the safety analysis set.
Terms are coded using WHODrug Global B3 format, Sep2021 release.

Source: **xxx**
PROGRAM SOURCE: **xxx.sas**, DATA CUT-OFF DATE: DDMMMYYYY RUN DATE: DDMMMYYYY hh:mm

Programming Note:
1) *Percentages are based on total patient count (N).*
2) *Sort by decreasing frequency patient count, by ATC class and preferred name on the total column.*
3) *Any uncoded terms to be displayed under a SOC 'Uncoded' and then the verbatim term for the PT (in all capital letters) and to be sorted to appear at the bottom of the table*

Table 14.1.8 Concomitant Medications
Safety Analysis Set

ATC Class (level 2) Preferred name [n (%) m]	dasiglucagon 0.3mg (N=XX)	dasiglucagon 0.6mg (N=XX)	Total (N=XX)
Any concomitant medications	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
ATC Class 1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Preferred Name 1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Preferred Name 2	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
...	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
ATC Class 2	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Preferred Name 1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Preferred Name 2	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
...	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx

n = Number of patients; m = Number of occurrences
Concomitant medications are those that started, stopped or are ongoing at the date/time of start of study drug administration.
At each level of summation (overall, ATC class, preferred name), patients reporting more than 1 medication are counted only once for the patient count.
Table is sorted by descending patient count, by ATC level and preferred name.
Percentages are based on the total number of patients in the safety analysis set.
Terms are coded using WHODrug Global B3 format, Sep2021 release.

Source: xxx
PROGRAM SOURCE: xxx.sas, DATA CUT-OFF DATE: DDMMMYYYY RUN DATE: DDMMMYYYY hh:mm

Programming Note:
1) *Percentages are based on total patient count (N).*
2) *Sort by decreasing frequency patient count, by ATC class and preferred name on the total column.*
3) *Any uncoded terms to be displayed under a SOC 'Uncoded' and then the verbatim term for the PT (in all capital letters) and to be sorted to appear at the bottom of the table*

Table 14.1.9 Current Diabetes Treatment
Safety Analysis Set

ATC Class (level 2) Preferred name [n (%) m]	dasiglucagon 0.3mg (N=XX)	dasiglucagon 0.6mg (N=XX)	Total (N=XX)
Any current diabetes treatment	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
ATC Class 1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Preferred Name 1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Preferred Name 2	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
...	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
ATC Class 2	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Preferred Name 1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Preferred Name 2	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
...	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx

n = Number of patients; m = Number of occurrences
Current diabetes treatments are collected on the Diabetes Information CRF.
At each level of summation (overall, ATC class, preferred name), patients reporting more than 1 medication are counted only once for the patient count.
Table is sorted by descending patient count, by ATC level and preferred name.
Percentages are based on the total number of patients in the safety analysis set.
Terms are coded using WHODrug Global B3 format, Sep2021 release.

Source: xxx
PROGRAM SOURCE: xxx.sas, DATA CUT-OFF DATE: DDMMMYYYY RUN DATE: DDMMMYYYY hh:mm

Programming Note:
1) *Percentages are based on total patient count (N).*
2) *Sort by decreasing frequency patient count, by ATC class and preferred name on the total column.*
3) *Any uncoded terms to be displayed under a SOC 'Uncoded' and then the verbatim term for the PT (in all capital letters) and to be sorted to appear at the bottom of the table*

14.2 Efficacy Data

14.2.1 Primary Efficacy Endpoint

Table 14.2.1.1 Plasma Glucose Change from Baseline at 30 minutes after IMP Injection
Full Analysis Set

	dasiglucagon 0.3mg (N=XX)		dasiglucagon 0.6mg (N=XX)		Total (N=XX)	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Plasma Glucose (mg/dL) at 30 minutes after IMP injection						
n	xx	xx	xx	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
95% CIs (Mean)		(xx.x, xx.x)		(xx.x, xx.x)		(xx.x, xx.x)

IMP = investigational medicinal product
Baseline is the last recorded value prior to study drug administration.
95% confidence interval for the mean plasma glucose change from baseline at 30 minutes after IMP injection, based on a *t* distribution.
Plasma glucose change from baseline at 30 minutes after trial product injection or at the time of rescue by IV glucose. For patients who required rescue IV glucose before the time of the endpoint assessment, the last available plasma glucose taken prior to rescue IV glucose is carried forward and used for analysis.

Source: xxx
PROGRAM SOURCE: xxx.sas, DATA CUT-OFF DATE: DDMMMYYYY RUN DATE: DDMMMYYYY hh:mm

Programming Note:
1) In general present mean to 1 decimal more than individual data, STD to 2 decimals more than individual data. Refer to SAP

14.2.2 Secondary Efficacy Endpoint

Table 14.2.2.1 Plasma Glucose Change from Baseline at 15 minutes after IMP Injection
Full Analysis Set

	dasiglucagon 0.3mg (N=XX)		dasiglucagon 0.6mg (N=XX)		Total (N=XX)	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Plasma Glucose (mg/dL) at 15 minutes after IMP injection						
n	xx	xx	xx	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx

IMP = investigational medicinal product
Baseline is the last recorded value prior to study drug administration.
Plasma glucose change from baseline at 15 minutes after trial product injection or at the time of rescue by IV glucose. For patients who required rescue IV glucose before the time of the endpoint assessment, the last available plasma glucose taken prior to rescue IV glucose is carried forward and used for analysis.

Source: xxx
PROGRAM SOURCE: xxx.sas, DATA CUT-OFF DATE: DDMMMYYYY RUN DATE: DDMMMYYYY hh:mm

Programming Note:
1) In general present mean to 1 decimal more than individual data, STD to 2 decimals more than individual data. Refer to SAP

14.2.3 Exploratory Analysis

Table 14.2.3.1 Plasma Glucose Change from Baseline at 30 minutes after IMP Injection in Subjects Without Rescue IV Glucose
Full Analysis Set

Programming Note:

1) *Repeat of Table 14.2.1.1 for subjects in FA but without intake of rescue INV Glucose*
2) *Remove footnote 'For patients who required rescue IV glucose before the time of the endpoint assessment, the last available plasma glucose taken prior to rescue IV glucose is carried forward and used for analysis.'*

Table 14.2.3.2 Plasma Glucose Change from Baseline at 15 minutes after IMP Injection in Subjects Without Rescue IV Glucose
Full Analysis Set

Programming Note:

1) *Repeat of Table 14.2.2.1 for subjects in FA but without intake of rescue INV Glucose*
2) *Remove footnote 'For patients who required rescue IV glucose before the time of the endpoint assessment, the last available plasma glucose taken prior to rescue IV glucose is carried forward and used for analysis.'*

Table 14.2.3.3 Plasma Glucose - untransformed and change from baseline at each time point
Full Analysis Set

		dasiglucagon 0.3mg (N=XX)		dasiglucagon 0.6mg (N=XX)		Total (N=XX)	
Time Point	Plasma Glucose (mg/dL)	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Pre-dose	n	xx		xx		xx	
	Mean (SD)	xx.x (xx.xx)		xx.x (xx.xx)		xx.x (xx.xx)	
	Median	xx.x		xx.x		xx.x	
	Min, Max	xx, xx		xx, xx		xx, xx	
15min post-dose	n	xx	xx	xx	xx	xx	xx
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
30min post-dose	n	xx	xx	xx	xx	xx	xx
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx

Baseline is the last recorded value prior to study drug administration.
Source: xxx
PROGRAM SOURCE: xxx.sas, DATA CUT-OFF DATE: DDMMMYYYY RUN DATE: DDMMMYYYY hh:mm

Programming Note:
1) In general present mean to 1 decimal more than individual data, STD to 2 decimals more than individual data. Refer to SAP

Figure 14.2.3.4 Mean glucose concentrations versus time - original scale
Full Analysis Set

Type of Graph:	Mean concentration-time profile
x-Axis	Nominal Time
x-Axis label	Nominal time after IMP administration (min)
y-Axis	Use linear scale
y-Axis Label	Mean plasma glucose concentration (mg/dL)
Additional Information	Same layout as figure 14.2.4.2
Notes	Mean Line Plot per treatment Error bars showing SEM Add mean value at each plot marker rounded to 1 decimal place Add data table with number of valid cases per time point
Footnotes	IMP = investigational medicinal product Figure shows mean results ± SEM (Standard Error of Mean)

Programming Notes:

QC dataset will consist of reproducing the means and SEM plotted.
So, produce a dataset with
- TRTP
- ATPTN
- Mean
- Lower bound of SEM error bar
- Upper bound of SEM error bar
- Number of valid cases

QC Dataset to be sorted by trtpn, atptn

Figure 14.2.3.5 Individual glucose concentrations versus time - original scale
Full Analysis Set

Programming Note:
- This is a repeat of figure 14.2.4.3 (Spaghetti/Overlay Plot) using Plasma Glucose results. Same timepoints as used in figure 14.2.3.4

Table 14.2.3.6 Plasma Glucose Change from Baseline at 30 minutes after IMP Injection – Sensitivity Analysis
Full Analysis Set

Programming Note:
- This is a repeat of table 14.2.1.1 using a 2nd baseline definition with the nominal time point 'pre-dose' as baseline result

Table 14.2.3.7 Plasma Glucose Change from Baseline at 15 minutes after IMP Injection – Sensitivity Analysis
Full Analysis Set

Programming Note:
- This is a repeat of table 14.2.2.1 using a 2nd baseline definition with the nominal time point 'pre-dose' as baseline result

Table 14.2.3.8 Plasma Glucose - untransformed and change from baseline at each time point– Sensitivity Analysis
Full Analysis Set

Programming Note:
- This is a repeat of table 14.2.3.3 using a 2nd baseline definition with the nominal time point 'pre-dose' as baseline result

14.2.4 Pharmacokinetic Data

Table 14.2.4.1 Descriptive Statistics for dasiglucagon Plasma Concentrations
PK Analysis Set

Treatment Group= <dasiglucagon 0.3mg(N=XX)/ dasiglucagon 0.6mg(N=XX)>

Result (pmol/L)		Post-dose								
	Pre-dose	10min	20min	30min	40min	60min	90min	140min	220min	300min
n	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
CV (%) Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
Max	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
Geo-Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
CV (%) geom-mean[a]	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x

All concentration values below the Limit of Quantification (BLOQ) are set to zero.
Results are displayed to 3 significant digits.
[a] Geometric mean CV (%) is calculated as $[\exp(SD^2)-1]^{1/2}*100$, where SD is standard deviation of the natural-log transformed data.

Source: xxx
PROGRAM SOURCE: xxx.sas, DATA CUT-OFF DATE: DDMMMYYYY RUN DATE: DDMMMYYYY hh:mm

Programming Note:

1) *In general present mean to 1 decimal more than individual data, STD to 2 decimals more than individual data. Refer to SAP*
2) ***For post-dose samples, the planned sampling time will be used in summary tables.***
3) ***For all pre-dose samples, the sampling time will be set to zero.***
4) ***All concentration values below the Limit of Quantification (BLOQ) will be set to zero.***
5) ***Missing post-dose values will not be replaced***
6) ***See further details in the SAP***
7) ***Table will be created for each treatment group***

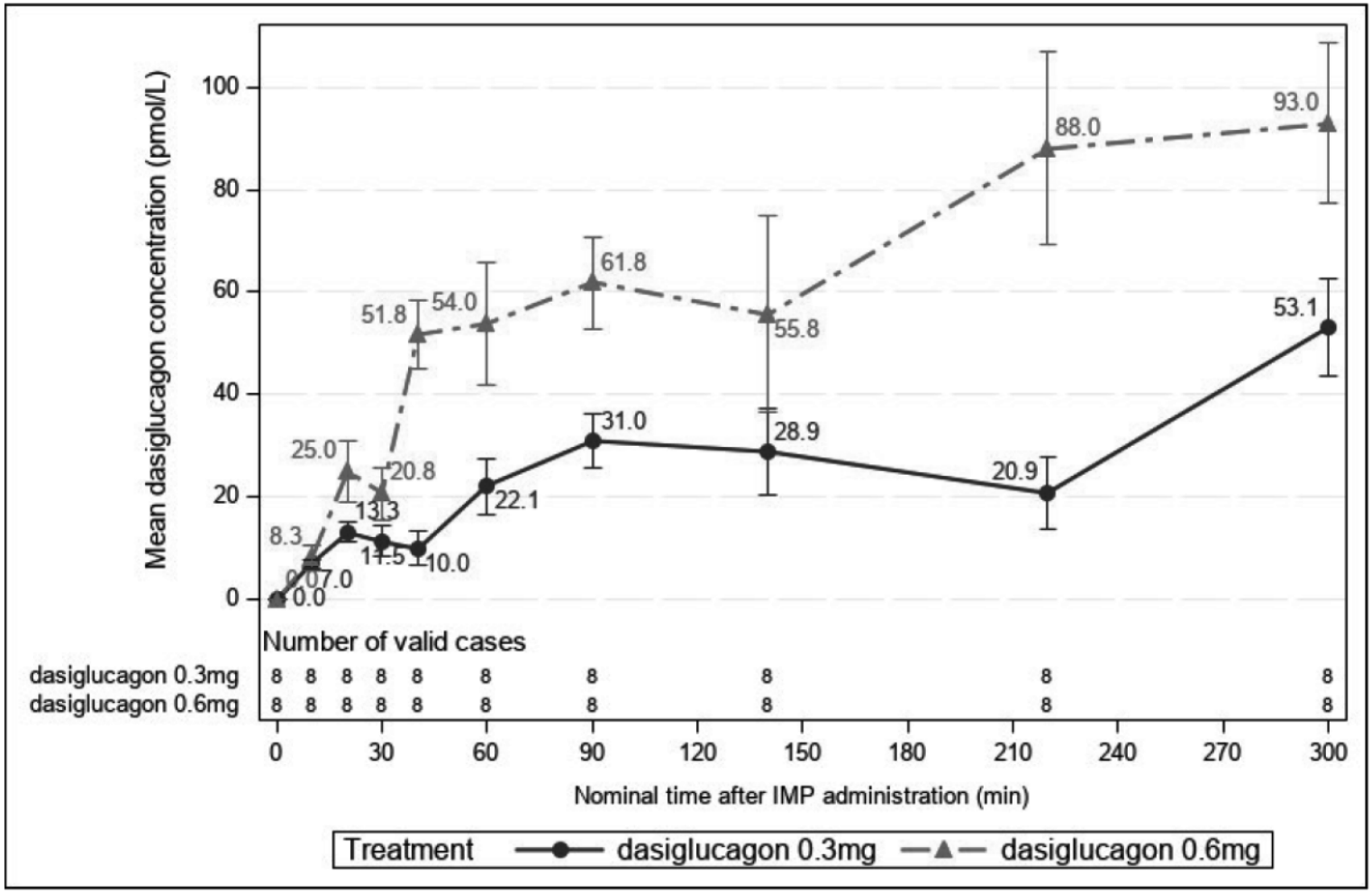
Figure 14.2.4.2 Mean dasiglucagon Concentration-time Profile – linear scale
PK Analysis Set

Type of Graph:	Mean concentration-time profile
x-Axis	See mock on next page
x-Axis label	Nominal time after IMP administration (min)
y-Axis	Use linear scale Use same scaling of y axis for all patients
y-Axis Label	**Mean dasiglucagon concentration (pmol/L)**
Additional Information	**See next page for mock.**
Notes	Mean Line Plot Error bars showing SEM Add data table as in example plot
Footnotes	IMP = investigational medicinal product Figure shows mean results ± SEM (Standard Error of Mean) Results BLQ are set to 0 pmol/L

Programming Notes:

QC dataset will consist of reproducing the means and SEM plotted.
So, produce a dataset with
- TRTP
- ATPTN
- Mean
- Lower bound of SEM error bar
- Upper bound of SEM error bar
- Number of valid cases

QC Dataset to be sorted by trtpn, atptn



IMP = investigational medicinal product
Figure shows mean results ± SEM (Standard Error of Mean)
Results BLQ are set to 0 pmol/L

Figure 14.2.4.3 Mean dasiglucagon Concentration-time Profile – semi-log scale
PK Analysis Set

Type of Graph:	Mean concentration-time profile
x-Axis	See mock on next page
x-Axis label	Nominal time after IMP administration (min)
y-Axis	Use semi-log scale Use same scaling of y axis for all patients
y-Axis Label	Mean dasiglucagon concentration (pmol/L)
Additional Information	
Notes	Mean Line Plot Error bars showing SEM Add data table as in example plot
Footnotes	IMP = investigational medicinal product Figure shows mean results ± SEM (Standard Error of Mean) Results BLQ are set to 0 pmol/L

Programming Note:
1) Repeat of Figure 14.2.4.2 on Semi-log scale

QC dataset will consist of reproducing the means and SEM plotted.
So, produce a dataset with
- TRTP
- ATPTN
- Mean
- Lower bound of SEM error bar
- Upper bound of SEM error bar
- Number of valid cases

QC Dataset to be sorted by trtpn, atptn

Figure 14.2.4.4 Individual overlayed dasiglucagon Concentration-time Profiles – linear scale
PK Analysis Set

Type of Graph:	Spaghetti plots
x-Axis	See mock on next page
x-Axis label	Actual time after IMP administration (min)
y-Axis	Use linear scale Use same scaling of y axis for all patients
y-Axis Label	dasiglucagon concentration (pmol/L)
Additional Information	**See next page for mock.**
Notes	Spaghetti Plot, one plot per dose Use different color (red/blue as in previous plot) for the 2 dose groups
Footnotes	IMP = investigational medicinal product For individual concentration-time profiles, the actual sampling times is used.

Programming Notes:

QC dataset will consist of reproducing the results plotted.
So, produce a dataset with
- TRTP
- SUBJID
- ARELTM2
- AVAL

QC Dataset to be sorted by trtpn, subjid, areltm2

Sample Plot (from other study)

Zealand Pharma A/S
Protocol Number: ZP4207-17086
Clinical Study Report
Page 1 of 2

14.4.1.5 Figure: Individual analyte concentrations versus time curves - original scale, FAS

Treatment=dasiglucagon

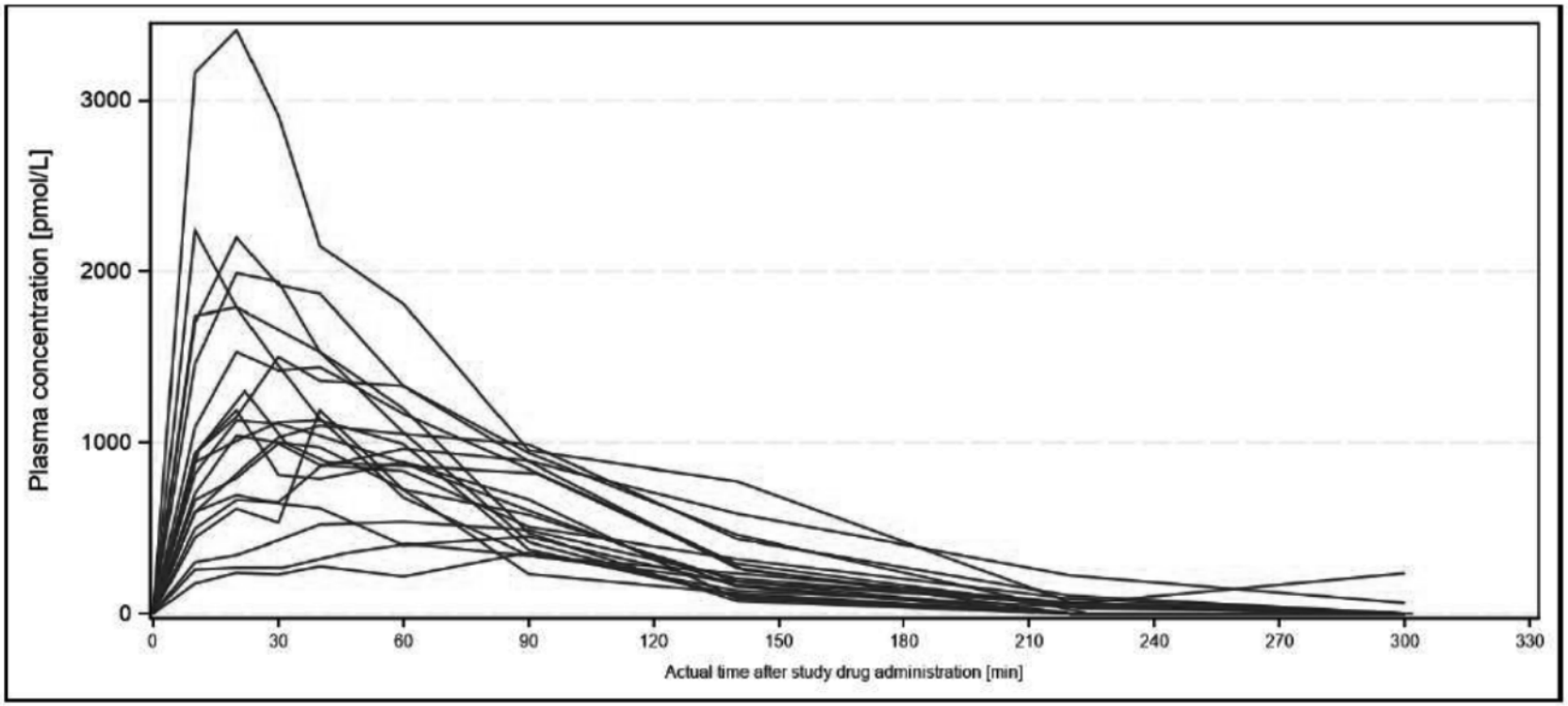


Figure 14.2.4.5 Individual dasiglucagon Concentration-time Profiles – linear scale
PK Analysis Set

Type of Graph:	Individual Patient concentration-time profiles
x-Axis	See mock on next page
x-Axis label	Actual time after IMP administration (min)
y-Axis	Use linear scale Use same scaling of y axis for all patients
y-Axis Label	dasiglucagon concentration (pmol/L)
Additional Information	**See next page for mock.**
Notes	Panel Plot, separate panel for each dosing group
Footnotes	IMP = investigational medicinal product For individual concentration-time profiles, the actual sampling times is used.

Programming Notes:

QC dataset will consist of reproducing the results plotted.
So, produce a dataset with
- TRTP
- SUBJID
- ARELTM2
- AVAL

QC Dataset to be sorted by trtpn, subjid, areltm2

Treatment=< dasiglucagon 0.6mg/ dasiglucagon 0.6mg >

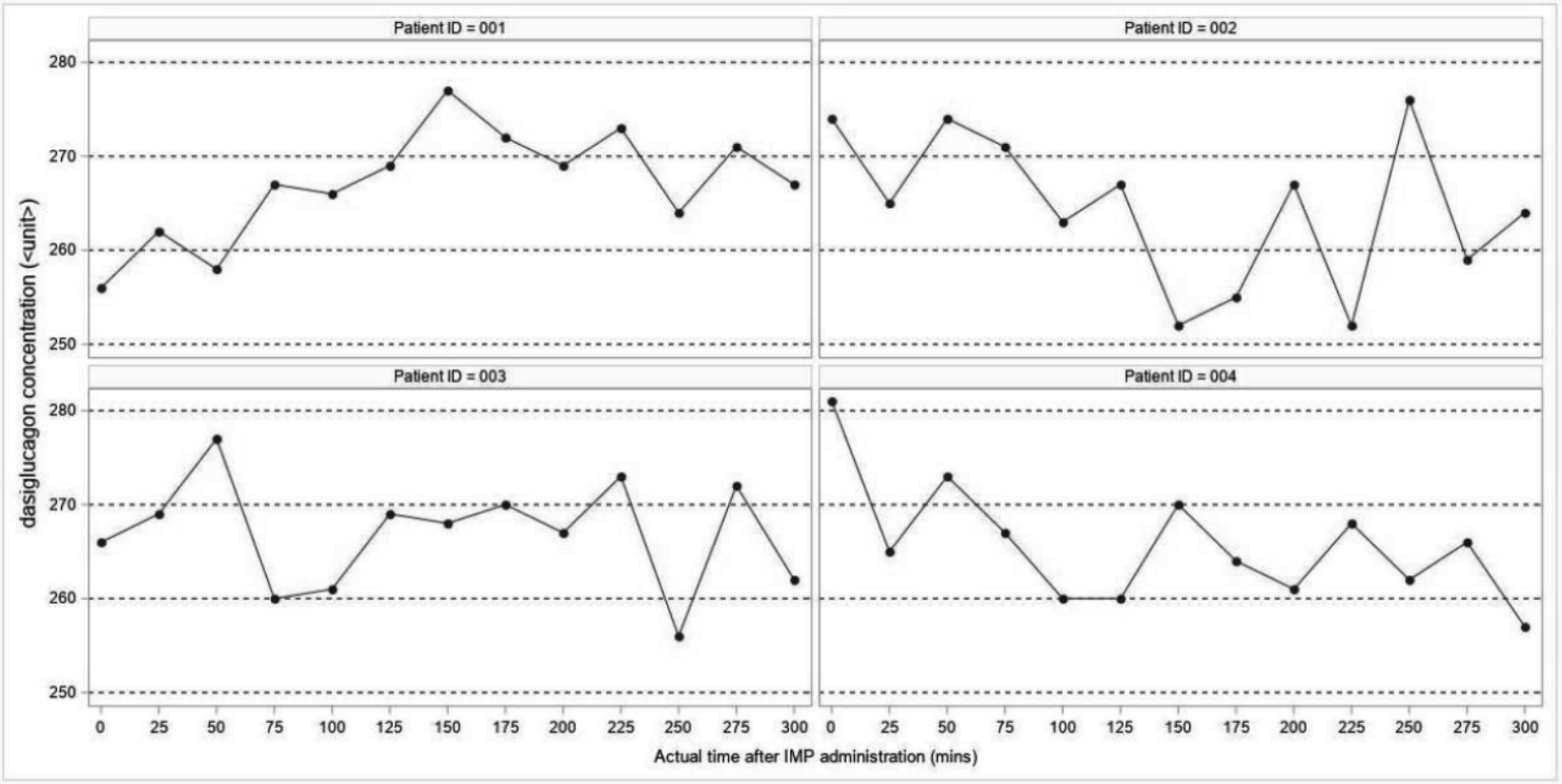


Figure 14.2.4.6 Individual dasiglucagon Concentration-time Profiles – Semi-log scale
PK Analysis Set

Type of Graph:	Individual Patient concentration-time profiles
x-Axis	See mock.
x-Axis label	Actual time after IMP administration (min)
y-Axis	Use semi-log scale Use same scaling of y axis for all patients
y-Axis Label	dasiglucagon concentration (pmol/L)
Additional Information	
Notes	Panel Plot, separate panel for each dosing group
Footnotes	IMP = investigational medicinal product For individual concentration-time profiles, the actual sampling times is used.

Programming Note:
2) Repeat of Figure 14.2.4.5 on Semi-log scale

Programming Notes:

QC dataset will consist of reproducing the results plotted.
So, produce a dataset with
- TRTP
- SUBJID
- ARELTM2
- AVAL

QC Dataset to be sorted by trtpn, subjid, areltm2

Table 14.2.4.7 Descriptive Statistics for PK Parameters
PK Analysis Set

Treatment Group= <dasiglucagon 0.3mg(N=XX)/ dasiglucagon 0.6mg(N=XX)>

Statistic	Cmax (pmol/L)	Tmax (h)	Lambda z (1/h)	T1/2 (h)	AUC (0-30mins) (unit)	AUC (0-300) (unit)	AUC (0-tlast) (unit)	AUC (0-inf) (unit)	CL/f (unit)	Vz/f (unit)	MRT (unit)
n	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Mean CV (%)	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Geometric Mean	xx, xx	-	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Geometric Mean CV (%) [a]	xx.x	-	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x

Results are displayed to 3 significant digits.
[a] Geometric CV (%) is calculated as $[\exp(SD^2)-1]^{1/2}*100$, where SD is standard deviation of the natural-log transformed data.

Source: xxx
PROGRAM SOURCE: xxx.sas, DATA CUT-OFF DATE: DDMMMYYYY RUN DATE: DDMMMYYYY hh:mm

Programming note:
1) *Extend to a 2nd page if not sufficient space to display full length of numbers*
2) *Order PK parameters per the order in Section 12.1 of the SAP.*
3) ***The geometric mean and CV% for the geometric mean will not be calculated for T_{max}***

14.3 Safety Data

14.3.1 Adverse Events

Table 14.3.1.1 Overall Summary of Adverse Events
Safety Analysis Set

Adverse Event Category [n (%) m]	dasiglucagon 0.3mg (N=XX)	dasiglucagon 0.6mg (N=XX)	Total (N=XX)
AEs that occurred during screening	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Treatment-emergent adverse events (TEAEs)	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Treatment-emergent adverse events (TEAEs) occurring within 12 hours after dosing	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
TEAEs of special interest	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
TEAEs which are other important events	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
TEAEs which are injection site reactions[a]	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
TEAEs which are related[b] to the study drug	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Serious TEAEs	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Serious TEAEs which are related to the study drug	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Adverse events leading to death	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx

n = Number of patients; m = Number of occurrences
[a] Based on investigator assessment on the eCRF
[b] Probable and possible relationships are included under the category related. In case of missing relationship will be set to related for the analysis.
Patients reporting more than 1 event are counted only once for the patient count.
Percentages are based on the total number of patients in the safety analysis set for the given dose group.
Treatment-emergence is defined as those AEs that occurred after dosing and those existing AEs that worsened during the study.

Source: xxx
PROGRAM SOURCE: xxx.sas, DATA CUT-OFF DATE: DDMMMYYYY RUN DATE: DDMMMYYYY hh:mm

Table 14.3.1.2 Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

System organ class Preferred term [n (%) m]	dasiglucagon 0.3mg (N=XX)	dasiglucagon 0.6mg (N=XX)	Total (N=XX)
Any treatment-emergent adverse events	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
System organ class 1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Preferred term 1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Preferred term 2	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Preferred term 3	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
...	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
System organ class 2	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Preferred term 1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Preferred term 2	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
...			

n = Number of patients; m = Number of events
Adverse events are coded using MedDRA version 24.1. At each level of summation (system organ class, preferred term) patients reporting more than 1 event are included only once.
Table is sorted by descending patient count, by system organ class and preferred term.
Percentages are based on the total number of patients in the safety analysis set for the given dose group.
Treatment-emergence is defined as those AEs that occurred after dosing and those existing AEs that worsened during the study.

Source: xxx

PROGRAM SOURCE: xxx.sas, DATA CUT-OFF DATE: DDMMMYYYY RUN DATE: DDMMMYYYY hh:mm

Programming Note:
1) *Percentages are based on total subject count (N) for each column*
2) *Sort by decreasing frequency of patients, by SOC and preferred term on the total column.*
3) *Any uncoded terms to be displayed under a SOC 'Uncoded' and then the verbatim term for the PT (in all capital letters) and to be sorted to appear at the bottom of the table*

Table 14.3.1.3 Treatment-Emergent Adverse Events occurring within 12 hours after dosing by System Organ Class and Preferred Term
Safety Analysis Set

n = Number of patients; m = Number of events
Adverse events are coded using MedDRA version 24.1. At each level of summation (system organ class, preferred term) patients reporting more than 1 event are included only once.
Table is sorted by descending patient count, by system organ class and preferred term.
Percentages are based on the total number of patients in the safety analysis set for the given dose group.
Treatment-emergence is defined as those AEs that occurred after dosing and those existing AEs that worsened during the study.

Source: xxx
PROGRAM SOURCE: xxx.sas, DATA CUT-OFF DATE: DDMMMYYYY RUN DATE: DDMMMYYYY hh:mm

Programming Note:

1) *Repeat of table 14.3.1.2 for treatment-emergent adverse events that occurred within 12 hours after dosing only.*
2) *Percentages are based on total subject count (N) for each column*
3) *Sort by decreasing frequency of patients, by SOC and preferred term on the total column.*
4) *Any uncoded terms to be displayed under a SOC 'Uncoded' and then the verbatim term for the PT (in all capital letters) and to be sorted to appear at the bottom of the table*

Table 14.3.1.4 Adverse Events that occurred during Screening, by System Organ Class and Preferred Term
Safety Analysis Set

n = Number of patients; m = Number of events
Adverse events are coded using MedDRA version 24.1. At each level of summation (system organ class, preferred term) patients reporting more than 1 event are included only once.
Table is sorted by descending patient count, by system organ class and preferred term.
Percentages are based on the total number of patients in the safety analysis set for the given dose group.

Source: xxx
PROGRAM SOURCE: xxx.sas, DATA CUT-OFF DATE: DDMMMYYYY RUN DATE: DDMMMYYYY hh:mm

Programming Note:

5) *Repeat of table 14.3.1.2 for adverse events that occurred during screening only.*
6) *Percentages are based on total subject count (N) for each column*
7) *Sort by decreasing frequency of patients, by SOC and preferred term on the total column.*
8) *Any uncoded terms to be displayed under a SOC 'Uncoded' and then the verbatim term for the PT (in all capital letters) and to be sorted to appear at the bottom of the table*
9) *Set first row in table to 'Any adverse events' instead of 'Any treatment-emergent adverse events'.*

Table 14.3.1.5 Treatment-Emergent Adverse Events of Special Interest, by System Organ Class and Preferred Term
Safety Analysis Set

n = Number of patients; m = Number of events
Adverse events are coded using MedDRA version 24.1. At each level of summation (system organ class, preferred term) patients reporting more than 1 event are included only once.
Table is sorted by descending patient count, by system organ class and preferred term.
Percentages are based on the total number of patients in the safety analysis set for the given dose group.
Treatment-emergence is defined as those AEs that occurred after dosing and those existing AEs that worsened during the study.

Source: xxx
PROGRAM SOURCE: xxx.sas, DATA CUT-OFF DATE: DDMMMYYYY RUN DATE: DDMMMYYYY hh:mm

Programming Note:

1) *Repeat of table 14.3.1.2 for treatment-emergent adverse events of special interest only.*
2) *Percentages are based on total subject count (N) for each column*
3) *Sort by decreasing frequency of patients, by SOC and preferred term on the total column.*
4) *Any uncoded terms to be displayed under a SOC 'Uncoded' and then the verbatim term for the PT (in all capital letters) and to be sorted to appear at the bottom of the table*

Table 14.3.1.6 Treatment-Emergent Adverse Events that are Other Important Events, by System Organ Class and Preferred Term
Safety Analysis Set

n = Number of patients; m = Number of events
Adverse events are coded using MedDRA version 24.1. At each level of summation (system organ class, preferred term) patients reporting more than 1 event are included only once.
Table is sorted by descending patient count, by system organ class and preferred term.
Percentages are based on the total number of patients in the safety analysis set for the given dose group.
Treatment-emergence is defined as those AEs that occurred after dosing and those existing AEs that worsened during the study.

Source: xxx
PROGRAM SOURCE: xxx.sas, DATA CUT-OFF DATE: DDMMMYYYY RUN DATE: DDMMMYYYY hh:mm

Programming Note:

1) *Repeat of table 14.3.1.2 for treatment-emergent adverse events that are other important events only.*
2) *Percentages are based on total subject count (N) for each column*
3) *Sort by decreasing frequency of patients, by SOC and preferred term on the total column.*
4) *Any uncoded terms to be displayed under a SOC 'Uncoded' and then the verbatim term for the PT (in all capital letters) and to be sorted to appear at the bottom of the table*

Table 14.3.1.7 Treatment-Emergent Adverse Events that are Injection Site Reactions, by System Organ Class and Preferred Term
Safety Analysis Set

n = Number of patients; m = Number of events
Adverse events are coded using MedDRA version 24.1. At each level of summation (system organ class, preferred term) patients reporting more than 1 event are included only once.
Table is sorted by descending patient count, by system organ class and preferred term.
Percentages are based on the total number of patients in the safety analysis set for the given dose group.
Treatment-emergence is defined as those AEs that occurred after dosing and those existing AEs that worsened during the study.

Source: xxx
PROGRAM SOURCE: xxx.sas, DATA CUT-OFF DATE: DDMMMYYYY RUN DATE: DDMMMYYYY hh:mm

Programming Note:

1) *Repeat of table 14.3.1.2 for treatment-emergent adverse events that are injection site reactions.*
2) *Percentages are based on total subject count (N) for each column*
3) *Sort by decreasing frequency of patients, by SOC and preferred term on the total column.*
4) *Any uncoded terms to be displayed under a SOC 'Uncoded' and then the verbatim term for the PT (in all capital letters) and to be sorted to appear at the bottom of the table*

Table 14.3.1.8 Treatment-Emergent Adverse Events that are IMP Related, by System Organ Class and Preferred Term
Safety Analysis Set

n = Number of patients; m = Number of events; IMP = investigational medicinal product
IMP related: Adverse events which were assessed by the investigator with a reported relationship to IMP of 'Possible' or 'Probable'.
Adverse events are coded using MedDRA version 24.1. At each level of summation (system organ class, preferred term) patients reporting more than 1 event are included only once.
Table is sorted by descending patient count, by system organ class and preferred term.
Percentages are based on the total number of patients in the safety analysis set for the given dose group.
Treatment-emergence is defined as those AEs that occurred after dosing and those existing AEs that worsened during the study.

Source: xxx
PROGRAM SOURCE: xxx.sas, DATA CUT-OFF DATE: DDMMMYYYY RUN DATE: DDMMMYYYY hh:mm

Programming Note:

1) *Repeat of table 14.3.1.2 for treatment-emergent adverse events with a reported relationship to study treatment of 'Possible' or 'Probable'.*
2) *Percentages are based on total subject count (N) for each column*
3) *Sort by decreasing frequency of patients, by SOC and preferred term on the total column.*
4) *Any uncoded terms to be displayed under a SOC 'Uncoded' and then the verbatim term for the PT (in all capital letters) and to be sorted to appear at the bottom of the table*

Table 14.3.1.9 Serious Treatment-Emergent Adverse Events, by System Organ Class and Preferred Term
Safety Analysis Set

n = Number of patients; m = Number of events
Adverse events are coded using MedDRA version 24.1. At each level of summation (system organ class, preferred term) patients reporting more than 1 event are included only once.
Table is sorted by descending patient count, by system organ class and preferred term.
Percentages are based on the total number of patients in the safety analysis set for the given dose group.
Treatment-emergence is defined as those AEs that occurred after dosing and those existing AEs that worsened during the study.

Source: **xxx**
PROGRAM SOURCE: **xxx.sas**, DATA CUT-OFF DATE: DDMMMYYYY RUN DATE: DDMMMYYYY hh:mm

Programming Note:

1) *Repeat of table 14.3.1.2 for serious treatment-emergent adverse events.*
2) *Percentages are based on total subject count (N) for each column*
3) *Sort by decreasing frequency of patients, by SOC and preferred term on the total column.*
4) *Any uncoded terms to be displayed under a SOC 'Uncoded' and then the verbatim term for the PT (in all capital letters) and to be sorted to appear at the bottom of the table*
5) *Set first row in table to 'Any serious treatment-emergent adverse events' instead of 'Any treatment-emergent adverse events'.*
6)

Table 14.3.1.10 Serious Treatment-Emergent Adverse Events that are IMP Related, by System Organ Class and Preferred Term
Safety Analysis Set

n = Number of patients; m = Number of events; IMP = investigational medicinal product
IMP related: Adverse events which were assessed by the investigator with a reported relationship to IMP of 'Possible' or 'Probable'.
Adverse events are coded using MedDRA version 24.1. At each level of summation (system organ class, preferred term) patients reporting more than 1 event are included only once.
Table is sorted by descending patient count, by system organ class and preferred term.
Percentages are based on the total number of patients in the safety analysis set for the given dose group.
Treatment-emergence is defined as those AEs that occurred after dosing and those existing AEs that worsened during the study.

Source: xxx
PROGRAM SOURCE: xxx.sas, DATA CUT-OFF DATE: DDMMMYYYY RUN DATE: DDMMMYYYY hh:mm

Programming Note:

1) *Repeat of table 14.3.1.2 for serious treatment-emergent adverse events with a reported relationship to study treatment of 'Possible' or 'Probable'.*
2) *Percentages are based on total subject count (N) for each column*
3) *Sort by decreasing frequency of patients, by SOC and preferred term on the total column.*
4) *Any uncoded terms to be displayed under a SOC 'Uncoded' and then the verbatim term for the PT (in all capital letters) and to be sorted to appear at the bottom of the table*

Table 14.3.1.11 Local Tolerability Assessment
Safety Analysis Set

Treatment Group= <dasiglucagon 0.3mg(N=XX)/ dasiglucagon 0.6mg(N=XX)>Time point	Type of Reaction	Mild	Moderate	Severe	Total
Dosing: 30 minutes post dose	Spontaneous Pain	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	Pain On Palpation	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	Itching	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	Redness	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	Edema	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	Induration/Infiltration	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	Other	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Dosing: 120 minutes post dose	Spontaneous Pain	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	Pain On Palpation	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	Itching	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	Redness	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	Edema	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	Induration/Infiltration	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	Other	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Dosing: 300 minutes post dose	Spontaneous Pain	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	Pain On Palpation	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	Itching	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	Redness	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	Edema	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	Induration/Infiltration	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	Other	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Follow-up	Spontaneous Pain	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	Pain On Palpation	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	Itching	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	Redness	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	Edema	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	Induration/Infiltration	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	Other	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)

Percentages are based on the number of patients who had a local tolerability assessment at that timepoint.

Source: **xxx**
PROGRAM SOURCE: **xxx.sas**, DATA CUT-OFF DATE: DDMMMYYYY RUN DATE: DDMMMYYYY hh:mm

Programming Note:
1) Only display 'Other' rows where there are counts populated.

14.3.2 Listings of Deaths, Other Serious and Significant Adverse Events

Listing 14.3.2.1 Serious Adverse Events
Safety Analysis Set

Treatment Group - Patient ID	AE #	TE-AE[a]	System Organ Class/ Preferred Term/ Verbatim Term	Start Date Time (Study Day[b])/ End Date Time (Study Day[b])	Severity/ Causality	Action Taken with Study Treatment	Outcome	AESI[c]/ Other Important Event?	Type of Other Important Event[d]	Hypo.[e]?	Plasma Glucose Start Time	Plasma Glucose Source	Plasma Glucose Value (unit)
xxxx	xx	Y/ N	xxxx/ xxxx/ xxxx	YYYY-MM-DDTHH:MM (Day XX)/ YYYY-MM-DDTHH:MM (Day XX)	Mild/ Possible	Dose Reduced	Unknown	N/ Y	Infection/ Overdose/ Abuse or misuse/ Error/ Accidental exposure/ Risk of liver injury	Y	HH:MM	xxxxxx	xxx (xxx)
				YYYY-MM-DD (Day XX)/ UNKNOWN									

Programming note:
1) This shell continues over two pages

Listing 14.3.2.1 Serious Adverse Events
Safety Analysis Set

Treatment Group - Patient ID	AE #	TE-AE[a]	System Organ Class/ Preferred Term/ Verbatim Term	Start Date Time (Study Day[b])/ End Date (Study Day[b])	Serious Criteria Met					
					Congenital Anomaly or Birth Defect	Significant Disability	Death	Hospitalization or Prolongation of Hospitalization	Life Threatening	Other Serious Important Medical Event
xxxx	xx	Y/ N	xxxx/ xxxx/ xxxx	YYYY-MM-DDTHH:MM (XX)/ YYYY-MM-DD (XX) YYYY-MM-DD (XX)/ ONGOING	Y/N	Y/N	Y/N	Y/N	Y/N	Y:xxxxxx

[a] TEAE: Treatment-emergent AE
[b] Study day is derived relative to the date/time of start of study drug administration.
[c] AESI: AE of special interest
[d] Infection=Suspicion of transmission of infectious agents via the trial product; Overdose=Overdose of the trial product; Abuse or misuse=Suspected abuse or misuse of the trial product; Error=Medication error involving the trial product; Accidental exposure=Inadvertent or accidental exposure to the trial product; Risk of liver injury=Risk of liver injury defined as ALT or AST > 3 x ULN and total bilirubin > 2 x ULN, where no alternative etiology exists;
[e] Hypoglycemia Episode?
Adverse events are coded using MedDRA version 24.1.

PROGRAM SOURCE: xxx.sas, DATA CUT-OFF DATE: DDMMMYYYY RUN DATE: DDMMMYYYY hh:mm

Programming note:
1) This shell continues over two pages
2) Sort by patient, start date and end date.

Listing 14.3.2.2 Adverse Events Leading to Death
Safety Analysis Set

[a] TEAE: Treatment-emergent AE
[b] Study day is derived relative to the date/time of start of study drug administration.
[c] AESI: AE of special interest
[d] Infection=Suspicion of transmission of infectious agents via the trial product; Overdose=Overdose of the trial product; Abuse or misuse=Suspected abuse or misuse of the trial product; Error=Medication error involving the trial product; Accidental exposure=Inadvertent or accidental exposure to the trial product; Risk of liver injury=Risk of liver injury defined as ALT or AST > 3 x ULN and total bilirubin > 2 x ULN, where no alternative etiology exists;
[e] Hypoglycemia Episode?
Adverse events were coded using MedDRA version 24.1.

PROGRAM SOURCE: **xxx.sas**, DATA CUT-OFF DATE: DDMMMYYYY RUN DATE: DDMMMYYYY hh:mm

Programming note:
1) Repeat Listing 14.3.2.1 for records where 'Outcome' = 'Fatal'.
2) Sort by patient, start date and end date.

14.3.3 Narratives of Deaths, Other Serious and Certain Other Significant Adverse Events

Please refer to section 12.3.2 of the CSR

PROGRAM SOURCE: tlf-###, DATA CUT-OFF DATE: DDMMMYYYY RUN DATE: DDMMMYYYY hh:mm

Programming Note: Create an empty table using the %nodata macro with that reference as message

14.3.4 Abnormal Laboratory Value Listing (Each Patient)

Listing 14.3.4.1 Abnormal Laboratory Values
Safety Analysis Set

Treatment Group - Patient ID	Category	Parameter (unit)	Visit[a]	Date/Time of Collection (Study Day[b])	Result[c]	Change from Baseline	Normal Range
xxxx	Hematology	xxxx	Screening (BL)	YYYY-MM-DDTHH:MM (Day XX)	xxxx (L)	xxxx	xx-xx
			Follow-up	YYYY-MM-DDTHH:MM (Day XX)	xxxx (H)		xx-xx
		xxxx	Screening				

[a] BL: Baseline Flag
[b] Study day is derived relative to the date/time of start of study drug administration.
[c] L: Below Normal Range, H: Above Normal Range

PROGRAM SOURCE: xxx.sas, DATA CUT-OFF DATE: DDMMMYYYY RUN DATE: DDMMMYYYY hh:mm

Programming Note:
1) ***Only display Abnormal lab results (i.e. where the result does not fall within the normal range)***
2) ***Sort by Patient, category (Hematology, chemistry, then coagulation), parameter and date/time***
3) ***After each parameter add a blank line***

14.3.5 Extent of Exposure

Table 14.3.5.1 Hypoglycemia Induction Procedure
Safety Analysis Set

	dasiglucagon 0.3mg (N=XX)	dasiglucagon 0.6mg (N=XX)	Total (N=XX)
Hypoglycemia induction procedure performed?			
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
MDI User: Duration between last basal dose before the hypoglycemia procedure and time when hypoglycemia procedure was initiated (min)			
n	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
Pump User: Duration between stop of insulin pump and time when hypoglycemia procedure was initiated (min)			
n	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
Total amount of insulin administered to induce hypoglycemia (IU)			
n	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
Glucose administered intravenously prior to dosing?			
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Total amount of glucose administered (mL)			
n	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx

	dasiglucagon 0.3mg (N=XX)	dasiglucagon 0.6mg (N=XX)	Total (N=XX)
Rescue IV Glucose given after dosing?			
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Time to first IV glucose infusion (min)			
n	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx

Time to first IV glucose infusion (min): Time of start of first glucose administration - Time of administration of study medication.

Source: xxx
PROGRAM SOURCE: xxx.sas, DATA CUT-OFF DATE: DDMMMYYYY RUN DATE: DDMMMYYYY hh:mm

14.3.6 Other Safety Data

Figure 14.3.6.1 Continuous Glucose Monitoring - Individual Glucose Concentration-time Profiles
Safety Analysis Set

Type of Graph:	Individual Patient concentration-time profiles
x-Axis	Actual time from the time of stopping patient's insulin pump (h)
x-Axis label	Actual time from the time of stopping patient's insulin pump (h)
y-Axis	Use linear scale Use same scaling of y axis for all patients
y-Axis Label	Glucose concentration (mg/dL) Secondary y axis: mmol/L Results are converted into the unit 'mmol/L' by using the conversion factor 0.0555 (i.e. Glucose [mmol/L]=Glucose [mg/dL] *0.0555).
Additional Information	**See next page for mock.**
Notes	Panel Plot, **separate panel for each dosing group. One page per subject.**
Footnotes	Glucose-time profiles based on continuous glucose monitoring from the time of stopping the patient's insulin pump to 300 minutes after dasiglucagon administration.

Programming Notes:

QC dataset will consist of reproducing the results plotted.
So, produce a dataset with
- TRTP
- USUBJID
- ARELTM
- AVAL (where PARAMCD=GLUCMG)
- AVAL (where PARAMCD=GLUCMOL)

QC Dataset to be sorted by trtpn, usubjid, areltm

Treatment=dasiglucagon 0.3mg

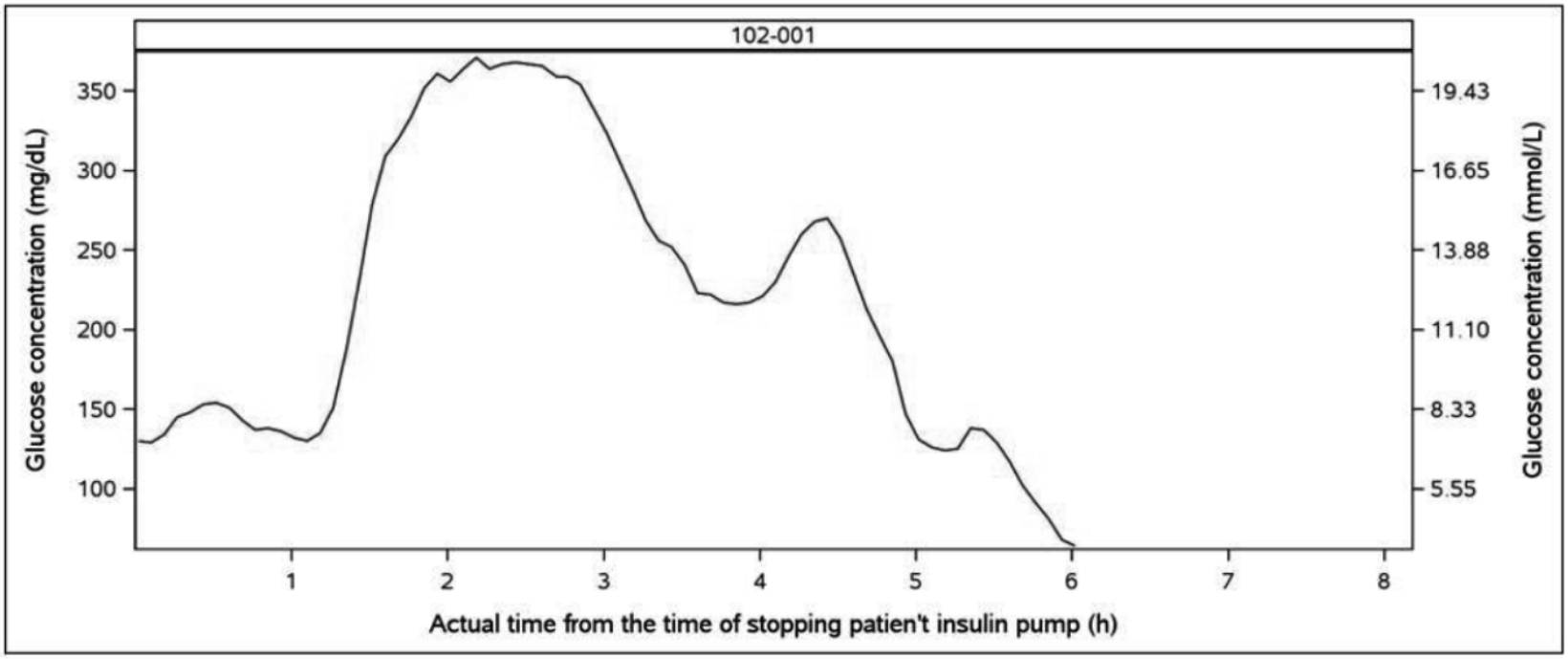


Figure 14.3.6.2 Glucose Analyser Data- Individual Glucose Concentration-time Profiles
Safety Analysis Set

Type of Graph:	Individual Patient concentration-time profiles
x-Axis	Relative time from start of first dosing of IMP
x-Axis label	Actual time from the time of first dosing (min)
y-Axis	Use linear scale Use same scaling of y axis for all patients
y-Axis Label	Glucose Analyser concentration (mg/dL)
Additional Information	Similar layout as plot as figure 14.3.6.1 using Glucose analyser data and only one y-axis
Notes	Panel Plot, **separate panel for each dosing group**
Footnotes	Glucose-time profiles based on Glucose Analyser Data.

Programming Notes:

QC dataset will consist of reproducing the results plotted.
So, produce a dataset with
- TRTP
- USUBJID
- ARELTM
- AVAL

QC Dataset to be sorted by trtpn, usubjid, areltm

17.1.1.1 14.3.6.3 Laboratory Data

Table 14.3.6.3.1 Hematology Results
Safety Analysis Set

Lab parameter (unit) Time point	dasiglucagon 0.3mg (N=XX)		dasiglucagon 0.6mg (N=XX)		Total (N=XX)	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Lab parameter (unit)						
Baseline						
n	xx		xx		xx	
Mean (SD)	xx.x (xx.xx)		xx.x (xx.xx)		xx.x (xx.xx)	
Median	xx.x		xx.x		xx.x	
Min, Max	xx, xx		xx, xx		xx, xx	
Follow-up						
n	xx	xx	xx	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
...						

Baseline is the last assessment prior to study drug administration.

Source: xxx
PROGRAM SOURCE: xxx.sas, DATA CUT-OFF DATE: DDMMMYYYY RUN DATE: DDMMMYYYY hh:mm

Programming Note:
2) In general present mean to 1 decimal more than individual data, STD to 2 decimals more than individual data. Refer to SAP
3) Order parameters alphabetically

Table 14.3.6.3.2 Hematology Results – Reference Range Analysis
Safety Analysis Set

Lab parameter (unit) Time point	dasiglucagon 0.3mg (N=XX)	dasiglucagon 0.6mg (N=XX)	Total (N=XX)
Lab parameter (unit)			
Baseline			
Low	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
High	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Follow-up			
Low	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
High	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
...			

Baseline is the last assessment prior to study drug administration.

Source: xxx
PROGRAM SOURCE: xxx.sas, DATA CUT-OFF DATE: DDMMMYYYY RUN DATE: DDMMMYYYY hh:mm

Programming Note:
1) Summarize the counts and percentages of the results above/below/within the reference range, for each parameter at each visit.

Table 14.3.6.3.3 Chemistry Results
Safety Analysis Set

Baseline is the last assessment prior to study drug administration.
Results reported as below the detection limit are set to missing in this table.

Source: xxx
PROGRAM SOURCE: xxx.sas, DATA CUT-OFF DATE: DDMMMYYYY RUN DATE: DDMMMYYYY hh:mm

Programming Note:

3) *Repeat of Table 14.3.6.3.1 for Chemistry parameters*
4) *In general present mean to 1 decimal more than individual data, STD to 2 decimals more than individual data. Refer to SAP*
5) *Order parameters alphabetically*

Table 14.3.6.3.4 Chemistry Results – Reference Range Analysis
Safety Analysis Set

Baseline is the last assessment prior to study drug administration.

Source: xxx
PROGRAM SOURCE: xxx.sas, DATA CUT-OFF DATE: DDMMMYYYY RUN DATE: DDMMMYYYY hh:mm

Programming Note:
1) *Repeat of Table 14.3.6.3.2 for Chemistry parameters*
2) *Summarize the counts and percentages of the results above/below/within the reference range, for each parameter at each visit.*

Table 14.3.6.3.5 Coagulation Results
Safety Analysis Set

Baseline is the last assessment prior to study drug administration.

Source: xxx
PROGRAM SOURCE: xxx.sas, DATA CUT-OFF DATE: DDMMMYYYY RUN DATE: DDMMMYYYY hh:mm

Programming Note:
1) *Repeat of Table 14.3.6.3.1 for Chemistry parameters*
2) *In general present mean to 1 decimal more than individual data, STD to 2 decimals more than individual data. Refer to SAP*
3) *Order parameters alphabetically*

Table 14.3.6.3.6 Coagulation Results – Reference Range Analysis
Safety Analysis Set

Baseline is the last assessment prior to study drug administration.

Source: xxx
PROGRAM SOURCE: xxx.sas, DATA CUT-OFF DATE: DDMMMYYYY RUN DATE: DDMMMYYYY hh:mm

Programming Note:
1) Repeat of Table 14.3.6.3.3 for Chemistry parameters
2) Summarize the counts and percentages of the results above/below/within the reference range, for each parameter at each visit.

Table 14.3.6.3.7 Immunogenicity
Safety Analysis Set

	dasiglucagon 0.3mg (N=XX)	dasiglucagon 0.6mg (N=XX)	Total (N=XX)
Occurrence of ADA			
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Missing	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Overall ADA including treatment-induced ADA and treatment-boosted ADA.
Percentages is derived from patients having an ADA assessment.

Source: xxx
PROGRAM SOURCE: xxx.sas, DATA CUT-OFF DATE: DDMMMYYYY RUN DATE: DDMMMYYYY hh:mm

Table 14.3.6.4 Vital Signs
Safety Analysis Set

Vital signs parameter (unit) Time point	dasiglucagon 0.3mg (N=XX)		dasiglucagon 0.6mg (N=XX)		Total (N=XX)	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Vital signs parameter (unit)						
Screening						
n	xx		xx		xx	
Mean (SD)	xx.x (xx.xx)		xx.x (xx.xx)		xx.x (xx.xx)	
Median	xx.x		xx.x		xx.x	
Min, Max	xx, xx		xx, xx		xx, xx	
Baseline						
n	xx		xx		xx	
Mean (SD)	xx.x (xx.xx)		xx.x (xx.xx)		xx.x (xx.xx)	
Median	xx.x		xx.x		xx.x	
Min, Max	xx, xx		xx, xx		xx, xx	
Dosing: 30 minutes post-dose						
n	xx	xx	xx	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
...						
Interpretation						
Baseline						
Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Abnormal (NCS)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Abnormal (CS)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
...						

Baseline is the last assessment prior to study drug administration.

Percentages are based on the total number of patients in the safety analysis set.

Source: **xxx**
PROGRAM SOURCE: **xxx.sas**, DATA CUT-OFF DATE: DDMMMYYYY RUN DATE: DDMMMYYYY hh:mm

Programming Note:

1) *In general present mean to 1 decimal more than individual data, STD to 2 decimals more than individual data.*
2) *Order parameters as follows: Height, Weight, BMI, Temperature, Systolic BP, Diastolic BP, Pulse, Interpretation.*
3) *Continue for each parameter at screening, baseline and each post-baseline assessment*
4) *Start a new page after each parameter*

Table 14.3.6.5 ECG Data
Safety Analysis Set

ECG parameter (unit) Time point	dasiglucagon 0.3mg (N=XX)	dasiglucagon 0.6mg (N=XX)	Total (N=XX)
ECG parameter (unit)			
Screening			
n	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
...			
Interpretation			
Screening			
Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Abnormal (NCS)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Abnormal (CS)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
...			

Percentages are based on the total number of patients in the safety analysis set.

Source: xxx
PROGRAM SOURCE: xxx.sas, DATA CUT-OFF DATE: DDMMMYYYY RUN DATE: DDMMMYYYY hh:mm

Programming Note:
1) *In general present mean to 1 decimal more than individual data, STD to 2 decimals more than individual data.*
2) *Order parameters as follows: Mean* Heart Rate, PR Interval, QRS, QT, QTc, QTcF, and Interpretation.

Appendix C2: Study-Specific Shells for Section 16.2

16.2. Patient Data Listings

16.2.1 Discontinued Patients

Listing 16.2.1.1 Patient Disposition
All Patients

Treatment Group	Patient ID	Enrolled Set[a]	Safety Analysis Set[b]	Full Analysis Set[c]	PK Analysis Set[d]	Date/Time at Start of Dosing	Completed Study	Completion or Discontinuation Date	Primary Reason for Discontinuation from Study
Xxxx	xxxx	Yes/No	Yes/No	Yes/No	Yes/No	YYYY-MM-DDTHH:MM	Yes/No	YYYY-MM-DD	xxxxxxxxxx

[a] Requires parent's/legal guardian's agreement for the child to participate in a clinical trial following completion of the informed consent process and further that the child is screened and found eligible for the trial.
[b] All patients who were enrolled and received at least 1 dose of study drug.
[c] All patients of the safety analysis set.
[d] All patients with at least one quantifiable plasma concentration.

Source: xxx
PROGRAM SOURCE: xxx.sas, DATA CUT-OFF DATE: DDMMMYYYY RUN DATE: DDMMMYYYY hh:mm

Programming Note:
1) Sort by Treatment group and Patient ID

16.2.2 Protocol Deviations

Listing 16.2.2.1 Protocol Deviations
Safety Analysis Set

Treatment Group	Patient ID	Category for Protocol Deviation	Protocol Deviation Coded Term	Protocol Deviation Term
xxxx	xxxx	xxxx	xxxx	xxxx

This listing displays all study protocol deviations that are not COVID-19 related.

Source: xxx
PROGRAM SOURCE: xxx.sas, DATA CUT-OFF DATE: DDMMMYYYY RUN DATE: DDMMMYYYY hh:mm

Programming Note:

1) *Sort by Treatment group and Patient ID*
2) *Exclude COVID-19 related protocol deviations*
3) *SHELL ID: LPDEVV1*

Listing 16.2.2.2 COVID-19 Related Protocol Deviations
Safety Analysis Set

Treatment Group	Patient ID	Category for Protocol Deviation	Protocol Deviation Coded Term	Protocol Deviation Term
xxxx	xxxx	xxxx	xxxx	xxxx

This listing displays all study protocol deviations that are COVID-19 related.

Source: xxx
PROGRAM SOURCE: xxx.sas, DATA CUT-OFF DATE: DDMMMYYYY RUN DATE: DDMMMYYYY hh:mm

Programming Note:

1) *Sort by Treatment group and Patient ID*
2) *Include COVID-19 related protocol deviations only*
3) *SHELL ID: LPDEVV1*

Listing 16.2.2.3 Patients not Fulfilling at least one Inclusion/Exclusion Criteria
All Screened Patients

Treatment Group	Patient ID	Date/Time of Informed Consent	Inclusion/Exclusion Criterion Short Name	Inclusion/Exclusion Criterion
xxxx	xxxx	YYYY-MM-DD	INCL2 / EXCL3	xxxxxxxxxx

Source: xxx
PROGRAM SOURCE: xxx.sas, DATA CUT-OFF DATE: DDMMMYYYY RUN DATE: DDMMMYYYY hh:mm

Programming Note:
1) Sort by treatment group and patient

16.2.3 Patients Excluded from the Analysis

Listing 16.2.3.1 Patients Excluded from Analysis
All Enrolled Patients

Treatment Group	Patient ID	Excluded from Safety Analysis Set	Reason for Exclusion from Safety Analysis Set	Excluded from Full Analysis Set	Reason for Exclusion from Full Analysis Set	Excluded from PK Analysis Set	Reason for Exclusion from PK Analysis Set
xxxx	xxxx	Yes/No	xxxxxxxxxxxx	Yes/No	xxxxxxxxxxxx	Yes/No	xxxxxxxxxxxx

Source: xxx
PROGRAM SOURCE: xxx.sas, DATA CUT-OFF DATE: DDMMMYYYY RUN DATE: DDMMMYYYY hh:mm

Programming Note:
1) Sort by treatment group and patient

16.2.4 Demographic Data

Listing 16.2.4.1 Demographic and Baseline Characteristics
Safety Analysis Set

Treatment Group	Patient ID	Re-screened Patient?: Previous Patient ID	Date/Time of Informed Consent	Date of Birth	Age (years)	Sex	Ethnicity	Race	Date of Diabetes Diagnosis	Protocol Version Originally Consented to
xxxx	xxxx	Y: xxxxx N	YYYY-MM-DD	YYYY-MM-DD	xxx	Male/ Female/ Unknown/ Undifferentiated	Hispanic or Latino/ Not Hispanic or Latino/ Not Reported/ Not Allowed to Ask per Local Regulation	xxxxxx	YYYY-MM-DD	xxxxxxxxxx

Source: xxx
PROGRAM SOURCE: xxx.sas, DATA CUT-OFF DATE: DDMMMYYYY RUN DATE: DDMMMYYYY hh:mm

Programming Note:
1) Sort by treatment group and patient

Listing 16.2.4.2 Medical History
Safety Analysis Set

Treatment Group	Patient ID	Reported Term/ MedDRA Preferred Term	Body System or System Organ Class	Start Date of Medical History Event	End Date of Medical History Event	End Relative to Reference Period
				YYYY-MM-DD/ Unknown	YYYY-MM-DD/ Unknown	
xxxx	xxxx	xxxx	xxxx			ONGOING

Terms are coded using MedDRA, version 24.1.

Source: xxx
PROGRAM SOURCE: xxx.sas, DATA CUT-OFF DATE: DDMMMYYYY RUN DATE: DDMMMYYYY hh:mm

Programming Note:
1) Sort by treatment group, patient and start date

Listing 16.2.4.3 Prior and Concomitant Medications
Safety Analysis Set

Treatment Group	Patient ID	CM#	P/C	Medication Name/ Preferred Name	Start Date (Study Day)	End Date (Study Day)	Dose (unit)	Route of Administration	Infusion Rate (mg/min)	Frequency	Indication (Event ID/Specify)
xxxx	xxxxx	xx	P/C	xxxxx/ xxxxx	YYYY-MM-DD (Day XX)	YYYY-MM-DD (Day XX) ONGOING	xxxx (xx)	xxxxxxx	xxx NA	xxxx	Medical History (X) Adverse Event (X) Other (xxxxx)

P: Prior medication C: Concomitant medication, #= number.
Study day is derived relative to the date/time of start of study drug administration.
Terms are coded using WHODrug Global B3 format, Sep2021 release.

Source: xxx
PROGRAM SOURCE: xxx.sas, DATA CUT-OFF DATE: DDMMMYYYY RUN DATE: DDMMMYYYY hh:mm

Programming note:
1) Sort by treatment group, patient and CM#
2) Study day is derived relative to the date/time of start of study drug administration.

Listing 16.2.4.4 Current Diabetes Treatment
Safety Analysis Set

Treatment Group	Patient ID	Diabetes Medication/ Preferred Name	Start Date (Study Day)	Dose (unit)	Route of Administration
xxxx	xxxxx	xxxxx/ xxxxx	YYYY-MM-DD (Day XX)	xxxx (xx)	xxxxxxx

Study day is derived relative to the date/time of start of study drug administration.
Terms are coded using WHODrug Global B3 format, Sep2021 release.

Source: xxx
PROGRAM SOURCE: xxx.sas, DATA CUT-OFF DATE: DDMMMYYYY RUN DATE: DDMMMYYYY hh:mm

Programming note:
1) *Sort by treatment group, patient and CM#*
2) *Study day is derived relative to the date/time of start of study drug administration.*

16.2.5 Compliance and/or Drug Concentration Data

Listing 16.2.5.1 Study Drug Administration
Safety Analysis Set

Treatment Group	Patient ID	Was Dasiglucagon Admnistered?	Reason Not Administered	Study Treatment Label Identifier (DUN)/ Lot Number	Dosing Date/Time	Dose (unit)	Route of Administration	Location
xxxx	xxxxx	Yes/ No	xxxxxxxxx	xxxxx/ xxxx	YYYY-MM-DD/HH:MM	xxx (xx)	Subcutaneous injection	Buttock xxxxxxx

Source: xxx
PROGRAM SOURCE: xxx.sas, DATA CUT-OFF DATE: DDMMMYYYY RUN DATE: DDMMMYYYY hh:mm

Programming note:
1) Sort by treatment group and patient number

Listing 16.2.5.2 Diabetes treatment prior hypoglycemia induction - MDI user
Safety Analysis Set

Treatment Group	Patient ID	Date/ Time of last basal dose before the Hypoglycemia procedure	Dose of last basal dose (IU)	Reduction of last basal dose compared to the dose before (%)
xxxx	xxxxx	YYYY-MM-DDTHH:MM	Xxxxx	Xxxxx

Source: xxx
PROGRAM SOURCE: xxx.sas, DATA CUT-OFF DATE: DDMMMYYYY RUN DATE: DDMMMYYYY hh:mm

Programming note:
1) Sort by treatment group and patient number

Listing 16.2.5.3 Diabetes treatment prior hypoglycemia induction - meal-time/ bolus insulins
Safety Analysis Set

Treatment Group	Patient ID	Bolus Insulin name	Date/Time of bolus(es) within 8 hours before Hypoglycemia procedure	Dose of last bolus dose within 8 hours before Hypoglycemia procedure (enter 0 if none given):
xxxx	xxxxx	Xxxx	YYYY-MM-DDTHH:MM	xxxx

Source: xxx
PROGRAM SOURCE: xxx.sas, DATA CUT-OFF DATE: DDMMMYYYY RUN DATE: DDMMMYYYY hh:mm

Programming note:
1) Sort by treatment group and patient number

Listing 16.2.5.4 Diabetes treatment prior hypoglycemia induction - pump user
Safety Analysis Set

Treatment Group	Patient ID	Insulin brand name	Date/Time of stopping insulin pump before initiation of Hypoglycemia procedure	Total amount of insulin infused 6 hours before initiating Hypoglycemia procedure (IU)
xxxx	xxxxx	Xxxx	YYYY-MM-DDTHH:MM	xxxx

Source: xxx
PROGRAM SOURCE: xxx.sas, DATA CUT-OFF DATE: DDMMMYYYY RUN DATE: DDMMMYYYY hh:mm

Programming note:
1) Sort by treatment group and patient number

Listing 16.2.5.5 Hypoglycemia Induction Procedure
Safety Analysis Set

			Insulin Infusion				Glucose Administration			
Treatment Group	Patient ID	Time Procedure Was Initiated	Plasma Glucose Before Start of Procedure (Unit)	Time Insulin Infusion Was Stopped	Confirmatory Plasma Glucose Before Dosing (Unit)	Total Insulin Administered (IU)	Glucose Administered Prior to Dosing?	Plasma Glucose Before Glucose Infusion (Unit)	Start Time/ Stop Time of Glucose Infusion	Total Glucose Administered (mL)
xxxxx	xxxxx	HH:MM	xxxxxx (xxxx)	HH:MM	xxxxxx (xxxx)	xxx	Y/ N	xxx (xxxx)	HH:MM/ HH:MM	xxxxx

Source: xxx
PROGRAM SOURCE: xxx.sas, DATA CUT-OFF DATE: DDMMMYYYY RUN DATE: DDMMMYYYY hh:mm

Programming note:
2) Sort by treatment group and patient number

Listing 16.2.5.6 dasiglucagon Plasma Concentrations
Safety Analysis Set

Treatment Group	Patient ID	Analyte (Unit)	Planned Timepoint	Not Done: Reason	Date/Time of Sample Collection	Elapsed Time (Minutes)	Concentration
xxxx	xxxx	dasiglucagon (pmol/L)	Predose		YYYY-MM-DDTHH:MM	-0.02	XX.X
			10 minutes post dose	Y: xxxxxxxx			
			20 minutes post dose		YYYY-MM-DDTHH:MM	0.34	XX.X
			30 minutes post dose		YYYY-MM-DDTHH:MM	0.51	XX.X
			40 minutes post dose		YYYY-MM-DDTHH:MM	0.68	XX.X
			60 minutes post dose		YYYY-MM-DDTHH:MM	1.02	XX.X
	...	...	...		...	...	...

dasiglucagon plasma concentrations at the Visit 2 (Dosing) visit.
Concentration values are displayed to 3 significant figures.

Source: xxx
PROGRAM SOURCE: xxx.sas, DATA CUT-OFF DATE: DDMMMYYYY RUN DATE: DDMMMYYYY hh:mm

Programming note:
1) Sort by treatment group, patient number and planned timepoint.

Listing 16.2.5.7 dasiglucagon PK Parameters
Safety Analysis Set

Treatment Group	Patient ID	Parameter (unit)	Result	Status	Reason Not Done
xxxx	xxxx	T_{max} (h)	XXX		
		AUC_{0-30} (<unit>)		NOT DONE	XXXXX
	...	...	...	...	...

Results are displayed to 3 significant figures.
Source: xxx
PROGRAM SOURCE: xxx.sas, DATA CUT-OFF DATE: DDMMMYYYY RUN DATE: DDMMMYYYY hh:mm

Programming note:
1) Complete for each PK parameter listed in the SAP.
2) Sort by treatment group, patient and parameter (according to the order in section 12.1 of the SAP)>.

Listing 16.2.5.8 Continuous Glucose Monitoring
Safety Analysis Set

Treatment Group	Patient ID	Collection Date	Collection Time	Result	Unit
xxxx	xxxx	YYYY-MM-DD	HH:MM	XX.X	mg/dL

Source: xxx
PROGRAM SOURCE: xxx.sas, DATA CUT-OFF DATE: DDMMMYYYY RUN DATE: DDMMMYYYY hh:mm

Programming note:
1) Sort by treatment group, patient number, Visit, Date/ Time

Listing 16.2.5.9 Glucose Analyzer data
Safety Analysis Set

Treatment Group	Patient ID	Visit	Collection Date	Collection Time	Result	Unit
xxxx	xxxx	Dosing	YYYY-MM-DD	HH:MM	XX.X	xxx
	xxxx					

Source: xxx
PROGRAM SOURCE: xxx.sas, DATA CUT-OFF DATE: DDMMMYYYY RUN DATE: DDMMMYYYY hh:mm

Programming note:
1) Sort by treatment group, patient number, Date/time

16.2.6 Individual Efficacy Response Data

Listing 16.2.6.1 Plasma Glucose Concentrations
Safety Analysis Set

Treatment Group	Patient ID	Parameter (unit)	Time Point[a]	Date/Time of Collection (Study Day[b])	Plasma Glucose (mg/dL)[c]	Completion Status	Change from Baseline	Normal Range
							xxxx or -/xxxx[d]	
xxxx	xxxx	xxxx	Pre-dose(BL)	YYYY-MM-DDTHH:MM (Day XX)	xxxx (L)			xx-xx
			10 min	YYYY-MM-DDTHH:MM (Day XX)	xxxx (H)			xx-xx
			...					
		xxxx	Pre-dose			NOT DONE		

[a] BL: Baseline Flag
[b] Study day is derived relative to the date/time of start of study drug administration.
[c] L: Below Normal Range, H: Above Normal Range
[d] Change to last recorded value prior to study drug administration / Change to recorded value at the nominal time point 'pre-dose' if different

Source: xxx
PROGRAM SOURCE: xxx.sas, DATA CUT-OFF DATE: DDMMMYYYY RUN DATE: DDMMMYYYY hh:mm

Programming Note:
1) Sort by treatment group, patient, then date/time.

16.2.7 Adverse Event Listings

Listing 16.2.7.1 Adverse Events
Safety Analysis Set

Treatment Group - Patient ID	AE #	TE-AE[a]	System Organ Class/ Preferred Term/ Verbatim Term	Start Date Time (Study Day[b])/ End Date Time (Study Day[b])	SAE[c]?	Severity/ Causality	Action Taken with Study Treatment	Outcome	AESI[d]/ Other Important Event?	Type of Other Important Event[e]	Hypo.[f]?	Start Time	Plasma Glucose Source	Plasma Glucose Value (unit)
xxxx	xx	Y/ N	xxxx/ xxxx/ xxxx	YYYY-MM-DDTHH:MM (Day XX)/ YYYY-MM-DD-DDTHH:MM (Day XX) YYYY-MM-DD (Day XX)/ UNKNOWN	Y	Mild/ Possible	Dose Reduced	Unknown	N/ Y	Infection/ Overdose/ Abuse or misuse/ Error/ Accidental exposure/ Risk of liver injury	Y	HH:MM	xxxxxx	xxx (xxx)

#= number.
[a] TEAE: Treatment-emergent AE
[b] Study day is derived relative to the date/time of start of study drug administration.
[c] SAE: Serious AE
[d] AESI: AE of special interest
[e] Infection=Suspicion of transmission of infectious agents via the trial product; Overdose=Overdose of the trial product; Abuse or misuse=Suspected abuse or misuse of the trial product; Error=Medication error involving the trial product; Accidental exposure=Inadverdent or accidental exposure to the trial product; Risk of liver injury=Risk of liver injury defined as ALT or AST > 3 x ULN and total bilirubin > 2 x ULN, where no alternative etiology exists;
[f] Hypoglycemia Episode?
Adverse events were coded using MedDRA version 24.1.

Source: xxx
PROGRAM SOURCE: xxx.sas, DATA CUT-OFF DATE: DDMMMYYYY RUN DATE: DDMMMYYYY hh:mm

Programming note:
1) Sort by treatment group, patient, start date and end date.

Listing 16.2.7.2 Adverse Events of Special Interest
Safety Analysis Set

#= number.
[a] TEAE: Treatment-emergent AE
[b] Study day is derived relative to the date/time of start of study drug administration.
[c] SAE: Serious AE
[d] Infection=Suspicion of transmission of infectious agents via the trial product; Overdose=Overdose of the trial product; Abuse or misuse=Suspected abuse or misuse of the trial product; Error=Medication error involving the trial product; Accidental exposure=Inadverdent or accidental exposure to the trial product; Risk of liver injury=Risk of liver injury defined as ALT or AST > 3 x ULN and total bilirubin > 2 x ULN, where no alternative etiology exists;
[e] Hypoglycemia Episode?
Adverse events were coded using MedDRA version 24.1.

Source: **xxx**
PROGRAM SOURCE: **xxx.sas**, DATA CUT-OFF DATE: DDMMMYYYY RUN DATE: DDMMMYYYY hh:mm

Programming note:
1) *Repeat Listing 16.2.7.1 for AESIs only*
2) *Remove AESI[d] variable*
3) *Update indexes [d] and [e] in column headers per footnotes above*
4) *Sort by treatment group, patient, start date and end date.*

Listing 16.2.7.3 Hemodynamic Changes During Adverse Events of Special Interest
Safety Analysis Set

		Start Date Time (Study Day[a])/ End Date (Study Day[a])	Event Associated With Any Signs Or Symptoms?		Measurements During The Event											
					Highest Pulse (bpm)		Lowest Pulse (bpm)		Highest Systolic BP (mmHg)		Lowest Systolic BP (mmHg)		Highest Diastolic BP (mmHg)		Lowest Diastolic BP (mmHg)	
Treatment Group - Patient ID	AE#			Narrative	Value	Date/Time	Value	Date/Time	Value	Date/Time	Value	Date/Time	Value	Date/Time	Value	Date/Time
xxxx	xx	YYYY-MM-DDTHH:MM (Day XX)/ YYYY-MM-DD (Day XX)	Y: xxxxxxxx N	xxxxxxxxx	xx	YYYY-MM-DD/ HH:MM	xx	YYYY-MM-DD/ HH:MM	xxx	YYYY-MM-DD/ HH:MM	xxx	YYYY-MM-DD/ HH:MM	xxx	YYYY-MM-DD/ HH:MM	xxx	YYYY-MM-DD/ HH:MM

#= number.
[a] Study day is derived relative to the date/time of start of study drug administration.

Source: xxx
PROGRAM SOURCE: xxx.sas, DATA CUT-OFF DATE: DDMMMYYYY RUN DATE: DDMMMYYYY hh:mm

Programming note:
1) Sort by treatment group, patient and AE#.

Listing 16.2.7.4 Other Important Events
Safety Analysis Set

#= number.
[a] TEAE: Treatment-emergent AE
[b] Study day is derived relative to the date/time of start of study drug administration.
[c] SAE: Serious AE
[d] Infection=Suspicion of transmission of infectious agents via the trial product; Overdose=Overdose of the trial product; Abuse or misuse=Suspected abuse or misuse of the trial product; Error=Medication error involving the trial product; Accidental exposure=Inadverdent or accidental exposure to the trial product; Risk of liver injury=Risk of liver injury defined as ALT or AST > 3 x ULN and total bilirubin > 2 x ULN, where no alternative etiology exists;
[e] Hypoglycemia Episode?
Adverse events were coded using MedDRA version 24.1.

Source: **xxx**
PROGRAM SOURCE: **xxx.sas**, DATA CUT-OFF DATE: DDMMMYYYY RUN DATE: DDMMMYYYY hh:mm

Programming note:
1) *Repeat Listing 16.2.7.1 for Other Important Events only*
2) *Remove Other Important Event? variable*
3) *Sort by treatment group, patient, start date and end date.*

Listing 16.2.7.5 Details of Other Important Events
Safety Analysis Set

Treatment Group	Patient ID	Other Important Event	Description of Event	Start Date Time (Study Day[a])/	End Date (Study Day[a])	Event Related to an AE or SAE[b]?
xxxx	xxxx	Suspicion of transmission of infectious agents via the trial product	xxxxxxxxxxx	YYYY-MM-DDTHH:MM (Day XX)	YYYY-MM-DDTHH:MM (Day XX)	Y/N

[a] Study day is derived relative to the date/time of start of study drug administration.
[b] SAE: Serious AE

Source: xxx
PROGRAM SOURCE: xxx.sas, DATA CUT-OFF DATE: DDMMMYYYY RUN DATE: DDMMMYYYY hh:mm

Programming note:
1) Sort by treatment group, patient, start date and end date.

Listing 16.2.7.6 Local Tolerability Assessment
Safety Analysis Set

Treatment Group	Patient ID	Visit	Date of Assessment (Study Day[a])	Planned Timepoint	Were any reactions observed?	Time of Assessment	Type of Reaction	Reaction Observed at Injection Site?	Severity	AE#	Action Taken	Likely Cause of Reaction
			YYYY-MM-DD (Day XX)	30 minutes post-dose			Spontaneous Pain	N				
xxxx	xxxx	Dosing			Y	HH:MM	Other: xxxxxx	Y	Mild	xx	Other: xxxx	Insertion Site
	...	Follow-up	...	...		...	...	...	...	...	...	...
					Y	HH:MM	Spontaneous Pain	Y	Severe	xx	No Action Taken	Drug
				...								
	. ..	Dosing	...	30 minutes post-dose	N				...	...	...	...

[a] Study day is derived relative to the date/time of start of study drug administration.

Source: xxx
PROGRAM SOURCE: xxx.sas, DATA CUT-OFF DATE: DDMMMYYYY RUN DATE: DDMMMYYYY hh:mm

Programming note:
1) Sort by treatment group, patient, date, planned timepoint, time and type of reaction.

Listing 16.2.7.7 Death Details
Safety Analysis Set

Treatment Group	Patient ID	Date of Death (Study Day[a])	Autopsy Performed?
xxxx	xxxx	YYYY-MM-DD (Day XX)	Y

[a] Study day is derived relative to the date/time of start of study drug administration.

Source: xxx
PROGRAM SOURCE: xxx.sas, DATA CUT-OFF DATE: DDMMMYYYY RUN DATE: DDMMMYYYY hh:mm

Programming note:
1) Sort by treatment group and patient.

Listing 16.2.7.8 Adverse Events for Screening Failures
Screening Failures

Programming note:
1) Repeat Listing 16.2.7.1 for AEs for screening failures (i.e. not belonging to the safety set)

16.2.8 Listing of Individual Laboratory Measurements by Subject, When Required by Regulatory Authorities

Listing 16.2.8.1 Hematology
Safety Analysis Set

Treatment Group	Patient ID	Parameter (unit)	Visit[a]	Date/Time of Collection (Study Day[b])	Result[c]	Completion Status	Change from Baseline	Normal Range
xxxx	xxxx	xxxx	Screening (BL)	YYYY-MM-DDTHH:MM (Day XX)	xxxx (L)		xxxx	xx-xx
			Follow-up	YYYY-MM-DDTHH:MM (Day XX)	xxxx (H)			xx-xx
		xxxx	Screening			NOT DONE		

[a] BL: Baseline Flag
[b] Study day is derived relative to the date/time of start of study drug administration.
[c] L: Below Normal Range, H: Above Normal Range

Source: xxx
PROGRAM SOURCE: xxx.sas, DATA CUT-OFF DATE: DDMMMYYYY RUN DATE: DDMMMYYYY hh:mm

Programming Note:
1) Sort by treatment group, patient, then Laboratory parameter (alphabetically), then date/time.
2) After each parameter, add a blank line

Listing 16.2.8.2 Chemistry
Safety Analysis Set

[a] BL: Baseline Flag
[b] Study day is derived relative to the date/time of start of study drug administration.
[c] L: Below Normal Range, H: Above Normal Range

Source: xxx
PROGRAM SOURCE: xxx.sas, DATA CUT-OFF DATE: DDMMMYYYY RUN DATE: DDMMMYYYY hh:mm

Programming Note:

1) *Repeat Listing 16.2.8.1 for Chemistry parameters.*
2) *Sort by treatment group, patient, then Laboratory parameter (alphabetically), then date/time.*
3) *After each parameter, add a blank line*
4) *Plasma glucose concentrations should be included in Listing 16.2.6.1 only*

Listing 16.2.8.3 Coagulation
Safety Analysis Set

[a] BL: Baseline Flag
[b] Study day is derived relative to the date/time of start of study drug administration.
[c] L: Below Normal Range, H: Above Normal Range

Source: xxx
PROGRAM SOURCE: xxx.sas, DATA CUT-OFF DATE: DDMMMYYYY RUN DATE: DDMMMYYYY hh:mm

Programming Note:
1) Repeat Listing 16.2.8.1 for Coagulation.
2) Sort by treatment group, patient, then Laboratory parameter (alphabetically), then date/time.
3) After each parameter, add a blank line

16.2.9 Other Data

Listing 16.2.9.1 Vital Signs
Safety Analysis Set

Treatment Group	Patient ID	Parameter (unit)	Visit[a]	Time Point	Date Time of Assessment (Study Day[b])	Completion Status	Result	Change from Baseline	Location
xxxx	xxxx	xxxx	Screening		YYYY-MM-DDTHH:MM (Day XX)		xxxx	xxxx	Axilla
			Dosing (BL)	Pre dose	YYYY-MM-DDTHH:MM (Day XX)				Rectum
				30 minutes post-dose		Not Done			
	...	...	...	...	...	...	...	...	
	xxxx	Interpretation	Screening		YYYY-MM-DDTHH:MM (Day XX)		Abnormal (CS)		
			Dosing (BL)	Pre dose	YYYY-MM-DDTHH:MM (Day XX)		Abnormal (NCS)		
	...	...	...	...	...	...	...	...	

[a] BL: Baseline Flag
[b] Study day is derived relative to the date/time of start of study drug administration.

Source: xxx
PROGRAM SOURCE: xxx.sas, DATA CUT-OFF DATE: DDMMMYYYY RUN DATE: DDMMMYYYY hh:mm

Programming Note:
1) *Sort by treatment group, patient, then parameter (Height, Weight, BMI, Temperature, Systolic BP, Diastolic BP, Pulse, Interpretation), then date/time.*
2) *After each parameter, add a blank line*

Listing 16.2.9.2 Physical Examination
Safety Analysis Set

Treatment Group	Patient ID	Body System	Visit[a]	Date Time of Exam (Study Day[b])	Completion Status	Result
	xxxx	HEAD, EARS, EYES, NOSE, THROAT INCLUDING THYROID	Screening (BL)	YYYY-MM-DDTHH:MM (Day XX)		Normal
xxxx		GLAND				
			Dosing	YYYY-MM-DDTHH:MM (Day XX)		Abnormal (CS)
			Follow-up		Not Done	
	...	...	...	...	...	...
	xxxx	ALL PHYSICAL EXAMINATIONS	Screening		Not Done	
	...	...	...	...	...	...

[a] BL: Baseline Flag
[b] Study day is derived relative to the date/time of start of study drug administration.

Source: xxx
PROGRAM SOURCE: xxx.sas, DATA CUT-OFF DATE: DDMMMYYYY RUN DATE: DDMMMYYYY hh:mm

Programming Note:
1) Sort by treatment group, patient, then parameter (match the order in the CRF), then date/time.
2) After each parameter, add a blank line

Listing 16.2.9.3 Electrocardiogram
Safety Analysis Set

Treatment Group	Patient ID	Parameter (unit)	Visit	Date Time of Assessment (Study Day[a])	Position	Completion Status	Reason Not Done	Result	Specify Abnormal Findings
xxxx	xxxx	xxxx	Screening	YYYY-MM-DDTHH:MM (Day XX)	Supine			xxxx	
	...	...	...	...	...	...	...	...	
		Interpretation						Abnormal (CS)	xxxxxxxxx
	...	...	...	...		...		...	
	xxxx	ALL ECG TESTS	Screening			Not Done	xxxxxxxx		
	...	...	...	...		...		...	

[a] Study day is derived relative to the date/time of start of study drug administration.

Source: xxx
PROGRAM SOURCE: xxx.sas, DATA CUT-OFF DATE: DDMMMYYYY RUN DATE: DDMMMYYYY hh:mm

Programming Note:
1) *Sort by treatment group, patient, then parameter (Heart Rate, PR Interval, QRS, QT, QTc, QTcF, and Interpretation) then date/time.*
2) *After each patient, add a blank line*

Listing 16.2.9.4 Hospitalization
Safety Analysis Set

Treatment Group	Patient ID	Date of Admission (Study Day[a])	Date of Discharge (Study Day[a])
	xxxx	YYYY-MM-DD (Day XX)	YYYY-MM-DD (Day XX)
xxxx			

[a] Study day is derived relative to the date/time of start of study drug administration.

Source: xxx
PROGRAM SOURCE: xxx.sas, DATA CUT-OFF DATE: DDMMMYYYY RUN DATE: DDMMMYYYY hh:mm

Programming note: Sort by treatment group and patient.

Listing 16.2.9.5 Immunogenicity
Safety Analysis Set

Treatment Group	Patient ID	Parameter (unit)	Visit[a]	Date Time of Assessment (Study Day[b])	Completion Status	Reason Not Done	Result
							xxxx
xxxx	xxxx	xxxx	Screening (BL)	YYYY-MM-DDTHH:MM (Day XX)			xxxx
			Follow-up	YYYY-MM-DDTHH:MM (Day XX)			xxxx
	...	...	...	...	...		...
	xxxx	All Immunogenicity Tests	xxxx		Not Done	xxxxxxxx	
							...
	...	...	...	...	...		...

[a] BL: Baseline Flag
[b] Study day is derived relative to the date/time of start of study drug administration.

Source: xxx
PROGRAM SOURCE: xxx.sas, DATA CUT-OFF DATE: DDMMMYYYY RUN DATE: DDMMMYYYY hh:mm

Programming note: Sort by treatment group, patient, parameter and visit.

Listing 16.2.9.6 Food and Drink Intake
Safety Analysis Set

Treatment Group	Patient ID	Visit	Pre Dose: Did Patient Refrain from Food/Drink[a]? Reason If No	Pre Dose: Date	Pre Dose: Time of Last Food/Drink[b]	Post Dose: Did Patient Take Any Food/Drink During Follow-up?	Post Dose: Time of Food/Drink[b]
xxx	xxxx	Dosing	Y	YYYY-MM-DD	HH:MM	N	
	xxxx	Dosing	N: xxxxxxx	YYYY-MM-DD	HH:MM	Y	HH:MM, HH:MM, HH:MM, HH:MM
	...	...	...	...		...	

[a] Except water, for 4 hours prior to dosing
[b] Excluding water

Source: xxx
PROGRAM SOURCE: xxx.sas, DATA CUT-OFF DATE: DDMMMYYYY RUN DATE: DDMMMYYYY hh:mm

Programming note: Sort by treatment group and patient. Add a blank line between patients.

Listing 16.2.9.7 Technical Complaints
Safety Analysis Set

Treatment Group	Patient ID	Date Technical Complaint Detected	Date Technical Complaint Reported	Difficulties Administering Drug?: Details	Trial DUN Number	Action Taken	Related to AE?: ID
							Yes: XX
xxxx	xxxx	YYYY-MM-DD YYYY-MM-DD	YYYY-MM-DD	Yes: Drug jammed	xxxxxxxx	xxxxxxxxxxx	
			YYYY-MM-DD	Yes: xxxxxxxxx	xxxxxxxxx	xxxxxxx	No
	...	...	...	...	...		...

Source: xxx
PROGRAM SOURCE: xxx.sas, DATA CUT-OFF DATE: DDMMMYYYY RUN DATE: DDMMMYYYY hh:mm

Programming note: Sort by treatment group, patient and date technical complaint detected