ABBOTT

Statistical Analysis Plan

Module 1
(Non-standard data and analyses)

Final Version 3.0, Date 03rd April 2025

Study: ITOP-322-0216

A Randomized, multicentre, parallel–group, open-label, active-controlled study to investigate the non-inferiority of Itopride Hydrochloride 150mg extended-release tablets once daily versus Itopride Hydrochloride 50 mg film coated tablets thrice daily in subjects with gastrointestinal symptoms caused by gastric dysmotility and delayed gastric emptying like bloating sensation, early satiety, postprandial fullness, upper abdominal pain or discomfort, anorexia, heartburn, nausea, and vomiting in functional (non-ulcer) dyspepsia or chronic gastritis.

Author: Mohammad Fazil Ansari
Biostatistician II
Tech-Observer India Pvt. Ltd.
1391/34A Nangal Raya, New Delhi 110046

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Date Signature

Statistical Analysis Plan is based on the Abbott template for clinical studies. Template Version 5.0

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1. ABBREVIATIONS

1.1 Standard Abbreviations

AE	Adverse Event
ANCOVA	Analysis of Covariance
BMI	Body Mass Index
CDISC	Clinical Data Standards Consortium
CRF	Case Report Form
CRO	Contract Research Organization
ECG	Electrocardiogram
FA	Full Analysis
GI	Gastrointestinal
HLT	High Level Term
ICH	International Conference on Harmonization
LDQ	Leeds Dyspepsia Questionnaire
LS Mean	Least Square Mean
Max	Maximum
MedDRA	Medical Dictionary for Regulatory Activities
Min	Minimum
N	No
N,n	Number of observations
NA	Not Applicable
NI Margin	Non Inferiority Margin
NRS	Numerical Rating Scale
PI	Principal Investigator
PP	Per Protocol
PPIs	Proton Pump Inhibitors
PT	Preferred Term
QoL	Quality of Life
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SAS	Statistical Analysis System
SD	Standard Deviation
SF-NDI	Short Form-Nepean Dyspepsia Index
SOC	System Organ Class
SOP	standard operating procedure
TEAE	treatment-emergent adverse event
TESAE	treatment-emergent serious adverse event
TID	Three times a day
TLF/T,L,F	tables, listings, and figures
UIN	Unique Identification Number
Y	Yes

2. INTRODUCTION

The statistical analysis plan – module 1 & 2 (SAP), produced in accordance with the Abbott standard operating procedures (SOPs) and International Conference on Harmonization (ICH) guidelines, contains a technical elaboration of the principal features of the statistical analyses as described in the protocol of study ITOP-322-0216 final version 1.0 dated 05SEP2023.

Module 1 is primarily restricted to the description of the analysis and reporting of the non-standard data. Module 2 [1] contains the details, including standard definitions and programming instructions, for the analysis and reporting of standard data (disposition, protocol deviation, demographics, medical history, concomitant medication, adverse events, safety laboratory data, vital signs, and safety electrocardiogram data). Module 2 is standard. Any text from Module 2 which is not applicable due to the study design, or otherwise, is specified and revised text is added to Module 1.

Analysis data sets and statistical output will be produced by the Biostatistics project planning and programming department of Tech-observer India, using the SAS® system Version 9.4 or higher.

3. SUMMARY OF THE PROTOCOL

3.1 Overall Study Plan

This is a Phase 3, randomized, open-label, multicenter, parallel-group, active-controlled study to evaluate the non-inferiority in efficacy of Itopride Hydrochloride 150mg extended release tablet (administered once daily) compared to Itopride Hydrochloride 50mg film coated tablets (administered TID) in subjects with gastrointestinal symptoms caused by gastric dysmotility and delayed gastric emptying, like sensation of bloating, early satiety, postprandial fullness, upper abdominal pain or discomfort, anorexia, heartburn, nausea and vomiting; functional (non-ulcer) dyspepsia or chronic gastritis.

The investigator or designee will explain the study to potentially interested subjects in detail, and if they voluntarily agree to participate in the study, consent will be obtained.
The study will screen approximately 700 subjects.

Screening will be carried out to evaluate the eligibility criteria. Upper GI endoscopy will be conducted to rule out any organic, structural disease. The upper GI endoscopy report should be within 6 months prior to randomization. If it is > 6 months old, then it will be performed during screening.

After meeting the eligibility criteria, subjects will be enrolled in the study and will be assigned Unique Identification Numbers (UINs) to maintain confidentiality.

After screening, 564 subjects (282 subjects in each arm) will be randomized in a 1:1 ratio to one of the following treatment groups:

- Test group - Itopride Hydrochloride 150 mg extended-release tablets once daily before one of the main meals (preferably the same meal throughout the treatment)
- Active Control group - Itopride Hydrochloride 50 mg film coated tablets 3 times daily before meals.

The study drugs will be administered, as mentioned above, for a period of 8 weeks.
The duration of treatment will be 8 weeks, and the subject follow up will be one week after the end of treatment.

Subjects must stop most drugs which are active on gastric function prior to the study. Rescue medication, i.e. PPIs or antacids, for subjects with persistent symptoms of gastric hypersecretion may be started, after confirmation by the PI, earliest after 4 weeks (visit 3).

3.2 Study Flowchart

The flowchart of the study can be found in Appendix 9.1.

3.3 Study Objectives

Primary Objective:

- To assess the comparable efficacy of Itopride Hydrochloride 150 mg extended-release tablet (administered once daily) and Itopride Hydrochloride 50 mg film coated tablets (administered TID) after 8 weeks' treatment.

Secondary Objectives:

- To assess the comparable efficacy of Itopride Hydrochloride 150 mg extended-release tablet (administered once daily) and Itopride Hydrochloride 50 mg film coated tablets (administered TID) after 4 weeks treatment.
- To assess quality of life for the two treatment arms using Disease Specific Quality of Life (Nepean Dyspepsia Index NDI) at baseline and end of treatment
- To assess the symptomatology (sensation of bloating, early satiety, postprandial fullness, upper abdominal pain, or discomfort (epigastric pain, epigastric burning), anorexia (loss of appetite), heartburn, nausea, and vomiting) of the disease in both treatment arms after 4 and 8 weeks of treatment.
- To assess the number of responders of adequate/satisfactory relief from functional dyspepsia symptoms.

Exploratory Objective:

- Treatment acceptance by subjects using 5-point Likert scale at the end of treatment

Safety Objective:

- To evaluate safety and tolerability in both treatment arms

4. STATISTICAL ANALYSIS

Data handling responsibility is of the Clinical Data Management (CDM) team of the tech-observer. The data will be inspected for inconsistencies by performing validation checks. Any inconsistencies found will be resolved by the monitor after contacting the Investigator. When the data in the database are considered clean the database will be made available as SAS® files for statistical analysis.

The Statistical Analysis Plan is prepared by Biostatistics projects Planning and Programming (BPP) team of the Tech-Observer and approved by Abbott before database lock.

The statistical analysis will be done by the BPP team of the tech-observer.

General Considerations:

Treatment Day:
All assessment Treatment day calculation/consideration refer section 2.3.1 of SAP module 2

Baseline:
For baseline definition refer section 2.3.2 of SAP module 2

Gap Period:
The Gap Period is defined as 7 days. In that case the last administration of study drug occurred on Day 30 relative to the start of treatment, an assessment obtained on Day 33 will be analyzed as part of that treatment.

The default summary statistics for quantitative variables and qualitative variables and decimal point presentation will be followed as per section 2.1 of SAP module 2.

4.1 Subject samples

The main subject samples of interest are defined as follows:

- All Subjects Consented subject sample will consist of all subjects who:
  - Gave their informed consent.
- All Subjects Allocated to Treatment subject sample will consist of all subjects who:
  - Were in all subjects consented sample, and
  - Were randomized to treatment.
- The Safety subject sample will consist of all subjects who:
  - Were in all subjects allocated to treatment sample; and
  - Had at least one dose of study medication administered.
- The Full Analysis (FA) subject sample will consist of all subjects who:
  - Were included in the safety sample; and

  - Had data for at least one post-baseline assessment of any efficacy measurement.
- The Per Protocol (PP) subject sample will be defined through blind data review and will consist of all subjects who:
  - Were included in the Full Analysis sample; and
  - Did not present any major protocol violation.

4.2 Efficacy analysis

The Full Analysis (FA) and Per Protocol (PP) sample will be used for the analysis of the primary efficacy data. The analysis for the per-protocol sample will be regarded as primary. Full analysis sample will be used for the analysis of the secondary endpoints.

The default summary statistics for quantitative and ordinal variables will be the number of non-missing observations (n), mean, standard deviation (SD), median, minimum (Min) and maximum (Max) for subjects with data.

For qualitative variables, per category the numbers and frequencies of subjects with non-missing data (n, %) will be the default summary presentation, and if appropriate, the number of missing values will be presented.

4.2.1 Primary Efficacy Analysis

- **Change in Leeds Dyspepsia Questionnaire (LDQ) Severity Score between baseline and week 8**

A by-participants data listing will be provided for all subject consented subject sample, which contains data information for Leeds Dyspepsia Questionnaire (LDQ) questionnaire from CRF. LDQ severity score and change in LDQ severity score from baseline will also be listed for all participants.

The primary endpoint is the change in the overall severity of functional dyspepsia between baseline and week 8, as measured by the Leeds Dyspepsia Questionnaire (LDQ) severity score.

The values of Leeds Dyspepsia Questionnaire (LDQ) severity score will be derived as per section 5.3.1.

The actual values at baseline and week 8 and values of change from baseline at week 8 will be summarized using the number of non-missing observations (n), mean, standard deviation (SD), median, minimum (Min) and maximum (Max) by Test group and Active Control group.

The primary endpoint Leeds Dyspepsia Questionnaire (LDQ) severity score will be analyzed using analysis of covariance (ANCOVA) model. The model will include change in the LDQ score as dependent variable and treatment groups, site and LDQ baseline value as covariates. Two-sided 95% confidence intervals will be constructed for the Least Square Mean (LS Mean) differences between Test group and Active Control group. Normal approximation will be assumed for the parametric analyses.

The following sample SAS code pertains to the analysis:

```
proc mixed;
    class TREATMENT SITE;
    model CHG = BASE TREATMENT SITE/solution;
    lsmeans TREATMENT/ stderr pdiff cl alpha=0.05;
  ods output diffs = DIFFS lsmeans = LSMEANS;
run;
*CHG: LDQ change from baseline values
*BASE: LDQ baseline values
```

Non-inferiority of Test group (Itopride Hydrochloride 150 mg extended-release tablets once daily before one of the main meals) compared to Active Control group (Itopride Hydrochloride 50 mg film coated tablets 3 times daily before meals) will be assessed using Full Analysis (FA) and Per Protocol (PP) subject sample for the entire study population.

The non-inferiority margin is set as 1.75 and thus the null and alternative hypothesis will be stated as follows:

Null Hypothesis:

Test group is inferior to active control group

Alternative Hypothesis:

Test group is non-inferior to active control group

Where,

Δ_T =Mean change in LDQ score from baseline for Test group

Δ_A=Mean change in LDQ score from baseline for Active Control group

Non inferiority will be achieved using the lower bound of the 95% confidence interval of the difference between the Test groups and Active Control group. If the lower bound of the 95% confidence interval of the difference between the Test groups and Active Control group is greater than 1.75 (NI-margin), Test group will be declared non-inferior to Active Control group, and the study will be considered a success.

The above analysis will be performed for both the per protocol and the full analysis set. The analysis for the per-protocol set will be regarded as primary.

For the primary PP analysis, the major protocol deviations/violations will be determined before DB lock.

All data points as results of major deviations/violations will be excluded.

Subjects who have taken the rescue medication marked as minor protocol deviation will be included in Per Protocol sample. All data points will be disregarded and considered as missing after the use of rescue medication.

Resulting missing values will be replaced using MI (like a hypothetical strategy in the estimand framework). Replacing missing values by MI will also be done as part of FAS analysis that otherwise includes all observed.

The data will be separated into two subsets based on the treatment groups which will ensure that the imputation process accounts for potential difference between these groups. Complete dataset will be generated using PROC MI and recombine the data set for subsequent analysis. The number of imputed data set should be sufficient to ensure reliable result. PROC MIANALYZE will be used to combine the results of complete dataset results.
The following sample SAS code pertains to the imputation:

/* Step 1: Separate data into two subsets based on treatments and Perform Multiple Imputation separately for each group */

PROC MI DATA=data OUT=imputed_data NIIMPUTE=X (usually considered 5 for data values missing up to 20%) SEED=XXXXX;
Class Site;
VAR var 1 var 2 var3;
MONOTONE/FCS REG;
Run;
/* Use Monotone or FCS regression imputation based on missing values pattern*/

/* Step 2:
Re-combine the imputed dataset for each group and Analyze the imputed dataset */

PROC MIXED DATA=combined;

CLASS treatment site;

MODEL chg = base treatment site/SOLUTION;

LSMEANS treatment/ STDERR PDIFF CL ALPHA=0.05;

```
 BY _imputation_; /* perform analysis for each imputed dataset */
 ODS OUTPUT DIFFS = diffs LSMEANS = lsmeans; /*Use the ODS Output tables required as per need*/;
run;
/* Step 3:
Pooled the result from multiple imputation */
ODS OOUTPUT PARAMETERESTIMATES=estimate; /*use the ODS Output tables required as per need*/
PROC MIANALYZE DATA=lsmeans/diffs;
/* If any By variable is required, use BY option*/
 MODELEFFECTS estimate;
 STDERR StdErr;
Run;
```

In order to test robustness of results following analyses will be performed:

- Leeds Dyspepsia Questionnaire (LDQ) severity score will be analyzed using mixed model repeated measure (MMRM) model for FAS population. No missing values will be imputed for the analysis.

- Leeds Dyspepsia Questionnaire (LDQ) severity score will be analyzed using mixed model repeated measure (MMRM) model for PP population where, missing values will be imputed for the data points not excluded due to deviation will be replaced using MI.

- Leeds Dyspepsia Questionnaire (LDQ) severity score will be analyzed using ANCOVA model for PP population that includes subjects who complete all visits of study as per protocol.

The following sample SAS code pertains to the MMRM analysis:

```
PROC MIXED DATA=data METHOD=REML;
  CLASS Treatment Site Subject Visit;
  MODEL aval = base treatment site visit treatment*visit /SOLUTION DDFM=kr;
  REPEATED Visit/ SUBJECT=Subject TYPE=un; /* If UN is not convergence, follow the sequence as TOEP, AR(1) and CS */
  LSMEANS Treatment*Visit /CL DIFF;
RUN;
```

4.2.2 Secondary Efficacy Analysis

- **Change in Leeds Dyspepsia Questionnaire (LDQ) Severity Score between baseline and week 4**

The actual values and change in values from baseline in Leeds Dyspepsia Questionnaire (LDQ) severity score will be summarized using the number of non-missing observations (n), mean, standard deviation (SD), median, minimum (Min) and maximum (Max) by Test group and Active Control group for baseline and week 8.

The endpoint will be analyzed by using analysis of covariance (ANCOVA) model. The model will include change in the LDQ score as dependent variable and treatment group, site and LDQ baseline values as covariates. Two-sided 95% confidence intervals will be constructed for the least square mean (LS Mean) differences between Test group and Active Control group.

The above analysis will be performed for Full Analysis (FA) subject sample.

- **Disease Specific Quality of Life (Nepean Dyspepsia Index NDI) assessed at baseline and week 8**

The Short Form Nepean Dyspepsia Index (SF-NDI) is composed of 10 QoL items investigating 5 domains. There are also an additional 15 items that measure frequency, intensity and bothersomeness. The symptom score can be modified to assess role functional dyspepsia score. The values of overall QoL score, QoL domain score, and functional dyspepsia score will be derived as per section 5.3.2

All 15 symptoms/items that measure frequency, intensity and bothersomeness will be summarized descriptively, using frequency count (n) and percentages by Test group and Active Control group for baseline and week 8.

All 15 symptoms/items will be converted to symptom scores by summing the values of frequency, intensity and bothersomeness for each symptom will be analyzed by using the number of non-missing observations (n), mean, standard deviation (SD), median, minimum (Min) and maximum (Max) by Test group and Active Control group for baseline and week 8.

Functional Dyspepsia score modified by specific symptom scores described in section 5.3.2 will be analyzed by using the number of non-missing observations (n), mean, standard deviation (SD), median, minimum (Min) and maximum (Max) by Test group and Active Control group for baseline and week 8.

Each QoL domain/subscale raw scores and transformed scale scores as described in section 5.3.2 and their overall scores will be summarized by using the number of non-missing observations (n), mean, standard deviation (SD), median, minimum (Min) and maximum (Max) by Test group and Active Control group for baseline and week 8.

A two sample t-test will be used to check the significance difference between Test group and Active Control group at 5% level of significance.

The above analysis will be performed for Full Analysis (FA) subject sample.

- **Change from baseline of NRS 11 score for symptoms after week 4 and week 8**

The patient is provided with the NRS 11 scale to mark changes for symptoms of sensation of bloating, early satiety, postprandial fullness, upper abdominal pain, or discomfort (epigastric pain, epigastric burning), anorexia (loss of appetite), heartburn, nausea, and vomiting.

The NRS scale scores for each symptom will be obtained as per section 5.3.2.

The actual scores and change in scores from baseline for each symptom will be summarized using the number of non-missing observations (n), mean, standard deviation (SD), median, minimum (Min) and maximum (Max) by Test group and Active Control group for baseline and week 8.

The change in symptoms score will be analyzed by using analysis of covariance (ANCOVA) model. The model will include change in Symptom Score as dependent variable and treatment group, site, and Symptom baseline score as covariates. Two-sided 95% confidence intervals will be constructed for the least square mean (LS Mean) differences between Test group and Active Control group.

The above analysis will be performed for Full Analysis (FA) subject sample.

- **Responder Analysis of Satisfactory relief assessed by LDQ and NRS 11**

Based on the LDQ score, at the end of the study treatment subjects will be categorized into responders and non-responders (refer section 5.3).
Number of responders and non-responders will be summarized descriptively by using frequency count (n) and percentages (%) by Test Arm and Active Control Arm.

To check the significant difference between two treatment arms a chi-square test will be used when the normal approximation to the binomial is valid. Otherwise, a Fisher's exact test will be used if >20% of expected cell counts are less than 5.

Similarly, based on the NRS11 score, study treatment subjects will be categorized into responders and non-responders for each symptom (refer section 5.3.2) and similar analysis specified above will be performed.

Exploratory analysis

- **Treatment acceptance and ease of use assessed by using 5-point Likert Scale**

The subject's response of treatment acceptance for each point i.e. 1-Not at all satisfied, 2-Slightly satisfied, 3-Neutral, 4-Very satisfied, 5-Extremely satisfied will be summarized descriptively, using frequency count (n) and percentages (%) by Test group and Active Control group at the end of the study treatment (i.e., at week 8).

A descriptive summary of treatment acceptance will also be provided using number of non-missing observation (n), median, minimum (Min) and maximum (Max) by Test group and Active Control.

To find the significant difference of acceptance and ease of use between Test group and Active Control group a two-sample t-test or Mann Whitney test will be used at 5% level of significance based the normality of the data.

Normality of the response of 5-point likert scale scores will be checked by using Q-Q Plot or KS test.

4.3 Safety analysis

The Safety subject sample will be used for the analysis of the safety data.
Descriptive statistics for all safety and tolerability data will be presented by the Test group and Active Control. Only the necessary tables as required for the study will be generated, as specified in section 9.3, which provides the list of required reports.

Adverse Events:
An AE that starts during a unique treatment or that already exists before the start of that unique treatment but worsens during the treatment, will be considered as treatment emergent for that unique treatment.
For the definition of treatment emergent, the following unique treatments are distinguished by applicable study period:

- Itopride Hydrochloride 150 mg extended release tablets

- Itopride Hydrochloride 50 mg film coated tablets

AEs will be reported on a per-subject basis, i.e. counting subjects rather than events. This means that if a subject suffers the same AEs repeatedly during the applicable study period, the event will be counted only once for that period. Repeated events per subject will be summarized according to the following rule: if a subject suffered the same AE more than once, the event will be assigned the worst severity, the closest relationship to the study drug and the earliest starting date. Only treatment emergent AEs will be reported.

A table which include TEAEs that have an incidence >=3% in any treatment arm will be produced as per standard TLF AET003. cut-point will be used as >=3%, instead of >=5%.

In the listings, however, all occurrences of the AEs will be presented. For each unique treatment, treatment emergent AEs will be summarized per primary SOC, per HLT by primary SOC and per PT by HLT and primary SOC. Severity and drug-event relationship of treatment emergent AEs are summarized separately. Refer section 3.6.1 of SAP module 2 for detailed analysis strategy of AEs.

Laboratory Data:
Laboratory variables for hematology and biochemistry, including changes from baseline will be summarized. A frequency table will be presented for markedly abnormal values. Markedly abnormality for hematology will be determined based on the standard criteria outlined in Table 3 of SAP module 2. Markedly abnormality for Biochemistry variables will be determined based on the standard criteria outlined in Table 2.

The criteria for non-specified variables are as follows:

Variable	SI Units		
	Unit	Lower Limit	Upper Limit
Random Blood Sugar	mmol/L	3.9	11.1
Serum Prolactin	mcg/L	--	0.1 (100ng/l)
Serum Lipase	U/L	--	420
Ionized Calcium	mmol/L	0.9	1.5

Blood differentials whose values are reported in %, the limits for markedly abnormal values that are as follows:

Variable	SI Units		
	Unit	Lower Limit	Upper Limit
Basophils	%	--	4
Eosinophils	%	--	5
Lymphocytes	%	--	40
Monocytes	%	--	10
Neutrophils	%	--	70

Shift tables will be presented according to the lab reference ranges (low, normal, or high). Refer section 3.6.2 of SAP Module 2 for detailed analysis strategy.

Vital Signs:
Vitals signs, including changes from baseline will be summarized. A frequency table will be presented for markedly abnormal values. Markedly abnormal will be determined based on the standard criteria outlined in Table 5 of SAP module 2. Listing VSL005 will include an addition column to present local lab reference ranges, if required. Refer section 3.6.3 of SAP module 2 for detailed analysis strategy of vital signs.

Additional safety laboratory data, if captured, will be presented in by-subject data listings.

Other analysis

Only the necessary tables as required for the study will be generated, as specified in section 9.3, which provides the list of required reports.

The assignment of subjects to subject samples, the disposition of subjects with respect to premature termination, reason for premature termination, protocol deviations will be summarized per treatment group as per section 3.1, 3.2 and 3.3 of SAP module 2.

Demographics and other baseline characteristics will be summarized per treatment group as per section 3.4.1 and 3.4.2 of SAP module 2.

Medical history, including coding data will be summarized per primary SOC, per HLT by primary SOC and per PT by HLT and primary SOC as per section 3.4.3 of SAP module 2.

Concomitant medication, including coding data will be summarized per assigned treatment period for incidence per subject, for primary therapeutic subgroup (3rd level ATC code) and for generic name by therapeutic subgroup as per section 3.5 of SAP module 2.

Rescue Medications will be presented in by-subject data listings only. Any impact on safety or efficacy endpoints will be evaluated after final BDR and the analysis strategy will be provided.

Drug exposure and treatment compliance will be summarized per treatment group. Refer section 5.5 of SAP module 1.

Additional data, if captured at screening, will be presented in by-subject data listings.

4.4 Interim Analysis

No interim analysis has been planned for this study.

4.5 Data Safety Monitoring Board

Not applicable.

4.6 Safety Management Team

Not applicable.

4.7 Subgroup Analysis

Primary, secondary efficacy endpoints (LDQ at 4 and 8 weeks, NRS11 (different symptoms), responder rate, functional dyspepsia score by SF-NDI, raw and transformed scores by SF NDI), exploratory endpoint of treatment acceptance and safety endpoints (overall summary of AEs, prolactin levels and change from baseline in prolactin) will be analyzed across subgroups using the same analysis as specified for the primary , secondary and safety endpoints.

The subgroups are defined as follows:
Gender:

- Female
- Male

Age Group:

- ≥ 18 to ≤ 44
- ≥ 45 to ≤ 59
- ≥ 60

Geographical region (Country):

- Armenia
- Malaysia
- Philippines
- Thailand
- Vietnam

5. DESCRIPTION OF NON-STANDARD DATA COLLECTED AND DERIVED VARIABLES

5.1 Other Non-Standard Baseline Characteristics

The following non-standard baseline characteristics have been collected at screening:

- Test Report for H-pylori
- Upper GI Ultrasound
- Endoscopy
- 12 Lead Electrocardiogram
- Pregnancy Test

5.2 Non-Standard Disease History

Not applicable.

5.3 Efficacy data

The following efficacy endpoints data values are collected, and the required derivation is provided:

5.3.1 Primary Efficacy Endpoint

- **Symptoms of dyspepsia using Leeds Dyspepsia Questionnaire (LDQ)**

The Leeds Dyspepsia Questionnaire (LDQ) consists of 15 questions out of which only 8 questions will be used to determine the severity of dyspepsia.

The eight questions from 1-8 are given below:

1. *Over the last FOUR WEEKS have you had any indigestion (a pain in the upper abdomen)?*

   [Yes/No]

2. *Over the past FOUR WEEKS have you ever experienced heartburn (a burning feeling behind the breastbone)?*

   [Yes/No]

3. *Over the past FOUR WEEKS has food or drink ever stuck behind your breast bone as it went down?*

   [Yes/No]

4. *Over the last FOUR WEEKS have you experienced any regurgitation (an acid taste coming up into your mouth from your stomach)?*

   [Yes/No]

5. *Over the last FOUR WEEKS have you noticed excessive burping or belching?*

[Yes/No]

6. *Over the last FOUR WEEKS have you ever experienced any nausea (a feeling of sickness without actually being sick)?*

   [Yes/No]

7. *Over the last FOUR WEEKS have you ever experienced any vomiting?*

   [Yes/No]

8. *Over the last FOUR WEEKS have you noticed an excessive feeling of fullness after eating?*

   [Yes/No]

All the eight questions have a Yes or No response.

The severity score of dyspepsia will be derived as follows:

Step 1:

If No is checked by a subject for any of the above 8 questions the zero severity score will be allocated to that question.

Step 2:

If Yes is checked by a subject for any of the above 8 questions, a further two additional questions will be asked.

For 1, 2, 4, 5, 6, 7, and 8 questions the two additional questions will be asked are as follows:

(a) *How often have you had [the respective symptom] over the last FOUR WEEKS?*

[1 = between once a month and once a week; 2 = more than once a week; 3 = at least one a day]

(b) *How severe has your [respective symptom] been over the last FOUR WEEKS?*

[1 = very mild; 2 = mild; 3 = moderate; 4 = severe; 5 = very severe]

Only question "(b)" will be used to determine the severity score.

Convert the categorical response of question b in numeric scores as follows:

Response	Score
Very Mild	1
Mild	2
Moderate	3
Severe	4
Very Severe	5

Hence, the possible severity score for the above questions is either 0 or (based on question b only) from 1 = very mild to 5 = very severe.

Step 3:

For the 3rd question, the two additional questions will be asked are as follows:

(a) *How often does it stick behind your breastbone?*

[1 = between once a month and once a week; 2 = more than once a week; 3 = at least one a day]

(b) *How severe has your [respective symptom] been over the last FOUR WEEKS?*

[1 = very mild; 2 = mild; 3 = moderate; 4 = severe; 5 = very severe]

Convert the categorical response of question a and b in numeric scores as follows:

Response	Score
Between once a month and once a week	1
More than once a week	2
At least once a day	3
Very Mild	1
Mild	2
Moderate	3
Severe	4
Very Severe	5

Both question (a) and (b) will be used to determine the severity score as follows:

Question 3 score = Score of (a) + Score of (b)

Hence, possible severity score for question 3 is either 0 or (based on sum of question a and b) 2 to 5.

Step 4:

The overall LDQ score will be obtained by summing all the 8 question's scores

Overall LDQ score

= Score of Q1 + Score of Q2 + Score of Q3 + Score of Q4 + Score of Q5 + Score of Q6 + Score of Q7 + Score of Q8

The following simulated example of patient's response and score calculation can be referred for better understanding of the scoring procedure:

Question No.	Response (Yes/No)	If Yes, Sub question (a)			If Yes, sub question (b)					Score
		1 = between once a month and once a week	2 = more than once a week	3 = at least one a day	Very Mild = 1	Mild = 2	Moderate = 3	Severe = 4	Very Severe = 5	
1	No	Ignore (a)			Ignore (b)					0
	Yes									
2	No	Ignore (a)								3
	Yes						3			
3	No									2+4 = 6
	Yes		2					4		
4	No	Ignore (a)								1
	Yes				1					
5	No	Ignore (a)								3
	Yes							3		
6	No	Ignore (a)								2
	Yes					2				
7	No	Ignore (a)			Ignore (b)					0
	Yes									
8	No	Ignore (a)								5
	Yes								5	
Overall LDQ Severity Score										20 = [0 + 3 + 6 + 1 + 3 + 2 + 0 + 5]

Note 1: The above table calculation is simulated to better understanding of the scoring procedure.

Note 2: The grey shaded shells indicating the response of patient for that particular question.

5.3.2 Secondary Efficacy Endpoints

- **Quality of Life assessment using Short Form - Nepean Dyspepsia Index (SF-NDI)**

The SF-NDI is composed of two parts:

Part 1:

Functional Dyspepsia by SF-NDI Symptoms

Step 1:

There are 15 symptoms (items) that measure frequency by evaluating "How OFTEN did you have it?", intensity by evaluating "If you had this problem, how INTENSE was it usually?" and bothersomeness by evaluating "If you had this problem, how BOTHERSOME was it?" to establish a symptom score.

Out of 15 symptoms only the following 4 symptoms will be used to calculate the score of functional dyspepsia by NDI.

- *Pain or ache in upper abdomen*
- *Burning sensation in upper abdomen PDS:*
- *Inability to finish a regular meal*
- *Fullness after eating or slow digestion*

Convert the responses of frequency, intensity and bothersomeness into numeric scores as follows:

Frequency How OFTEN did you have it?		Intensity "If you had this problem, how INTENSE was it usually?"		Bothersomeness "If you had this problem, how BOTHERSOME was it?"	
Not at all	0	Not at all	0	Not at all	0
One to four days	1	Very mild	1	A little bit	1
Five to eight days	2	mild	2	Moderately	2
Nine to twelve days	3	Moderate	3	Quite a bit	3
Every day/Almost every day	4	Severe	4	Extremely	4
		Very Severe	5		

Step 2:

Calculate each symptom score as follows:

Symptom score = Frequency score + Intensity score+ Bothersomeness score

Step 3:

Calculate the Functional Dyspepsia score as follows:

Functional Dyspepsia score = sum of all 4 symptom (*Pain or ache in upper abdomen + Burning sensation in upper abdomen PDS + Inability to finish a regular meal + Fullness after eating or slow digestion)* score

Part 2:

QoL

The SF-NDI is composed of 10 QoL items investigating 5 domains.

Transformation for Raw Score,

Step 1:

Convert the responses of QoL items into numeric scores as follows:

Response of QoL items	Score
Not at all	1
Not applicable	1
Almost Never	1
A little	2
Sometimes	2
Moderately	3
Fairly often	3
Quite a lot	4
Very often	4
Extremely	5
Always	5

Step 2:

Categorize the five domains as follows (categorized in CRF as well):

Domain	Number of Items	Cluster of Items
Tension	2	1, 2
Interference with daily activities	2	3, 4
Eating/Drinking	2	5, 6
Knowledge/Control	2	7, 8
Work/Study	2	9, 10

Step 3:

Calculate the score of each domain as follows:

Tension = Score of 1 + Score of 2; similarly for each domain.

Step 4:

The overall total score is obtained by using the mean of the 5 subscale/domain total scores

Overall QoL Raw Score

=

Raw scores for (Tension + Interference with daily activities + Eating/Drinking + knowledge/Control + Work/Study) ÷ 5

Transformation for Standardized Score,

Convert the responses of QoL items into numeric scores as per step 1 and categorize the five domains as per step 2 defined above for transformation of raw score.

Step 3:

Calculate the score of each domain as follows:

Tension = Score of 1 + Score of 2; similarly for each domain.

Step 4:

Transform the domain scores as follows:

$$Transformed\ Scale\ Score = 100 - \left[\frac{(Actual\ Raw\ Score - Minimum\ Possible\ Score)}{Range} \times 100\right]$$

Where,

$Minimum\ Possible\ Score = 2$
$Range = (Maximum\ Possible\ Score - Minimum\ Possible\ Score) = (10 - 2) = 8$
Note:

Each item is scored on likert scale and converted into numeric scores as per step 1. Each domain is measured using 2 questions as per step 2.

Step 5:

overall SF-NDI total score is obtained by mean of 5 domain score as follows:

Overall QoL Transformed Score

=

Transformed scores for (Tension + Interference with daily activities + Eating/Drinking + knowledge/Control + Work/Study) ÷ 5

The following simulated example of patient's response and score calculation can be referred for better understanding of the scoring procedure:

Question No.	Response	Converted Response Into Numeric Score	Categorization of Domains	Score for each domain	Transformed Scale Score
1	QUITE A LOT	4	Tension	4 + 3 = 7	$\frac{(7-2)}{8} \times 100 = 62.5$
2	MODERATELY	3			
3	EXTREMELY	5	Interference with daily activities	5 + 4 = 9	$\frac{(9-2)}{8} \times 100 = 87.5$
4	QUITE A LOT	4			
5	MODERATELY	3	Eating/Drinking	3 + 4 = 7	$\frac{(7-2)}{8} \times 100 = 62.5$
6	QUITE A LOT	4			
7	FAIRLY OFTEN	3	knowledge/Control	3 + 5 = 8	$\frac{(8-2)}{8} \times 100 = 75.0$
8	ALWAYS	5			
9	QUITE A LOT	4	Work/Study	4 + 3 = 7	$\frac{(7-2)}{8} \times 100 = 62.5$
10	MODERATELY	3			

Overall QoL Transformed Score	(62.5 + 87.5 + 62.5 + 75.0 + 62.5) ÷ 5 = 70.0

- **Symptoms of dyspepsia assessed by Numerical Rating Scale (NRS 11)**

Convert each NRS 11 responses into numeric score as follows:

Symptom response	Score
No	0
Very Mild	1
Discomforting	2
Tolerable	3
Distressing	4
Very distressing	5
Intense	6
Very Intense	7
Horrible	8
Unbearable	9
Unspeakable	10

Each symptom will be analyzed separately according to symptom score.

- **Responders for adequate/satisfactory relief as assessed**

By LDQ Score:

The subject is considered to be as responder if, at the end of the treatment the overall LDQ score is < 9.

By NRS-11 Score:

The subject is considered to be as responder if, each NRS11 symptoms change from baseline score at the end of the study treatment is at least 2 (i.e., NRS-11 symptoms CFB >= -2). only subjects with a score of the respective symptom of at least 5 at baseline will be used.

- **Treatment acceptance and ease of use assessed by Likert Scale**

Convert the responses of treatment acceptance into numeric score as follows and analyze the scores:

Acceptance response	Score
Not at all satisfied	1
Slightly satisfied	2
Neutral	3
Very satisfied	4
Extremely satisfied	5

5.4 Non-standard Safety Data

Not Applicable

5.5 Drug Accountability and Exposure

5.5.1 Drug Accountability

Drug accountability will be defined as the number of tablets that were actually taken relative to the number of tablets that should have been taken for the duration of actual treatment exposure.

The overall compliance assessed by tablets count will be calculated as follows:

$$\text{Treatment Compliance (\%)} = \left[\frac{\text{N of capsules/tablets dispensed - N of capsules/tablets returned}}{(\text{LDA} * \text{N of capsules/tablets pescriber per day})}\right] \times 100$$

Where,
N of tablets dispensed = N of tablets dispensed at baseline + N of tablets dispensed at visit 3 (week 4)
N of tablets returned = N of tablets returned at visit 3 (week 4) + N of tablets returned at visit 4 (week 8)
LDA = Day number of the last day of drug administration

The calculated compliance will be categorized as:
Too Low: Compliance of drug < 80%
Adequate: 80% ≤ Compliance of drug ≤ 120%
Too High: Compliance of drug > 120%
Overall compliance be summarized descriptively, and the compliance categories will be summarized using frequency count (n) and percentages (%) by treatment group.

5.5.2 Exposure

Exposure to treatment in duration will be summarized descriptively by treatment groups for safety subject sample.

Duration of treatment exposure will be calculated as follows:
Exposure = Date of last drug administration – Date of first drug administration + 1

6. FURTHER SPECIFICATIONS TO THE STANDARD ANALYSES IN MODULE 2

6.1 Trial Design [2]

6.1.1 Trial Periods

The combination of trial arms and trial periods for the current trial is presented in the following diagram:

	Screening Period	Treatment Period	Follow-up Periods
Test Arm	2 weeks	8 weeks	1 week
Active Control Arm	2 weeks	8 weeks	1 week

6.1.2 Trial Elements

The start time of each intervention will be expressed relative to <<the first administration of investigational study drug/medication/start of the infusion>> closest to that intervention.

The Trial Elements are presented in the following diagram:

Trial Element	Description of Element	Rule for Start of Element	Rule for End of Element	Planned Duration of Element
Screen	Screening Period	Date of Informed Consent	First dose of study treatment	NA
Itopride Hydrochloride 150 mg (administered once daily)	Treatment Period; Test Arm	First dose of Test Arm	Last dose of Test Arm	8 weeks or less
Itopride Hydrochloride 50 mg (administered TID)	Treatment Period: Active Control Arm	First dose of Active Control Arm	Last dose of Active Control Arm	8 weeks or less
Follow up	Follow up period	Last dose of study treatment	Investigator's phone call after end of treatment visit	7 days or less

6.1.3 Trial Arms

The trial arms for this study are made up of the following trial elements:

Trial Arm	Elements			
	Screen	Itopride Hydrochloride 150 mg (administered once daily)	Itopride Hydrochloride 50 mg (administered TID)	Follow-up
Test Arm	Y	Y	N	Y
Active Control Arm	Y	N	Y	Y

6.1.4 Visits and related definitions

Tests and examinations that were scheduled in the protocol will be related to the general time axis of the trial by relating the visit date on which a test or examination is performed to the start date of the trial element that describes the first administration of investigational study drug closest in time to the visit date of that test or examination (Reference Start Date/ Time).

Test / Examination	Visit name	Visit Label	Visit Number	Reference Start Date/Time	Relative Day Number
Informed Consent	Screening	Screening	1	Date of first dose of study treatment	Day -1
Inclusion/Exclusion	Screening	Screening	1	Date of first dose of study treatment	Day -1
Inclusion/Exclusion	Baseline	Treatment Period	2	Date of first dose of study treatment	Day 1
Demographic Data	Screening	Screening	1	Date of first dose of study treatment	Day -1
Medical History	Screening	Screening	1	Date of first dose of study treatment	Day -1
Randomization	Baseline	Treatment	2	Date of first dose of study	Day 1

		Period		treatment	
Physical Examination	Screening	Screening	1	Date of first dose of study treatment	Day -1
Physical Examination	Baseline	Treatment Period	2	Date of first dose of study treatment	Day 1
Physical Examination	Treatment Period	Treatment Period	3	Date of first dose of study treatment	Day 29
Physical Examination	End of Treatment	End of Treatment	4	Date of first dose of study treatment	Day 57
Height	Screening	Screening	1	Date of first dose of study treatment	Day -1
BMI, Weight	Screening	Screening	1	Date of first dose of study treatment	Day -1
BMI, Weight	Baseline	Treatment Period	2	Date of first dose of study treatment	Day 1
BMI, Weight	Treatment Period	Treatment Period	3	Date of first dose of study treatment	Day 29
BMI, Weight	End of Treatment	End of Treatment	4	Date of first dose of study treatment	Day 57
Vital signs	Screening	Screening	1	Date of first dose of study treatment	Day -1
Vital signs	Baseline	Treatment Period	2	Date of first dose of study treatment	Day 1
Vital signs	Treatment Period	Treatment Period	3	Date of first dose of study treatment	Day 29

Vital signs	End of Treatment	End of Treatment	4	Date of first dose of study treatment	Day 57
Hematology	Screening	Screening	1	Date of first dose of study treatment	Day -1
Hematology	End of Treatment	End of Treatment	4	Date of first dose of study treatment	Day 57
Biochemistry	Screening	Screening	1	Date of first dose of study treatment	Day -1
Biochemistry	End of Treatment	End of Treatment	4	Date of first dose of study treatment	Day 57
Pregnancy test	Screening	Screening	1	Date of first dose of study treatment	Day -1
Test report for H. pylori[2]	Screening	Screening	1	Date of first dose of study treatment	Day -1
Upper GI Ultrasound	Screening	Screening	1	Date of first dose of study treatment	Day -1
Endoscopy	Screening	Screening	1	Date of first dose of study treatment	Day -1
ECG	Screening	Screening	1	Date of first dose of study treatment	Day -1
Leeds Dyspepsia Questionnaire (LDQ)	Screening	Screening	1	Date of first dose of study treatment	Day -1
Leeds Dyspepsia Questionnaire (LDQ)	Treatment Period	Treatment Period	3	Date of first dose of study treatment	Day 29
Leeds Dyspepsia Questionnaire (LDQ)	End of Treatment	End of Treatment	4	Date of first dose of study	Day 57

				treatment	
SF-NDI questionnaire	Baseline	Treatment Period	2	Date of first dose of study treatment	Day 1
SF-NDI questionnaire	End of Treatment	End of Treatment	4	Date of first dose of study treatment	Day 57
NRS 11 (Onsite)	Baseline	Treatment Period	2	Date of first dose of study treatment	Day 1
NRS 11 (patient diary)	Baseline	Treatment Period	2	Date of first dose of study treatment	Day 1
NRS 11 (patient diary)	Treatment Period	Treatment Period	3	Date of first dose of study treatment	Day 29
Adverse Event	Screening	Screening	1	Date of first dose of study treatment	Day -1
Adverse Event	Baseline	Treatment Period	2	Date of first dose of study treatment	Day 1
Adverse Event	Treatment Period	Treatment Period	3	Date of first dose of study treatment	Day 29
Adverse Event	End of Treatment	End of Treatment	4	Date of first dose of study treatment	Day 57
Adverse Event	Follow up	Follow up	TC	Date of first dose of study treatment	Day 64
Concomitant Medication	Screening	Screening	1	Date of first dose of study treatment	Day -1
Concomitant Medication	Baseline	Treatment Period	2	Date of first dose of study treatment	Day 1

Concomitant Medication	Treatment Period	Treatment Period	3	Date of first dose of study treatment	Day 29
Concomitant Medication	End of Treatment	End of Treatment	4	Date of first dose of study treatment	Day 57
Concomitant Medication	Follow up	Follow up	TC	Date of first dose of study treatment	Day 64
Drug Return and Accountability	Treatment Period	Treatment Period	3	Date of first dose of study treatment	Day 29
Drug Return and Accountability	End of Treatment	End of Treatment	4	Date of first dose of study treatment	Day 57
Treatment acceptance and ease of use	End of Treatment	End of Treatment	4	Date of first dose of study treatment	Day 57

6.2 Further Specifications to the Standard Tables in Module 2

Not Applicable

6.3 Other Further Specifications

Not Applicable

7. CHANGES TO PLANNED ANALYSES

7.1 Changes to the Analysis Laid Down in the Protocol

Change in	Study Protocol	Statistical Analysis Plan
Subject sample	All subjects randomized to treatment sample has been used	Changed to All subjects allocated to treatment subject sample

7.2 Changes from previous SAP Version

Sr. No.	Changes
1	Added General Considerations for the Analysis section
2	Included sample SAS code for Missing Values Imputation and for MMRM Model.
3	Summarized all 15 symptoms of SF-NDI as a score in addition to individual symptom's summaries
4	QoL domains are now summarized based on both raw scores and transformed scores; initially, only raw scores were provided. Derivation also added for transformed scores.
5	Updated AE table summarizing adverse events with incidence ≥ 3% instead of incidence ≥ 5%
6	Elaborated the Safety Analysis section and added other analysis section specifying baseline tables, summaries, and listings.
7	Defined markedly abnormal ranges for non-standard variables of Hematology and Biochemistry.

8. REFERENCE

1. Clinical Study Protocol, Protocol No. ITOP-322-0216, Version 1.0, Dated 05-SEP-2023
2. Abbott SAP Module 2
3. CDISC terminology, see http://www.cdisc.org.

9. APPENDICES

9.1 Study Flowchart

All study assessments will be conducted as indicated in the below Table, which displays the frequency and timing of all measurements.

Table : Study Assessments

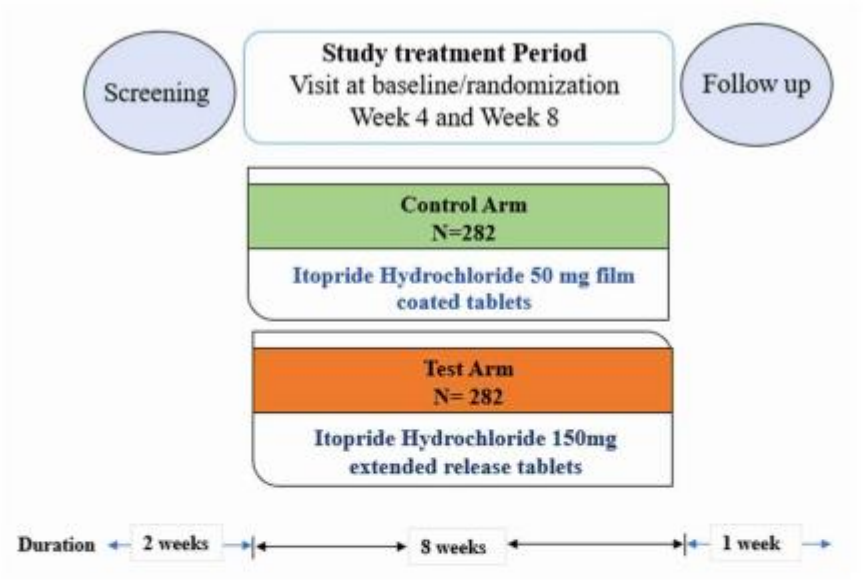
Periods	**Screening period**	**Treatment period**			**Follow up**
Visits (V)	**V1**	**V2**	**V3**	**V4 (ET/ED)**	**TC**
Week			***W4***	***W8***	
Day	***Day -1***	***Day 1***	***Day 29***	***Day 57***	***Day 64***
Visit window	***-14 to -1 days***		***±1 day***	***±1 day***	***+1 day***
Informed Consent	X				
Demographic data	X				
Medical history	X				
Inclusion/Exclusion criteria	X	X			
Physical examination	X	X	X	X	
Weight, Height (screening only), BMI[5]	X	X	X	X	
Vital signs	X	X	X	X	
Hematology	X			X	
Biochemistry (including RBS, Serum prolactin (fasting), Serum lipase[7])	X			X	
Pregnancy test[1]	X				
Test report for H. pylori[2]	X				
Upper GI Ultrasound	X				
Endoscopy[3]	X				
ECG	X				
Randomization		X			
Leeds Dyspepsia Questionnaire (LDQ)	X		X	X	
Short From Nepean Dyspepsia Index (SF-NDI) questionnaire		X		X	
NRS 11 onsite (baseline only)		X			
Patient diary distribution		X	X		
NRS 11 recorded in patient diary[4]		X	X		
Dispense Study drug		X	X		
Drug intake recorded in patient diary[6]		X	X		
Diary return			X	X	

Study drug return			X	X	
Study drug accountability and adherence assessment			X	X	
Adverse events	X	X	X	X	X
Concomitant medications	X	X	X	X	X
Treatment acceptance and ease of use assessment using Likert scale				X	

ET – End of treatment, ED – Early discontinuation, TC – Telephone contact, D – day, V – Visit

1. For women of child-bearing potential (including those without history of surgical sterilization and women with <2 years post-menopause)
2. H. pylori test report in medical history within 3 months before randomization, otherwise to be performed during screening.
3. Endoscopy in medical history within 6 months before randomization, otherwise to be performed during screening.
4. Symptoms will be recorded by the subject over the last 2 weeks prior to the next visit.
5. Will be calculated during analysis, not by investigator.
6. Will be recorded daily.
7. Serum Lipase at V1 (baseline) only.

9.2 Study Design



9.3 Tables, Listings and Figures

9.3.1 Tables

For the shells of the non-standard tables, see Section 10.1.

Output Code	Clinical Domain	Output Number	Title	Produced for:		
				Headline Results	SMT	Interim Analysis
DST001	Subject Disposition	10.1.1.1	Subject Disposition - All Subjects Allocated to Treatment Subject Sample	X	NA	NA
DVT001	Protocol Deviations	10.1.1.2	Major Protocol Deviations – All Subjects Allocated to Treatment Subject Sample		NA	NA
DVT002	Protocol Deviations	10.1.1.3	Subject Samples - All Subjects Allocated to Treatment Subject Sample		NA	NA
DMT002	Demographic Data	10.1.1.4	Demographics – All Subjects Allocated to Treatment Subject Sample	X	NA	NA
VST003	Vital Signs	10.1.1.5	Other Baseline Characteristics – All Subjects Allocated to Treatment Subject Sample		NA	NA
MHT001	Medical History	10.1.1.6	Medical History – All Subjects Allocated to Treatment Subject Sample		NA	NA

Output Code	Clinical Domain	Output Number	Title	Produced for:		
				Headline Results	SMT	Interim Analysis
CMT001	Concomitant Medications	10.1.1.7	Concomitant Medication – All Subject Allocated to Treatment Subject Sample		NA	NA
	Treatment Exposure	10.1.1.8.1	Exposure to Study Drug – Safety Subject Sample	X	NA	NA
DAT001	Treatment Compliance	10.1.1.8.2	Compliance to Study Drug – Safety Subject Sample		NA	NA
	LDQ	10.1.2.1.1.1	Change in Leeds Dyspepsia Questionnaire (LDQ) Severity Score at week 8 (HDL) – Per Protocol Subject Sample	X	NA	NA
	LDQ	10.1.2.1.1.2	Change in Leeds Dyspepsia Questionnaire (LDQ) Severity Score at week 8 (by Gender) – Per Protocol Subject Sample		NA	NA
	LDQ	10.1.2.1.1.3	Change in Leeds Dyspepsia Questionnaire (LDQ) Severity Score at week 8 (by Age Group) – Per Protocol Subject Sample		NA	NA

Output Code	Clinical Domain	Output Number	Title	Produced for:		
				Headline Results	SMT	Interim Analysis
	LDQ	10.1.2.1.1.4	Change in Leeds Dyspepsia Questionnaire (LDQ) Severity Score at week 8 (by Geographical Region) – Per Protocol Subject Sample		NA	NA
	LDQ	10.1.2.1.1.5	Change in Leeds Dyspepsia Questionnaire (LDQ) Severity Score at week 8 (HDL) with Missing Imputation – Per Protocol Subject Sample		NA	NA
	LDQ	10.1.2.1.1.6	Change in Leeds Dyspepsia Questionnaire (LDQ) Severity Score at week 8 (HDL) by using MMRM Model with Multiple Imputation – Per Protocol Subject Sample		NA	NA
	LDQ	10.1.2.1.1.7	Change in Leeds Dyspepsia Questionnaire (LDQ) Severity Score at week 8 (HDL) for subjects completed the study – Per Protocol Subject Sample		NA	NA

Output Code	Clinical Domain	Output Number	Title	Produced for:		
				Headline Results	SMT	Interim Analysis
	LDQ	10.1.2.1.2.1	Change in Leeds Dyspepsia Questionnaire (LDQ) Severity Score (HDL) – Full Analysis Subject Sample	X	NA	NA
	LDQ	10.1.2.1.2.2	Change in Leeds Dyspepsia Questionnaire (LDQ) Severity Score (by Gender) – Full Analysis Subject Sample	X	NA	NA
	LDQ	10.1.2.1.2.3	Change in Leeds Dyspepsia Questionnaire (LDQ) Severity Score (by Age Group) Full Analysis Subject Sample	X	NA	NA
	LDQ	10.1.2.1.2.4	Change in Leeds Dyspepsia Questionnaire (LDQ) Severity Score (by Geographical Region) – Full Analysis Subject Sample	X	NA	NA

Output Code	Clinical Domain	Output Number	Title	Produced for:		
				Headline Results	SMT	Interim Analysis
	LDQ	10.1.2.1.2.5	Change in Leeds Dyspepsia Questionnaire (LDQ) Severity Score (HDL) at week 8 with Multiple Imputation – Full Analysis Subject Sample			
	LDQ	10.1.2.1.2.6	Change in Leeds Dyspepsia Questionnaire (LDQ) Severity Score (HDL) at week 8 by using MMRM Model – Full Analysis Subject Sample			
	SF-NDI Questionnaire	10.1.2.2.1.1	Summary of Symptoms response assessed by Short Form Nepean Dyspepsia Index (SF-NDI) Questionnaire – Full Analysis Subject Sample	X	NA	NA
	SF-NDI Questionnaire	10.1.2.2.1.2	Summary of Symptoms score assessed by Short Form Nepean Dyspepsia Index (SF-NDI) Questionnaire – Full Analysis Subject Sample	X	NA	NA

Output Code	Clinical Domain	Output Number	Title	Produced for:		
				Headline Results	SMT	Interim Analysis
	SF-NDI Questionnaire	10.1.2.2.2.1	Summary of Functional Dyspepsia Score assessed by Short Form Nepean Dyspepsia Index (SF-NDI) Questionnaire (HDL) – Full Analysis Subject Sample	X	NA	NA
	SF-NDI Questionnaire	10.1.2.2.2.2	Summary of Functional Dyspepsia Score assessed by Short Form Nepean Dyspepsia Index (SF-NDI) Questionnaire (by Gender) – Full Analysis Subject Sample		NA	NA
	SF-NDI Questionnaire	10.1.2.2.2.3	Summary of Functional Dyspepsia Score assessed by Short Form Nepean Dyspepsia Index (SF-NDI) Questionnaire (by Age Group) – Full Analysis Subject Sample		NA	NA

Output Code	Clinical Domain	Output Number	Title	Produced for:		
				Headline Results	SMT	Interim Analysis
	SF-NDI Questionnaire	10.1.2.2.2.4	Summary of Functional Dyspepsia Score assessed by Short Form Nepean Dyspepsia Index (SF-NDI) Questionnaire (by Geographical Region) – Full Analysis Subject Sample		NA	NA
	SF-NDI Questionnaire	10.1.2.2.3.1	Summary of Raw Score of Quality of Life (QoL) Assessed by Nepean Dyspepsia Index (SF-NDI) Questionnaire (HDL) - Full Analysis Subject Sample	X	NA	NA
	SF-NDI Questionnaire	10.1.2.2.3.2	Summary of Raw Score of Quality of Life (QoL) Assessed by Nepean Dyspepsia Index (SF-NDI) Questionnaire (by Gender) - Full Analysis Subject Sample		NA	NA

Output Code	Clinical Domain	Output Number	Title	Produced for:		
				Headline Results	SMT	Interim Analysis
	SF-NDI Questionnaire	10.1.2.2.3.3	Summary of Raw Score of Quality of Life (QoL) Assessed by Nepean Dyspepsia Index (SF-NDI) Questionnaire (by Age Group) - Full Analysis Subject Sample		NA	NA
	SF-NDI Questionnaire	10.1.2.2.3.4	Summary of Raw Score of Quality of Life (QoL) Assessed by Nepean Dyspepsia Index (SF-NDI) Questionnaire (by Geographical Region) - Full Analysis Subject Sample		NA	NA
	SF-NDI Questionnaire	10.1.2.2.3.5	Summary of Transformed Score of Quality of Life (QoL) Assessed by Nepean Dyspepsia Index (SF-NDI) Questionnaire (HDL) - Full Analysis Subject Sample	X	NA	NA

Output Code	Clinical Domain	Output Number	Title	Produced for:		
				Headline Results	SMT	Interim Analysis
	SF-NDI Questionnaire	10.1.2.2.3.6	Summary of Transformed Score of Quality of Life (QoL) Assessed by Nepean Dyspepsia Index (SF-NDI) Questionnaire (by Gender) - Full Analysis Subject Sample		NA	NA
	SF-NDI Questionnaire	10.1.2.2.3.7	Summary of Transformed Score of Quality of Life (QoL) Assessed by Nepean Dyspepsia Index (SF-NDI) Questionnaire (by Age Group) - Full Analysis Subject Sample		NA	NA
	SF-NDI Questionnaire	10.1.2.2.3.8	Summary of Transformed Score of Quality of Life (QoL) Assessed by Nepean Dyspepsia Index (SF-NDI) Questionnaire (by Geographical Region) - Full Analysis Subject Sample		NA	NA
	NRS-11	10.1.2.2.4.1	Change in NRS 11 Symptoms Scores After Week 4 and Week 8 (HDL) - Full Analysis Subject Sample	X	NA	NA

Output Code	Clinical Domain	Output Number	Title	Produced for:		
				Headline Results	SMT	Interim Analysis
	NRS-11	10.1.2.2.4.2	Change in NRS 11 Symptoms Scores After Week 4 and Week 8 (by Gender) - Full Analysis Subject Sample	X	NA	NA
	NRS-11	10.1.2.2.4.3	Change in NRS 11 Symptoms Scores After Week 4 and Week 8 (by Age Group) - Full Analysis Subject Sample	X	NA	NA
	NRS-11	10.1.2.2.4.4	Change in NRS 11 Symptoms Scores After Week 4 and Week 8 (by Geographical Region) - Full Analysis Subject Sample		NA	NA
	LDQ and NRS 11	10.1.2.2.5.1	Responder Analysis of Satisfactory Relief Assessed by LDQ and NRS 11 (HDL) - Full Analysis Subject Sample	X	NA	NA
	LDQ and NRS 11	10.1.2.2.5.2	Responder Analysis of Satisfactory Relief Assessed by LDQ and NRS 11 (by Gender) - Full Analysis Subject Sample		NA	NA

Output Code	Clinical Domain	Output Number	Title	Produced for:		
				Headline Results	SMT	Interim Analysis
	LDQ and NRS 11	10.1.2.2.5.3	Responder Analysis of Satisfactory Relief Assessed by LDQ and NRS 11 (by Age Group) - Full Analysis Subject Sample		NA	NA
	LDQ and NRS 11	10.1.2.2.5.4	Responder Analysis of Satisfactory Relief Assessed by LDQ and NRS 11 (by Geographical Region) - Full Analysis Subject Sample		NA	NA
	Treatment Acceptance & Ease of Use Assessment	10.1.2.3.1.1	Treatment Acceptance & Ease of Use Assessment using Likert Scale (HDL) - Full Analysis Subject Sample		NA	NA
	Treatment Acceptance & Ease of Use Assessment	10.1.2.3.1.2	Treatment Acceptance & Ease of Use Assessment using Likert Scale (by Gender) - Full Analysis Subject Sample		NA	NA
	Treatment Acceptance & Ease of Use Assessment	10.1.2.3.1.3	Treatment Acceptance & Ease of Use Assessment using Likert Scale (by Age Group) - Full Analysis Subject Sample		NA	NA

Output Code	Clinical Domain	Output Number	Title	Produced for:		
				Headline Results	SMT	Interim Analysis
	Treatment Acceptance & Ease of Use Assessment	10.1.2.3.1.4	Treatment Acceptance & Ease of Use Assessment using Likert Scale (by Geographical Region) - Full Analysis Subject Sample		NA	NA
AET001	Adverse Events	10.1.3.1.1.1	Overall Summary of Adverse Events – Safety Subject Sample	X	NA	NA
	Adverse Events	10.1.3.1.1.2	Overall Summary of Adverse Events (by Gender) – Safety Subject Sample		NA	NA
	Adverse Events	10.1.3.1.1.3	Overall Summary of Adverse Events (by Age Group) – Safety Subject Sample		NA	NA
	Adverse Events	10.1.3.1.1.4	Overall Summary of Adverse Events (by Geographical Region) – Safety Subject Sample		NA	NA
AET002	Adverse Events	10.1.3.1.2	Incidence of TEAEs – Safety Subject Sample	X	NA	NA
AET003	Adverse Events	10.1.3.1.3	Incidence of TEAEs in ≥ 3% of the Subjects in Any Treatment Group – Safety Subject Sample		NA	NA

Output Code	Clinical Domain	Output Number	Title	Produced for:		
				Headline Results	SMT	Interim Analysis
AET005	Adverse Events	10.1.3.1.4	Incidence of TEAEs With a Reasonable Possibility for a Causal Relationship (Investigator's Judgment) – Safety Subject Sample		NA	NA
AET006	Adverse Events	10.1.3.1.5	Incidence of TEAEs by Maximum Severity (Investigator's Judgment) – Safety Subject Sample		NA	NA
AET007	Adverse Events	10.1.3.1.6	Incidence of TESAEs – Safety Subject Sample		NA	NA
AET008	Adverse Events	10.1.3.1.7.1	Incidence of TEAEs Leading to Study Termination – Safety Subject Sample		NA	NA
AET009	Adverse Events	10.1.3.1.8	Incidence of non-serious TEAEs – Safety Subject Sample		NA	NA
AET010	Adverse Events	10.1.3.1.9	Incidence of non-serious TEAEs in >= 3% of the Subjects in Any Treatment Group – Safety Subject Sample		NA	NA

Output Code	Clinical Domain	Output Number	Title	Produced for:		
				Headline Results	SMT	Interim Analysis
LBT001	Laboratory Tests	10.1.3.2.1.1	Summary of Quantitative Safety Laboratory Variables (Biochemistry)– Safety Subject Sample		NA	NA
LBT001	Laboratory Tests	10.1.3.2.1.2	Summary of Quantitative Safety Laboratory Variables (Hematology)– Safety Subject Sample		NA	NA
	Laboratory Tests	10.1.3.2.1.3	Summary of Quantitative Safety Laboratory Variable Serum Prolactin (by Gender) – Safety Subject Sample		NA	NA
	Laboratory Tests	10.1.3.2.1.4	Summary of Quantitative Safety Laboratory Variable Serum Prolactin (by Age Group) – Safety Subject Sample		NA	NA
	Laboratory Tests	10.1.3.2.1.5	Summary of Quantitative Safety Laboratory Variables Serum Prolactin (by Geographical Region) – Safety Subject Sample		NA	NA

Output Code	Clinical Domain	Output Number	Title	Produced for:		
				Headline Results	SMT	Interim Analysis
LBT003	Laboratory Tests	10.1.3.2.2.1	Shifts of Quantitative Safety Laboratory Variables from Baseline to Each Post-Baseline Visit Based on Reference Ranges (Biochemistry)– Safety Subject Sample		NA	NA
LBT003	Laboratory Tests	10.1.3.2.2.2	Shifts of Quantitative Safety Laboratory Variables from Baseline to Each Post-Baseline Visit Based on Reference Ranges (Hematology) – Safety Subject Sample		NA	NA
LBT004	Laboratory Tests	10.1.3.2.3.1	Incidence of Markedly Abnormal Safety Laboratory Variables (Biochemistry) – Safety Subject Sample		NA	NA
LBT004	Laboratory Tests	10.1.3.2.3.2	Incidence of Markedly Abnormal Safety Laboratory Variables (Hematology) – Safety Subject Sample		NA	NA

Output Code	Clinical Domain	Output Number	Title	Produced for:		
				Headline Results	SMT	Interim Analysis
VST001	Vital Signs	10.1.3.3.1	Summary of Vital Signs – Safety Subject Sample		NA	NA
VST002	Vital Signs	10.1.3.3.2	Incidence of Markedly Abnormal Vital Signs – Safety Subject Sample		NA	NA

Note: The blank output code denotes a non-standard output.

9.3.2 Listings

For the shells of the non-standard listings, see Section 10.2.

Output Code	Clinical Domain	Output Number	Title	Produced for:		
				Headline Results	SMT	Interim Analysis
DSL001	Subject Disposition	12.2.1.1	Subjects Who Prematurely Terminated the Study Prior to Treatment Allocation - All Subjects Consented Subject Sample		NA	NA
DSL002	Subject Disposition	12.2.1.2	Subjects Allocated to Treatment - All Subjects Allocated to Treatment Subject Sample		NA	NA

Output Code	Clinical Domain	Output Number	Title	Produced for:		
				Headline Results	SMT	Interim Analysis
DSL003	Subject Disposition	12.2.1.3	Subjects Allocated to Treatment Who Prematurely Terminated the Study - All Subjects Allocated to Treatment Subject Sample		NA	NA
IEL002	Inclusion/Exclusion	12.2.2	Subjects With Deviations from Inclusion or Exclusion Criteria - All Subjects Consented Subject Sample		NA	NA
DVL001	Major Protocol Deviations	12.2.2.1	Subjects With Major Protocol Deviations - All Subjects Allocated to Treatment Subject Sample		NA	NA
DVL002	Major Protocol Deviations	12.2.3.1	Subjects Excluded from the Subject Samples - All Subjects Allocated to Treatment Subject Sample		NA	NA
DML002	Demographic Data	12.2.4.1	Demographics - All Subjects Allocated to Treatment Subject Sample		NA	NA
VSL003	Vital Signs	12.2.4.2	Other Baseline Characteristics - All Subjects Allocated to Treatment Subject Sample		NA	NA

Output Code	Clinical Domain	Output Number	Title	Produced for:		
				Headline Results	SMT	Interim Analysis
	Non-Standard Baseline	12.2.4.3.1	H-Pylori and Upper Gastrointestinal Ultrasound - All Subjects Allocated to Treatment Subject Sample		NA	NA
	Non-Standard Baseline	12.2.4.3.2	Endoscopy - All Subjects Allocated to Treatment Subject Sample		NA	NA
MHL001	Medical History	12.2.4.4	Medical History: General - All Subjects Allocated to Treatment Subject Sample		NA	NA
MHL002	Medical History	12.2.4.5	Medical History: MedDRA Coding - All Subjects Allocated to Treatment Subject Sample		NA	NA
CML001	Concomitant Medications	12.2.4.6	Concomitant Medication: General - All Subjects Allocated to Treatment Subject Sample		NA	NA
CML002	Concomitant Medications	12.2.4.7	Concomitant Medication: WHO-DD Coding - All Subjects Allocated to Treatment Subject Sample		NA	NA

Output Code	Clinical Domain	Output Number	Title	Produced for:		
				Headline Results	SMT	Interim Analysis
	Non-Standard Baseline	12.2.4.8	12 Lead Electrocardiogram and Pregnancy Test - All Subjects Allocated to Treatment Subject Sample		NA	NA
	Drug Accountability and Compliance	12.2.5.1	Treatment Drug Exposure, Accountability and Compliance - All Subjects Allocated to Treatment Subject Sample		NA	NA
NSL003	LDQ	12.2.6.1.1	Leeds Dyspepsia Questionnaire (LDQ); Question 1 to 8 - All Subjects Allocated to Treatment Subject Sample			
NSL004	LDQ	12.2.6.1.2	Leeds Dyspepsia Questionnaire (LDQ); Question 9 to 15 - All Subjects Allocated to Treatment Subject Sample			
NSL005	LDQ	12.2.6.1.3	Leeds Dyspepsia Questionnaire (LDQ); Severity Scores - All Subjects Allocated to Treatment Subject Sample			

Output Code	Clinical Domain	Output Number	Title	Produced for:		
				Headline Results	SMT	Interim Analysis
NSL005	SF-NDI Questionnaire	12.2.6.2.1	Symptoms Questionnaire using Short Form-Nepean Dyspepsia Index (SF-NDI) - All Subjects Allocated to Treatment Subject Sample			
NSL007	SF-NDI Questionnaire	12.2.6.2.2	All Symptoms & Functional Dyspepsia Scores Assessed by Short Form Nepean Dyspepsia Index (SF-NDI) Questionnaire - All Subjects Allocated to Treatment Subject Sample			
NSL006	SF-NDI Questionnaire	12.2.6.3.1	Quality of Life (QoL) Questionnaire using Short Form-Nepean Dyspepsia Index (SF-NDI) - All Subjects Allocated to Treatment Subject Sample			

Output Code	Clinical Domain	Output Number	Title	Produced for:		
				Headline Results	SMT	Interim Analysis
NSL008	SF-NDI Questionnaire	12.2.6.3.2	Quality of Life (QoL) Raw and Transformed Scores Assessed by Short Form Nepean Dyspepsia Index (SF-NDI) Questionnaire - All Subjects Allocated to Treatment Subject Sample Subject Sample			
NSL009	NRS 11	12.2.6.4.1	Numerical Rating Scale (NRS 11) Questionnaire - All Subjects Allocated to Treatment Subject Sample			
NSL010	Treatment Acceptance & Ease of Use Assessment	12.2.6.5.1	Treatment Acceptance & Ease of Use Assessment using likert Scale - All Subjects Allocated to Treatment Subject Sample			
AEL008	Adverse Events	12.2.7.1	AEs: General - All Subjects Consented Subject Sample		NA	NA
AEL002	Adverse Events	12.2.7.2	AEs: MedDRA Coding - All Subjects Consented Subject Sample		NA	NA

Output Code	Clinical Domain	Output Number	Title	Produced for:		
				Headline Results	SMT	Interim Analysis
AEL011	Adverse Events	10.1.3.1.7.2	Listing of TEAEs Leading to Study Termination – Safety Subject Sample			
AEL009	Adverse Events	10.1.3.1.10	Listing of Deaths - All Subjects Consented Subject Sample			
AEL010	Adverse Events	10.1.3.1.11	Listing of Other SAEs - All Subjects Consented Subject Sample			
AEL012	Adverse Events	12.2.7.3	Listing of TEAEs Leading to Discontinuation of Study Drug – Safety Subject Sample		NA	NA
AEL013	Adverse Events	8.3.2.1	Data Portion for Subject Narratives – All Subjects Consented Subject Sample		NA	NA
LBL003	Laboratory Data	12.2.8.1.1	Quantitative Safety Laboratory Variables (Biochemistry) - All Subject Consented Sample		NA	NA
LBL003	Laboratory Data	12.2.8.1.2	Quantitative Safety Laboratory Variables (Hematology) - All Subject Consented Sample		NA	NA

Output Code	Clinical Domain	Output Number	Title	Produced for:		
				Headline Results	SMT	Interim Analysis
LBL008	Laboratory Data	12.2.8.2.1	Markedly Abnormal and/or Clinically Significant Safety Laboratory Variables (Biochemistry)– Safety Subject Sample		NA	NA
LBL008	Laboratory Data	12.2.8.2.2	Markedly Abnormal and/or Clinically Significant Safety Laboratory Variables (Hematology) – Safety Subject Sample		NA	NA
LBL007	Laboratory Data	12.2.8.3	Reference Ranges - All Subject Consented Sample		NA	NA
VSL005	Vital Signs	12.2.8.4	Vital Signs - All Subject Allocated to Treatment Subject Sample		NA	NA
VSL004	Vital Signs	12.2.8.5	Markedly Abnormal Vital Signs – Safety Subject Sample		NA	NA

Note: The blank output code denotes a non-standard output.

9.3.3 Figures

For the shells of the non-standard figures, see Section 10.3.

Output Code	Clinical Domain	Output Number	Title	Produced for:		
				Headline results	SMT	Interim analysis
DSF001	Subject Disposition	10.1.4.1	Flowchart of Subject Disposition	X	NA	NA
DSF002	Subject Disposition	10.1.4.2	Flowchart of Subject samples	X	NA	NA

10. NON-STANDARD TABLES, LISTINGS AND FIGURES SHELLS

10.1 Non-Standard Tables

Table 10.1.1.8.1: Exposure to Study Drug

SAFETY SUBJECT SAMPLE

	Statistics	<Tr Arm 2> (N=xxx)	<Tr Arm 2> (N=xxx)
Duration of Treatment Exposure (Days)	n	xxx	xxx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx

Source: LXX00X.sas, <CRO>.Run DDMMMYYYY HH:MM Page x/y
Abbott Protocol CCCC-xxx-yyyy

Table 10.1.2.1.1.1: Change in Leeds Dyspepsia Questionnaire (LDQ) Severity Score at week 8

PER PROTCOL SUBJECT SAMPLE

Visit	Statistics	<Tr Arm 1> (N=xxx)	<Tr Arm 2> (N=xxx)
Baseline	n	xxx	xxx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Week 8	n	xxx	xxx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Change from Baseline at Week 8	n	xxx	xxx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
	LS Mean (SE)	xx.x (x.x)	xx.x (x.x)
	95% CI for LS Mean	xx.x, xx.x	xx.x, xx.x
	LS Mean difference (SE)	xx.x (x.x)	
	95% CI for LS Mean difference	xx.x, xx.x	
	p-value	x.xxx	

Note 1: Baseline is defined as the last available observation prior to the first study drug administration.
Note 2: LS Mean, LS Mean difference, SE, 95% CI and p-value is calculated by using the analysis of covariance (ANCOVA) model includes change in the LDQ score as dependent variable and treatment group, site and LDQ baseline value as covariates.

Source: LXX00X.sas, <CRO>.Run DDMMMYYYY HH:MM Page x/y
Abbott Protocol CCCC-xxx-yyyy

Remark (Not part of the Table)
Repeat similar table for
Table 10.1.2.1.1.5: Change in Leeds Dyspepsia (LDQ) Severity Score at week 8 with Missing Imputation
Repeat similar table for
Table 10.1.2.1.1.6: Change in Leeds Dyspepsia (LDQ) Severity Score at week 8 by Using MMRM Model with Missing Imputation
Repeat similar table for
Table 10.1.2.1.1.7: Change in Leeds Dyspepsia (LDQ) Severity Score at week 8 for Subjects Completed the Study
Min/Max are represented as recorded; mean, median and SD with one more decimal place.

Table 10.1.2.1.1.2: Change in Leeds Dyspepsia Questionnaire (LDQ) Severity Score at week 8 (by Gender)

PER PROTCOL SUBJECT SAMPLE

Gender Visit	Statistics	<Tr Arm 1> (N=xxx)	<Tr Arm 2> (N=xxx)
Male,	n	xx	xx
Baseline	n	xxx	xxx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Week 8	n	xxx	xxx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Change from Baseline at Week 8	n	xxx	xxx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
	LS Mean (SE)	xx.x (x.x)	xx.x (x.x)
	95% CI for LS Mean	xx.x, xx.x	xx.x, xx.x
	LS Mean difference (SE)	xx.x (x.x)	

95% CI for LS Mean difference	xx.x, xx.x
p-value	x.xxx

Note 1: Baseline is defined as the last available observation prior to the first study drug administration.
Note 2: LS Mean, LS Mean difference, SE, 95% CI and p-value is calculated by using the analysis of covariance (ANCOVA) model includes change in the LDQ score as dependent variable and treatment group, site and LDQ baseline value as covariates.

Source: LXX00X.sas, <CRO>.Run DDMMMYYYY HH:MM Page x/y
Abbott Protocol CCCC-xxx-yyyy

Remark (not part of the table):
Repeat similar table for
Table 10.1.2.1.1.3: Change in Leeds Dyspepsia (LDQ) Severity Score at week 8 by (by Age Group)
Repeat similar table for
Table 10.1.2.1.1.4: Change in Leeds Dyspepsia (LDQ) Severity Score at week 8 (by Geographical Region)
Min/Max are represented as recorded; mean, median and SD with one more decimal place.

Table 10.1.2.1.2.1: Change in Leeds Dyspepsia Questionnaire (LDQ) Severity Score at week 4 and week 8

FULL ANALYSIS SUBJECT SAMPLE

Visit	Statistics	<Tr Arm 1> (N=xxx)	<Tr Arm 2> (N=xxx)
Baseline	n	xxx	xxx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Week 4	n	xxx	xxx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Change from Baseline at Week 4	n	xxx	xxx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
	LS Mean (SE)	xx.x (x.x)	xx.x (x.x)
	95% CI for LS Mean	xx.x, xx.x	xx.x, xx.x
	LS Mean difference (SE)	xx.x (x.x)	
	95% CI for LS Mean difference	xx.x, xx.x	
	p-value	x.xxx	
Week 8	n	xxx	xxx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)

	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Change from Baseline at Week 8	n	xxx	xxx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
	LS Mean (SE)	xx.x (x.x)	xx.x (x.x)
	95% CI for LS Mean	xx.x, xx.x	xx.x, xx.x
	LS Mean difference (SE)	xx.x (x.x)	
	95% CI for LS Mean difference	xx.x, xx.x	
	p-value	x.xxx	

Note 1: Baseline is defined as the last available observation prior to the first study drug administration.
Note 2: LS Mean, LS Mean difference, SE, 95% CI and p-value is calculated by using the analysis of covariance (ANCOVA) model includes change in the LDQ score as dependent variable and treatment group, site and LDQ baseline value as covariates.

Source: LXX00X.sas, <CRO>.Run DDMMMYYYY HH:MM Page x/y
Abbott Protocol CCCC-xxx-yyyy

Remark (not part of the table):
Repeat similar table for **Table 10.1.2.1.2.5: Change in Leeds Dyspepsia (LDQ) Severity Score at week 8 with Missing Imputation**
Repeat similar table for **Table 10.1.2.1.2.6: Change in Leeds Dyspepsia (LDQ) Severity Score at week 8 by Using MMRM Model**
Programmers Note: Table 10.1.2.1.2.5 and Table 10.1.2.1.2.6 will be created for week 8 only.

Min/Max are represented as recorded; mean, median and SD with one more decimal place.

Table 10.1.2.1.2.2: Change in Leeds Dyspepsia Questionnaire (LDQ) Severity Score at week 4 and week 8 (by Gender)

FULL ANALYSIS SUBJECT SAMPLE

Group Visit	Statistics	<Tr Arm 1> (N=xxx)	<Tr Arm 2> (N=xxx)
Male,	n,	xxx	xxx
Baseline	n	xxx	xxx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Week 4	n	xxx	xxx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Change from Baseline at Week 4	n	xxx	xxx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
	LS Mean (SE)	xx.x (x.x)	xx.x (x.x)
	95% CI for LS Mean	xx.x, xx.x	xx.x, xx.x
	LS Mean difference (SE)	xx.x (x.x)	
	95% CI for LS Mean	xx.x, xx.x	

	difference		
	p-value	x.xxx	
Week 8	n	xxx	xxx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Change from Baseline at Week 8	n	xxx	xxx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
	LS Mean (SE)	xx.x (x.x)	xx.x (x.x)
	95% CI for LS Mean	xx.x, xx.x	xx.x, xx.x
	LS Mean difference (SE)	xx.x (x.x)	
	95% CI for LS Mean difference	xx.x, xx.x	
	p-value	x.xxx	
Female,	n,	xxx	xxx
Baseline	n	xxx	xxx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Week 4	n	xxx	xxx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)

	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Change from Baseline at Week 4	n	xxx	xxx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
	LS Mean (SE)	xx.x (x.x)	xx.x (x.x)
	95% CI for LS Mean	xx.x, xx.x	xx.x, xx.x
	LS Mean difference (SE)	xx.x (x.x)	
	95% CI for LS Mean difference	xx.x, xx.x	
	p-value	x.xxx	
Week 8	n	xxx	xxx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Change from Baseline at Week 8	n	xxx	xxx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
	LS Mean (SE)	xx.x (x.x)	xx.x (x.x)
	95% CI for LS Mean	xx.x, xx.x	xx.x, xx.x
	LS Mean difference	xx.x (x.x)	

(SE)	
95% CI for LS Mean difference	xx.x, xx.x
p-value	x.xxx

Note 1: Baseline is defined as the last available observation prior to the first study drug administration.
Note 2: LS Mean, LS Mean difference, SE, 95% CI and p-value is calculated by using the analysis of covariance (ANCOVA) model includes change in the LDQ score as dependent variable and treatment group, site and LDQ baseline value as covariates.

Source: LXX00X.sas, <CRO>.Run DDMMMYYYY HH:MM Page x/y
Abbott Protocol CCCC-xxx-yyyy

Remark (not part of the table):
Repeat similar table for **Table 10.1.2.1.2.3: Change in Leeds Dyspepsia (LDQ) Severity Score at week 4 and week 8 (by Age Group)**
Repeat similar table for **Table 10.1.2.1.2.4: Change in Leeds Dyspepsia (LDQ) Severity Score at week 4 and week 8 (by Geographical Region)**
Min/Max are represented as recorded; mean, median and SD with one more decimal place.

Table 10.1.2.2.1.1: Summary of Symptoms Response Assessed by Short Form Nepean Dyspepsia Index (SF-NDI) Questionnaire

FULL ANALYSIS SUBJECT SAMPLE

Symptoms	Measure	Visit	Response	Statistics	<Tr Arm 1> (N=xxx)	<Tr Arm 2> (N=xxx)
Pain or Ache in Upper Abdomen	Frequency	Baseline	Not at all	n (%)	xx (xx.x)	xx (xx.x)
			One to Four Days	n (%)	xx (xx.x)	xx (xx.x)
			Five to Eight Days	n (%)	xx (xx.x)	xx (xx.x)
			Nine to Twelve Days	n (%)	xx (xx.x)	xx (xx.x)
			Every Day/Almost Every Day	n (%)	xx (xx.x)	xx (xx.x)
		Week 8	Not at all	n (%)	xx (xx.x)	xx (xx.x)
			One to Four Days	n (%)	xx (xx.x)	xx (xx.x)
			Five to Eight Days	n (%)	xx (xx.x)	xx (xx.x)
			Nine to Twelve Days	n (%)	xx (xx.x)	xx (xx.x)
			Every Day/Almost Every Day	n (%)	xx (xx.x)	xx (xx.x)
	Intensity	Baseline	Not at all	n (%)	xx (xx.x)	xx (xx.x)
			Very Mild	n (%)	xx (xx.x)	xx (xx.x)
			Mild	n (%)	xx (xx.x)	xx (xx.x)
			Moderate	n (%)	xx (xx.x)	xx (xx.x)
			Severe	n (%)	xx (xx.x)	xx (xx.x)
			Very Severe	n (%)	xx (xx.x)	xx (xx.x)
		Week 8	Not at all	n (%)	xx (xx.x)	xx (xx.x)

			Very Mild	n (%)	xx (xx.x)	xx (xx.x)
			Mild	n (%)	xx (xx.x)	xx (xx.x)
			Moderate	n (%)	xx (xx.x)	xx (xx.x)
			Severe	n (%)	xx (xx.x)	xx (xx.x)
			Very Severe	n (%)	xx (xx.x)	xx (xx.x)
	Bothersomeness	Baseline	Not at all	n (%)	xx (xx.x)	xx (xx.x)
			A little bit	n (%)	xx (xx.x)	xx (xx.x)
			Moderately	n (%)	xx (xx.x)	xx (xx.x)
			Quite a bit	n (%)	xx (xx.x)	xx (xx.x)
			Extremely	n (%)	xx (xx.x)	xx (xx.x)
		Baseline	Not at all	n (%)	xx (xx.x)	xx (xx.x)
			A little bit	n (%)	xx (xx.x)	xx (xx.x)
			Moderately	n (%)	xx (xx.x)	xx (xx.x)
			Quite a bit	n (%)	xx (xx.x)	xx (xx.x)
			Extremely	n (%)	xx (xx.x)	xx (xx.x)
Discomfort in Upper Abdomen	Frequency	Baseline	Not at all	n (%)	xx (xx.x)	xx (xx.x)
			One to Four Days	n (%)	xx (xx.x)	xx (xx.x)
			Five to Eight Days	n (%)	xx (xx.x)	xx (xx.x)
			Nine to Twelve Days	n (%)	xx (xx.x)	xx (xx.x)
			Every Day/Almost Every Day	n (%)	xx (xx.x)	xx (xx.x)
		Week 8	Not at all	n (%)	xx (xx.x)	xx (xx.x)
			One to Four Days	n (%)	xx (xx.x)	xx (xx.x)
			Five to Eight Days	n (%)	xx (xx.x)	xx (xx.x)
			Nine to Twelve Days	n (%)	xx (xx.x)	xx (xx.x)
			Every Day/Almost Every Day	n (%)	xx (xx.x)	xx (xx.x)

	Intensity	Baseline	Not at all	n (%)	xx (xx.x)	xx (xx.x)
			Very Mild	n (%)	xx (xx.x)	xx (xx.x)
			Mild	n (%)	xx (xx.x)	xx (xx.x)
			Moderate	n (%)	xx (xx.x)	xx (xx.x)
			Severe	n (%)	xx (xx.x)	xx (xx.x)
			Very Severe	n (%)	xx (xx.x)	xx (xx.x)
		Week 8	Not at all	n (%)	xx (xx.x)	xx (xx.x)
			Very Mild	n (%)	xx (xx.x)	xx (xx.x)
			Mild	n (%)	xx (xx.x)	xx (xx.x)
			Moderate	n (%)	xx (xx.x)	xx (xx.x)
			Severe	n (%)	xx (xx.x)	xx (xx.x)
			Very Severe	n (%)	xx (xx.x)	xx (xx.x)
	Bothersomeness	Baseline	Not at all	n (%)	xx (xx.x)	xx (xx.x)
			A little bit	n (%)	xx (xx.x)	xx (xx.x)
			Moderately	n (%)	xx (xx.x)	xx (xx.x)
			Quite a bit	n (%)	xx (xx.x)	xx (xx.x)
			Extremely	n (%)	xx (xx.x)	xx (xx.x)
		Baseline	Not at all	n (%)	xx (xx.x)	xx (xx.x)
			A little bit	n (%)	xx (xx.x)	xx (xx.x)
			Moderately	n (%)	xx (xx.x)	xx (xx.x)
			Quite a bit	n (%)	xx (xx.x)	xx (xx.x)
			Extremely	n (%)	xx (xx.x)	xx (xx.x)
Burning sensation in Upper Abdomen	Frequency	Baseline	Not at all	n (%)	xx (xx.x)	xx (xx.x)
			One to Four Days	n (%)	xx (xx.x)	xx (xx.x)
			Five to Eight Days	n (%)	xx (xx.x)	xx (xx.x)

Nine to Twelve Days	n (%)	xx (xx.x)	xx (xx.x)
Every Day/Almost Every Day	n (%)	xx (xx.x)	xx (xx.x)

Note 1: Percentages are based on number of subjects in full analysis subject sample.

Source: LXX00X.sas, <CRO>.Run DDMMMYYYY HH:MM Page x/y
Abbott Protocol CCCC-xxx-yyyy

Remark (not part of the table):
Continue the above table for all the other symptoms specified in CRF.

Table 10.1.2.2.1.2: Summary of Symptoms Score Assessed by Short Form Nepean Dyspepsia Index (SF-NDI) Questionnaire

FULL ANALYSIS SUBJECT SAMPLE

Symptoms	Visit	Statistics	<Tr Arm 1> (N=xxx)	<Tr Arm 2> (N=xxx)
Pain or Ache in Upper Abdomen	Baseline	n	xxx	xxx
		Mean (SD)	xx.x (x.x)	xx.x (x.x)
		Median	xx.x	xx.x
		Min/Max	xx/xx	xx/xx
	Week 8	n	xxx	xxx
		Mean (SD)	xx.x (x.x)	xx.x (x.x)
		Median	xx.x	xx.x
		Min/Max	xx/xx	xx/xx
Discomfort in Upper Abdomen	Baseline	n	xxx	xxx
		Mean (SD)	xx.x (x.x)	xx.x (x.x)
		Median	xx.x	xx.x
		Min/Max	xx/xx	xx/xx
	Week 8	n	xxx	xxx
		Mean (SD)	xx.x (x.x)	xx.x (x.x)
		Median	xx.x	xx.x
		Min/Max	xx/xx	xx/xx

Note 1: Baseline is defined as the last available observation prior to the first study drug administration.

Source: LXX00X.sas, <CRO>.Run DDMMMYYYY HH:MM Page x/y
Abbott Protocol CCCC-xxx-yyyy

Remark (not part of the table):
Min/Max are represented as recorded; mean, median and SD with one more decimal place.
All symptoms are to be included. " -----" refers to continuation of symptoms.

Table 10.1.2.2.2.1: Summary of Functional Dyspepsia Score Assessed by Short Form Nepean Dyspepsia Index (SF-NDI) Questionnaire

FULL ANALYSIS SUBJECT SAMPLE

Characteristics	Visit	Statistics	<Tr Arm 1> (N=xxx)	<Tr Arm 2> (N=xxx)
Functional Dyspepsia	Baseline	n	xxx	xxx
		Mean (SD)	xx.x (x.x)	xx.x (x.x)
		Median	xx.x	xx.x
		Min/Max	xx/xx	xx/xx
	Week 8	n	xxx	xxx
		Mean (SD)	xx.x (x.x)	xx.x (x.x)
		Median	xx.x	xx.x
		Min/Max	xx/xx	xx/xx
Symptoms: Pain or Ache in Upper Abdomen	Baseline	n	xxx	xxx
		Mean (SD)	xx.x (x.x)	xx.x (x.x)
		Median	xx.x	xx.x
		Min/Max	xx/xx	xx/xx
	Week 8	n	xxx	xxx
		Mean (SD)	xx.x (x.x)	xx.x (x.x)
		Median	xx.x	xx.x
		Min/Max	xx/xx	xx/xx

Burning/Sensation in Upper Abdomen	Baseline	n	xxx	xxx
		Mean (SD)	xx.x (x.x)	xx.x (x.x)
		Median	xx.x	xx.x
		Min/Max	xx/xx	xx/xx
	Week 8	n	xxx	xxx
		Mean (SD)	xx.x (x.x)	xx.x (x.x)
		Median	xx.x	xx.x
		Min/Max	xx/xx	xx/xx
Inability to finish a Regular Meal	Baseline	n	xxx	xxx
		Mean (SD)	xx.x (x.x)	xx.x (x.x)
		Median	xx.x	xx.x
		Min/Max	xx/xx	xx/xx
	Week 8	n	xxx	xxx
		Mean (SD)	xx.x (x.x)	xx.x (x.x)
		Median	xx.x	xx.x
		Min/Max	xx/xx	xx/xx
Fullness after eating or slow digestion	Baseline	n	xxx	xxx
		Mean (SD)	xx.x (x.x)	xx.x (x.x)
		Median	xx.x	xx.x
		Min/Max	xx/xx	xx/xx
	Week 8	n	xxx	xxx
		Mean (SD)	xx.x (x.x)	xx.x (x.x)
		Median	xx.x	xx.x

	Min/Max	xx/xx	xx/xx

Note 1: Baseline is defined as the last available observation prior to the first study drug administration.

Source: LXX00X.sas, <CRO>.Run DDMMMYYYY HH:MM Page x/y
Abbott Protocol CCCC-xxx-yyyy

Remark (not part of the table):
Min/Max are represented as recorded; mean, median and SD with one more decimal place.
All 4 symptoms (i.e., Pain or ache in upper abdomen, Burning sensation in upper abdomen PDS, Inability to finish a regular meal, Fullness after eating or slow digestion used) are to be included. " -----" refers to continuation of symptoms.

Table 10.1.2.2.2.2: Summary of Functional Dyspepsia Score Assessed by Short Form Nepean Dyspepsia Index (SF-NDI) Questionnaire (by Gender)

FULL ANALYSIS SUBJECT SAMPLE

Group Characteristics	Visit	Statistics	<Tr Arm 2> (N=xxx)	<Tr Arm 2> (N=xxx)
Male,		n	xxx	xxx
Functional Dyspepsia	Baseline	n	xxx	xxx
		Mean (SD)	xx.x (x.x)	xx.x (x.x)
		Median	xx.x	xx.x
		Min/Max	xx/xx	xx/xx
	Week 8	n	xxx	xxx
		Mean (SD)	xx.x (x.x)	xx.x (x.x)
		Median	xx.x	xx.x
		Min/Max	xx/xx	xx/xx
Symptoms:				
Pain or Ache in Upper Abdomen	Baseline	n	xxx	xxx
		Mean (SD)	xx.x (x.x)	xx.x (x.x)
		Median	xx.x	xx.x
		Min/Max	xx/xx	xx/xx
	Week 8	n	xxx	xxx
		Mean (SD)	xx.x (x.x)	xx.x (x.x)
		Median	xx.x	xx.x

		Min/Max	xx/xx	xx/xx
Burning/Sensation in Upper Abdomen	Baseline	n	xxx	xxx
		Mean (SD)	xx.x (x.x)	xx.x (x.x)
		Median	xx.x	xx.x
		Min/Max	xx/xx	xx/xx
	Week 8	n	xxx	xxx
		Mean (SD)	xx.x (x.x)	xx.x (x.x)
		Median	xx.x	xx.x
		Min/Max	xx/xx	xx/xx
Inability to finish a Regular Meal	Baseline	n	xxx	xxx
		Mean (SD)	xx.x (x.x)	xx.x (x.x)
		Median	xx.x	xx.x
		Min/Max	xx/xx	xx/xx
	Week 8	n	xxx	xxx
		Mean (SD)	xx.x (x.x)	xx.x (x.x)
		Median	xx.x	xx.x
		Min/Max	xx/xx	xx/xx
Fullness after eating or slow digestion	Baseline	n	xxx	xxx
		Mean (SD)	xx.x (x.x)	xx.x (x.x)
		Median	xx.x	xx.x
		Min/Max	xx/xx	xx/xx
	Week 8	n	xxx	xxx

	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx

Note 1: Baseline is defined as the last available observation prior to the first study drug administration.

Source: LXX00X.sas, <CRO>.Run DDMMMYYYY HH:MM Page x/y
Abbott Protocol CCCC-xxx-yyyy

Remark (not part of the table):
Min/Max are represented as recorded; mean, median and SD with one more decimal place.
All 4 symptoms (i.e., Pain or ache in upper abdomen, Burning sensation in upper abdomen PDS, Inability to finish a regular meal, Fullness after eating or slow digestion used) are to be included. " -----" refers to continuation of symptoms.

Repeat similar table for **Table 10.1.2.2.2.3: Summary of Functional Dyspepsia Score Assessed by Short Form Nepean Dyspepsia Index (SF-NDI) Questionnaire (by Age Group)**
Repeat similar table for **Table 10.1.2. 2.2.4: Summary of Functional Dyspepsia Score Assessed by Short Form Nepean Dyspepsia Index (SF-NDI) Questionnaire (by Geographical Region)**

Table 10.1.2.2.3.1: Summary of Raw Score of Quality of Life (QoL) Assessed by Nepean Dyspepsia Index (SF-NDI) Questionnaire

FULL ANALYSIS SUBJECT SAMPLE

Characteristics	Visit	Statistics	<Tr Arm 1> (N=xxx)	<Tr Arm 2> (N=xxx)
Overall QoL Score	Baseline	n	xxx	xxx
		Mean (SD)	xx.x (x.x)	xx.x (x.x)
		Median	xx.x	xx.x
		Min/Max	xx/xx	xx/xx
		p-value	x.xxx	
	Week 8	n	xxx	xxx
		Mean (SD)	xx.x (x.x)	xx.x (x.x)
		Median	xx.x	xx.x
		Min/Max	xx/xx	xx/xx
		p-value	x.xxx	
Domains:				
Tension	Baseline	n	xxx	xxx
		Mean (SD)	xx.x (x.x)	xx.x (x.x)
		Median	xx.x	xx.x
		Min/Max	xx/xx	xx/xx
	Week 8	n	xxx	xxx
		Mean (SD)	xx.x (x.x)	xx.x (x.x)

		Median	xx.x	xx.x
		Min/Max	xx/xx	xx/xx
		p-value	x.xxx	
Interference With Daily Activities	Baseline	n	xxx	xxx
		Mean (SD)	xx.x (x.x)	xx.x (x.x)
		Median	xx.x	xx.x
		Min/Max	xx/xx	xx/xx
		p-value	x.xxx	
	Week 8	n	xxx	xxx
		Mean (SD)	xx.x (x.x)	xx.x (x.x)
		Median	xx.x	xx.x
		Min/Max	xx/xx	xx/xx
		p-value	x.xxx	
Eating/Drinking	Baseline	n	xxx	xxx
		Mean (SD)	xx.x (x.x)	xx.x (x.x)
		Median	xx.x	xx.x
		Min/Max	xx/xx	xx/xx
		p-value	x.xxx	
	Week 8	n	xxx	xxx
		Mean (SD)	xx.x (x.x)	xx.x (x.x)
		Median	xx.x	xx.x
		Min/Max	xx/xx	xx/xx

		p-value	x.xxx	
Knowledge/Control	Baseline	n	xxx	xxx
		Mean (SD)	xx.x (x.x)	xx.x (x.x)
		Median	xx.x	xx.x
		Min/Max	xx/xx	xx/xx
		p-value	x.xxx	
	Week 8	n	xxx	xxx
		Mean (SD)	xx.x (x.x)	xx.x (x.x)
		Median	xx.x	xx.x
		Min/Max	xx/xx	xx/xx
		p-value	x.xxx	
Work/Study	Baseline	n	xxx	xxx
		Mean (SD)	xx.x (x.x)	xx.x (x.x)
		Median	xx.x	xx.x
		Min/Max	xx/xx	xx/xx
		p-value	x.xxx	
	Week 8	n	xxx	xxx
		Mean (SD)	xx.x (x.x)	xx.x (x.x)
		Median	xx.x	xx.x
		Min/Max	xx/xx	xx/xx
		p-value	x.xxx	

Note 1: Baseline is defined as the last available observation prior to the first study drug administration.

Note 2: P-value is calculated by using two sample t-test at 5% level of significance.

Source: LXX00X.sas, <CRO>.Run DDMMMYYYY HH:MM Page x/y
Abbott Protocol CCCC-xxx-yyyy

Remark (not part of the table):
Min/Max are represented as recorded; mean, median and SD with one more decimal place.

Table 10.1.2.2.3.2: Summary of Raw Score of Quality of Life (QoL) Assessed by Nepean Dyspepsia Index (SF-NDI) Questionnaire (by Gender)

FULL ANALYSIS SUBJECT SAMPLE

Group Characteristics	Visit	Statistics	<Tr Arm 1> (N=xxx)	<Tr Arm 2> (N=xxx)
Male,				
Overall QoL Score	Baseline	n	xxx	xxx
		Mean (SD)	xx.x (x.x)	xx.x (x.x)
		Median	xx.x	xx.x
		Min/Max	xx/xx	xx/xx
		p-value	x.xxx	
	Week 8	n	xxx	xxx
		Mean (SD)	xx.x (x.x)	xx.x (x.x)
		Median	xx.x	xx.x
		Min/Max	xx/xx	xx/xx
		p-value	x.xxx	
Domains:				
Tension	Baseline	n	xxx	xxx
		Mean (SD)	xx.x (x.x)	xx.x (x.x)
		Median	xx.x	xx.x
		Min/Max	xx/xx	xx/xx

	Week 8	n	xxx	xxx
		Mean (SD)	xx.x (x.x)	xx.x (x.x)
		Median	xx.x	xx.x
		Min/Max	xx/xx	xx/xx
		p-value	x.xxx	
Interference With Daily Activities	Baseline	n	xxx	xxx
		Mean (SD)	xx.x (x.x)	xx.x (x.x)
		Median	xx.x	xx.x
		Min/Max	xx/xx	xx/xx
		p-value	x.xxx	
	Week 8	n	xxx	xxx
		Mean (SD)	xx.x (x.x)	xx.x (x.x)
		Median	xx.x	xx.x
		Min/Max	xx/xx	xx/xx
		p-value	x.xxx	
Eating/Drinking	Baseline	n	xxx	xxx
		Mean (SD)	xx.x (x.x)	xx.x (x.x)
		Median	xx.x	xx.x
		Min/Max	xx/xx	xx/xx
		p-value	x.xxx	
	Week 8	n	xxx	xxx
		Mean (SD)	xx.x (x.x)	xx.x (x.x)

		Median	xx.x	xx.x
		Min/Max	xx/xx	xx/xx
		p-value	x.xxx	
Knowledge/Control	Baseline	n	xxx	xxx
		Mean (SD)	xx.x (x.x)	xx.x (x.x)
		Median	xx.x	xx.x
		Min/Max	xx/xx	xx/xx
		p-value	x.xxx	
	Week 8	n	xxx	xxx
		Mean (SD)	xx.x (x.x)	xx.x (x.x)
		Median	xx.x	xx.x
		Min/Max	xx/xx	xx/xx
		p-value	x.xxx	
Work/Study	Baseline	n	xxx	xxx
		Mean (SD)	xx.x (x.x)	xx.x (x.x)
		Median	xx.x	xx.x
		Min/Max	xx/xx	xx/xx
		p-value	x.xxx	
	Week 8	n	xxx	xxx
		Mean (SD)	xx.x (x.x)	xx.x (x.x)
		Median	xx.x	xx.x
		Min/Max	xx/xx	xx/xx
		p-value	x.xxx	

Note 1: Baseline is defined as the last available observation prior to the first study drug administration.
Note 2: P-value is calculated by using two sample t-test at 5% level of significance.

Source: LXX00X.sas, <CRO>.Run DDMMMYYYY HH:MM Page x/y
Abbott Protocol CCCC-xxx-yyyy

Remark (not part of the table):
Min/Max are represented as recorded; mean, median and SD with one more decimal place.

Repeat similar table for **Table 10.1.2.2.3.3: Summary of Raw Score of Quality of Life (QoL) assessed by Nepean Dyspepsia Index (SF-NDI) Questionnaire (by Age Group)**
Repeat similar table for **Table 10.1.2.2.3.4: Summary of Raw Score of Quality of Life (QoL) assessed by Nepean Dyspepsia Index (SF-NDI) Questionnaire (by Geographical Region)**

Table 10.1.2.2.3.5: Summary of Transformed Scores of Quality of Life (QoL) Assessed by Nepean Dyspepsia Index (SF-NDI) Questionnaire

FULL ANALYSIS SUBJECT SAMPLE

Characteristics	Visit	Statistics	<Tr Arm 1> (N=xxx)	<Tr Arm 2> (N=xxx)
Overall QoL Score	Baseline	n	xxx	xxx
		Mean (SD)	xx.x (x.x)	xx.x (x.x)
		Median	xx.x	xx.x
		Min/Max	xx/xx	xx/xx
		p-value	x.xxx	
	Week 8	n	xxx	xxx
		Mean (SD)	xx.x (x.x)	xx.x (x.x)
		Median	xx.x	xx.x
		Min/Max	xx/xx	xx/xx
		p-value	x.xxx	
Domains:				
Tension	Baseline	n	xxx	xxx
		Mean (SD)	xx.x (x.x)	xx.x (x.x)
		Median	xx.x	xx.x
		Min/Max	xx/xx	xx/xx
	Week 8	n	xxx	xxx
		Mean (SD)	xx.x (x.x)	xx.x (x.x)

		Median	xx.x	xx.x
		Min/Max	xx/xx	xx/xx
		p-value	x.xxx	
Interference With Daily Activities	Baseline	n	xxx	xxx
		Mean (SD)	xx.x (x.x)	xx.x (x.x)
		Median	xx.x	xx.x
		Min/Max	xx/xx	xx/xx
		p-value	x.xxx	
	Week 8	n	xxx	xxx
		Mean (SD)	xx.x (x.x)	xx.x (x.x)
		Median	xx.x	xx.x
		Min/Max	xx/xx	xx/xx
		p-value	x.xxx	
Eating/Drinking	Baseline	n	xxx	xxx
		Mean (SD)	xx.x (x.x)	xx.x (x.x)
		Median	xx.x	xx.x
		Min/Max	xx/xx	xx/xx
		p-value	x.xxx	
	Week 8	n	xxx	xxx
		Mean (SD)	xx.x (x.x)	xx.x (x.x)
		Median	xx.x	xx.x
		Min/Max	xx/xx	xx/xx

		p-value	x.xxx	
Knowledge/Control	Baseline	n	xxx	xxx
		Mean (SD)	xx.x (x.x)	xx.x (x.x)
		Median	xx.x	xx.x
		Min/Max	xx/xx	xx/xx
		p-value	x.xxx	
	Week 8	n	xxx	xxx
		Mean (SD)	xx.x (x.x)	xx.x (x.x)
		Median	xx.x	xx.x
		Min/Max	xx/xx	xx/xx
		p-value	x.xxx	
Work/Study	Baseline	n	xxx	xxx
		Mean (SD)	xx.x (x.x)	xx.x (x.x)
		Median	xx.x	xx.x
		Min/Max	xx/xx	xx/xx
		p-value	x.xxx	
	Week 8	n	xxx	xxx
		Mean (SD)	xx.x (x.x)	xx.x (x.x)
		Median	xx.x	xx.x
		Min/Max	xx/xx	xx/xx
		p-value	x.xxx	

Note 1: Baseline is defined as the last available observation prior to the first study drug administration.

Note 2: P-value is calculated by using two sample t-test at 5% level of significance.

Source: LXX00X.sas, <CRO>.Run DDMMMYYYY HH:MM Page x/y
Abbott Protocol CCCC-xxx-yyyy

Remark (not part of the table):
Min/Max are represented as recorded; mean, median and SD with one more decimal place.

Table 10.1.2.2.3.6: Summary of Transformed Scores of Quality of Life (QoL) assessed by Nepean Dyspepsia Index (SF-NDI) Questionnaire (by Gender)

FULL ANALYSIS SUBJECT SAMPLE

Group Characteristics	Visit	Statistics	<Tr Arm 1> (N=xxx)	<Tr Arm 2> (N=xxx)
Male,				
Overall QoL Score	Baseline	n	xxx	xxx
		Mean (SD)	xx.x (x.x)	xx.x (x.x)
		Median	xx.x	xx.x
		Min/Max	xx/xx	xx/xx
		p-value	x.xxx	
	Week 8	n	xxx	xxx
		Mean (SD)	xx.x (x.x)	xx.x (x.x)
		Median	xx.x	xx.x
		Min/Max	xx/xx	xx/xx
		p-value	x.xxx	
Domains:				
Tension	Baseline	n	xxx	xxx
		Mean (SD)	xx.x (x.x)	xx.x (x.x)
		Median	xx.x	xx.x
		Min/Max	xx/xx	xx/xx

	Week 8	n	xxx	xxx
		Mean (SD)	xx.x (x.x)	xx.x (x.x)
		Median	xx.x	xx.x
		Min/Max	xx/xx	xx/xx
		p-value	x.xxx	
Interference With Daily Activities	Baseline	n	xxx	xxx
		Mean (SD)	xx.x (x.x)	xx.x (x.x)
		Median	xx.x	xx.x
		Min/Max	xx/xx	xx/xx
		p-value	x.xxx	
	Week 8	n	xxx	xxx
		Mean (SD)	xx.x (x.x)	xx.x (x.x)
		Median	xx.x	xx.x
		Min/Max	xx/xx	xx/xx
		p-value	x.xxx	
Eating/Drinking	Baseline	n	xxx	xxx
		Mean (SD)	xx.x (x.x)	xx.x (x.x)
		Median	xx.x	xx.x
		Min/Max	xx/xx	xx/xx
		p-value	x.xxx	
	Week 8	n	xxx	xxx
		Mean (SD)	xx.x (x.x)	xx.x (x.x)

		Median	xx.x	xx.x
		Min/Max	xx/xx	xx/xx
		p-value	x.xxx	
Knowledge/Control	Baseline	n	xxx	xxx
		Mean (SD)	xx.x (x.x)	xx.x (x.x)
		Median	xx.x	xx.x
		Min/Max	xx/xx	xx/xx
		p-value	x.xxx	
	Week 8	n	xxx	xxx
		Mean (SD)	xx.x (x.x)	xx.x (x.x)
		Median	xx.x	xx.x
		Min/Max	xx/xx	xx/xx
		p-value	x.xxx	
Work/Study	Baseline	n	xxx	xxx
		Mean (SD)	xx.x (x.x)	xx.x (x.x)
		Median	xx.x	xx.x
		Min/Max	xx/xx	xx/xx
		p-value	x.xxx	
	Week 8	n	xxx	xxx
		Mean (SD)	xx.x (x.x)	xx.x (x.x)
		Median	xx.x	xx.x
		Min/Max	xx/xx	xx/xx
		p-value	x.xxx	

Note 1: Baseline is defined as the last available observation prior to the first study drug administration.
Note 2: P-value is calculated by using two sample t-test at 5% level of significance.

Source: LXX00X.sas, <CRO>.Run DDMMMYYYY HH:MM Page x/y
Abbott Protocol CCCC-xxx-yyyy

Remark (not part of the table):
Min/Max are represented as recorded; mean, median and SD with one more decimal place.

Repeat similar table for **Table 10.1.2.2.3.7: Summary of Transformed Score of Quality of Life (QoL) for assessed by Nepean Dyspepsia Index (SF-NDI) Questionnaire (by Age Group)**
Repeat similar table for **Table 10.1.2.2.3.8: Summary of Quality of Life (QoL) for Raw Score assessed by Nepean Dyspepsia Index (SF-NDI) Questionnaire (by Geographical Region)**

Table 10.1.2.2.4.1: Change in NRS 11 Symptoms Score after Week 4 and Week 8

FULL ANALYSIS SUBJECT SAMPLE

Symptoms	Visit	Statistics	<Tr Arm 1> (N=xxx)	<Tr Arm 2> (N=xxx)
Bloating Sensation	Baseline	n	xxx	xxx
		Mean (SD)	xx.x (x.x)	xx.x (x.x)
		Median	xx.x	xx.x
		Min/Max	xx/xx	xx/xx
	Week 4	n	xxx	xxx
		Mean (SD)	xx.x (x.x)	xx.x (x.x)
		Median	xx.x	xx.x
		Min/Max	xx/xx	xx/xx
	Change from Baseline at Week 4	n	xxx	xxx
		Mean (SD)	xx.x (x.x)	xx.x (x.x)
		Median	xx.x	xx.x
		Min/Max	xx/xx	xx/xx
		LS Mean (SE)	xx.x (x.x)	xx.x (x.x)
		95% CI for LS Mean	xx.x, xx.x	xx.x, xx.x
		LS Mean difference (SE)	xx.x (x.x)	
		95% CI for LS Mean difference	xx.x, xx.x	
		p-value	x.xxx	

	Week 8	n	xxx	xxx
		Mean (SD)	xx.x (x.x)	xx.x (x.x)
		Median	xx.x	xx.x
		Min/Max	xx/xx	xx/xx
	Change from Baseline at Week 8	n	xxx	xxx
		Mean (SD)	xx.x (x.x)	xx.x (x.x)
		Median	xx.x	xx.x
		Min/Max	xx/xx	xx/xx
		LS Mean (SE)	xx.x (x.x)	xx.x (x.x)
		95% CI for LS Mean	xx.x, xx.x	xx.x, xx.x
		LS Mean difference (SE)	xx.x (x.x)	
		95% CI for LS Mean difference	xx.x, xx.x	
		p-value	x.xxx	
Early Satiety	Baseline	n	xxx	xxx
		Mean (SD)	xx.x (x.x)	xx.x (x.x)
		Median	xx.x	xx.x
		Min/Max	xx/xx	xx/xx
	Week 4	n	xxx	xxx
		Mean (SD)	xx.x (x.x)	xx.x (x.x)
		Median	xx.x	xx.x
		Min/Max	xx/xx	xx/xx
	Change from Baseline at Week 4	n	xxx	xxx
		Mean (SD)	xx.x (x.x)	xx.x (x.x)
		Median	xx.x	xx.x

Min/Max	xx/xx	xx/xx
LS Mean (SE)	xx.x (x.x)	xx.x (x.x)
95% CI for LS Mean	xx.x, xx.x	xx.x, xx.x
LS Mean difference (SE)	xx.x (x.x)	
95% CI for LS Mean difference	xx.x, xx.x	
p-value	x.xxx	

Note 1: Baseline is defined as the last available observation prior to the first study drug administration.

Note 2: LS Mean, LS Mean difference, SE, 95% CI and p-value is calculated by using the analysis of covariance (ANCOVA) model includes change in the LDQ score as dependent variable and treatment group, site and LDQ baseline value as covariates.

Source: LXX00X.sas, <CRO>.Run DDMMMYYYY HH:MM Page x/y
Abbott Protocol CCCC-xxx-yyyy

Remark (not part of the table):
Min/Max are represented as recorded; mean, median and SD with one more decimal place.
All symptoms are to be included.“ -----" refer continuation of visit/symptoms.

Table 10.1.2.2.4.2: Change in NRS 11 Symptoms Score after week 4 and week 8 (by Gender)

FULL ANALYSIS SUBJECT SAMPLE

Symptoms	Visit	Statistics	<Tr Arm 1> (N=xxx)	<Tr Arm 2> (N=xxx)
Male,				
Bloating Sensation	Baseline	n	xxx	xxx
		Mean (SD)	xx.x (x.x)	xx.x (x.x)
		Median	xx.x	xx.x
		Min/Max	xx/xx	xx/xx
	Week 4	n	xxx	xxx
		Mean (SD)	xx.x (x.x)	xx.x (x.x)
		Median	xx.x	xx.x
		Min/Max	xx/xx	xx/xx
	Change from Baseline at Week 4	n	xxx	xxx
		Mean (SD)	xx.x (x.x)	xx.x (x.x)
		Median	xx.x	xx.x
		Min/Max	xx/xx	xx/xx
		LS Mean (SE)	xx.x (x.x)	xx.x (x.x)
		95% CI for LS Mean	xx.x, xx.x	xx.x, xx.x
		LS Mean difference (SE)	xx.x (x.x)	
		95% CI for LS Mean difference	xx.x, xx.x	

		p-value	x.xxx	
	Week 8	n	xxx	xxx
		Mean (SD)	xx.x (x.x)	xx.x (x.x)
		Median	xx.x	xx.x
		Min/Max	xx/xx	xx/xx
	Change from Baseline at Week 8	n	xxx	xxx
		Mean (SD)	xx.x (x.x)	xx.x (x.x)
		Median	xx.x	xx.x
		Min/Max	xx/xx	xx/xx
		LS Mean (SE)	xx.x (x.x)	xx.x (x.x)
		95% CI for LS Mean	xx.x, xx.x	xx.x, xx.x
		LS Mean difference (SE)	xx.x (x.x)	
		95% CI for LS Mean difference	xx.x, xx.x	
		p-value	x.xxx	
Early Satiety	Baseline	n	xxx	xxx
		Mean (SD)	xx.x (x.x)	xx.x (x.x)
		Median	xx.x	xx.x
		Min/Max	xx/xx	xx/xx
	Week 4	n	xxx	xxx
		Mean (SD)	xx.x (x.x)	xx.x (x.x)
		Median	xx.x	xx.x
		Min/Max	xx/xx	xx/xx
	Change from Baseline at	n	xxx	xxx

	Week 4	Mean (SD)	xx.x (x.x)	xx.x (x.x)
		Median	xx.x	xx.x
		Min/Max	xx/xx	xx/xx
		LS Mean (SE)	xx.x (x.x)	xx.x (x.x)
		95% CI for LS Mean	xx.x, xx.x	xx.x, xx.x
		LS Mean difference (SE)	xx.x (x.x)	
		95% CI for LS Mean difference	xx.x, xx.x	
		p-value	x.xxx	

Note 1: Baseline is defined as the last available observation prior to the first study drug administration.

Note 2: LS Mean, LS Mean difference, SE, 95% CI and p-value is calculated by using the analysis of covariance (ANCOVA) model includes change in the LDQ score as dependent variable and treatment group, site and LDQ baseline value as covariates.

Source: LXX00X.sas, <CRO>.Run DDMMMYYYY HH:MM Page x/y
Abbott Protocol CCCC-xxx-yyyy

Remark (not part of the table):
Min/Max are represented as recorded; mean, median and SD with one more decimal place.
All symptoms are to be included.“ -----" refer continuation of visit/symptoms.

*Repeat similar table for **10.1.2.2.4.3*** **Change in NRS 11 Symptoms Score after week 4 and week 8 (by Age Group)**
*Repeat similar table for **10.1.2.2.4.4*** **Change in NRS 11 Symptoms Score after week 4 and week 8 (by Geographical Region)**

Table 10.1.2.2.5.1: Responder Analysis of Satisfactory Relief Assessed by LDQ and/or NRS 11

FULL ANALYSIS SUBJECT SAMPLE

	Statistics	<Tr Arm 2> (N=xxx)	<Tr Arm 2> (N=xxx)
LDQ			
Number of subjects satisfactory relief assessed as:			
Responders	n (%)	xx.x (x.x)	xx.x (x.x)
Non-responders	n (%)	xx.x (x.x)	xx.x (x.x)
	p-value	x.xxx	
NRS 11			
Bloating Sensation			
Number of subjects satisfactory relief assessed as:			
Responders	n (%)	xx.x (x.x)	xx.x (x.x)
Non-responders	n (%)	xx.x (x.x)	xx.x (x.x)
	p-value	x.xxx	
Early Satiety			
Number of subjects satisfactory relief assessed as:			
Responders	n (%)	xx.x (x.x)	xx.x (x.x)
Non-responders	n (%)	xx.x (x.x)	xx.x (x.x)
	p-value	x.xxx	

Note 1: P-value is calculated by using chi-square test/Fisher Exact test.

Note 2:

By LDQ Score:

The subject is considered to be as responder if, at the end of the treatment the overall LDQ score is<9.

By NRS-11 Score:

The subject is considered to be as responder if, each NRS11 symptoms change from baseline score at the end of the study treatment is at least 2 (i.e., NRS-11 symptoms CFB >= 2). only subjects with a score of the respective symptom of at least 5 at baseline will be used.

Table 10.1.2.2.5.2: Responder Analysis of Satisfactory Relief Assessed by LDQ and/or NRS 11 (by Gender)

FULL ANALYSIS SUBJECT SAMPLE

Group, Characteristics	Statistics	<Tr Arm 2> (N=xxx)	<Tr Arm 2> (N=xxx)
Male,	n	xxx	xxx
LDQ			
Number of subjects satisfactory relief assessed as:			
Responders	n (%)	xx.x (x.x)	xx.x (x.x)
Non-responders	n (%)	xx.x (x.x)	xx.x (x.x)
	p-value	x.xxx	
NRS 11			
Bloating Sensation			
Number of subjects satisfactory relief assessed as:			
Responders	n (%)	xx.x (x.x)	xx.x (x.x)
Non-responders	n (%)	xx.x (x.x)	xx.x (x.x)
	p-value	x.xxx	
Early Satiety			
Number of subjects satisfactory relief assessed as:			
Responders	n (%)	xx.x (x.x)	xx.x (x.x)
Non-responders	n (%)	xx.x (x.x)	xx.x (x.x)
	p-value	x.xxx	

Note 1: P-value is calculated by using chi-square test/Fisher Exact test.
Note 2:

By LDQ Score:
The subject is considered to be as responder if, at the end of the treatment the overall LDQ score is<9.

By NRS-11 Score:
The subject is considered to be as responder if, each NRS11 symptoms change from baseline score at the end of the study treatment is at least 2 (i.e., NRS-11 symptoms CFB >= -2). only subjects with a score of the respective symptom of at least 5 at baseline will be used.

Source: LXX00X.sas, <CRO>.Run DDMMMYYYY HH:MM Page x/y
Abbott Protocol CCCC-xxx-yyyy

Repeat similar table for **10.1.2.2.5.3 Responder Analysis of Satisfactory Relief Assessed by LDQ and/or NRS 11 (by Age Group)**
Repeat similar table for **10.1.2.2.5.4 Responder Analysis of Satisfactory Relief Assessed by LDQ and/or NRS 11 (by Geographical Region)**

Table 10.1.2.3.1.1: Treatment Acceptance & Ease of Use Assessment

FULL ANALYSIS SUBJECT SAMPLE

Response	Statistics	<Tr Arm 1> (N=xxx)	<Tr Arm 2> (N=xxx)
Missing	n (%)	xx.x (x.x)	xx.x (x.x)
1-Not all satisfied	n (%)	xx.x (x.x)	xx.x (x.x)
2-Slightly satisfied	n (%)	xx.x (x.x)	xx.x (x.x)
3-Neutral	n (%)	xx.x (x.x)	xx.x (x.x)
4-Very satisfied	n (%)	xx.x (x.x)	xx.x (x.x)
5-Extremely Satisfied	n (%)	xx.x (x.x)	xx.x (x.x)
Treatment Acceptance	n	xxx	xxx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
	p-value	x.xxx	

Note 1: Percentages are based on the number of subjects allocated to treatment.
Note 2: P-value is calculated by using two sample t-test or Mann Whitney U test..

Source: LXX00X.sas, <CRO>.Run DDMMMYYYY HH:MM Page x/y
Abbott Protocol CCCC-xxx-yyyy

Table 10.1.2.3.1.2: Treatment Acceptance & Ease of Use Assessment (by Gender)

FULL ANALYSIS SUBJECT SAMPLE

Group, Response	Statistics	<Tr Arm 2> (N=xxx)	<Tr Arm 2> (N=xxx)
Male,			
Missing	n (%)	xx.x (x.x)	xx.x (x.x)
1-Not all satisfied	n (%)	xx.x (x.x)	xx.x (x.x)
2-Slightly satisfied	n (%)	xx.x (x.x)	xx.x (x.x)
3-Neutral	n (%)	xx.x (x.x)	xx.x (x.x)
4-Very satisfied	n (%)	xx.x (x.x)	xx.x (x.x)
5-Extremely Satisfied	n (%)	xx.x (x.x)	xx.x (x.x)
Treatment Acceptance	n	xxx	xxx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
	p-value	x.xxx	
Female,			
Missing	n (%)	xx.x (x.x)	xx.x (x.x)
1-Not all satisfied	n (%)	xx.x (x.x)	xx.x (x.x)
2-Slightly satisfied	n (%)	xx.x (x.x)	xx.x (x.x)
3-Neutral	n (%)	xx.x (x.x)	xx.x (x.x)
4-Very satisfied	n (%)	xx.x (x.x)	xx.x (x.x)
5-Extremely Satisfied	n (%)	xx.x (x.x)	xx.x (x.x)

Treatment Acceptance	n	xxx	xxx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
	p-value	x.xxx	

Note 1: Percentages are based on the number of subjects allocated to treatment.
Note 2: P-value is calculated by using two sample t-test/ Wilcoxon signed rank test.

Source: LXX00X.sas, <CRO>.Run DDMMMYYYY HH:MM Page x/y
Abbott Protocol CCCC-xxx-yyyy

Repeat similar table for **Table 10.1.2.3.1.3: Treatment Acceptance & Ease of Use Assessment (by Age Group)**
Repeat similar table for **Table 10.1.2.3.1.4: Treatment Acceptance & Ease of Use Assessment (by Geographical Region)**

Table 10.1.3.1.1.1: Overall Summary of Adverse Events (by Gender)

SAFETY SUBJECT SAMPLE

Group, Characteristics	Statistic	<Tr Arm 1> (N=xxx)	<Tr Arm 2> (N=xxx)
Male,	n	xx	xx
Number of Deaths	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx
Number of TE Deaths	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx
Number of Subjects With at Least One SAE	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx
Number of Subjects With at Least One TESAE	n(%) E	xx (xx.x%) xx	xx (xx.x%) xx
Number of Subjects With at Least One TEAE Leading to Study Termination	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx
Number of Subjects With at Least One TEAE	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx
Number of Subjects With at Least One Severe TEAE	n (%) E	xx (xx.x%) xx	xx (xx.x%) xx
Number of Subjects With at Least One TEAE with a Reasonable Possibility for a Causal Relationship	n (%) E	xx(xx.x%) xx	xx(xx.x%) xx
Number of Subjects Without Any TEAE	n (%)	xx (xx.x%)	xx (xx.x%)

Note: n = Number of subjects; E = Number of events.
Note: Percentages are based on the number of subjects in the Safety Subject Sample.
Note: A treatment-emergent adverse event (TEAE) is defined as an AE that started or worsened in severity on or after the first study drug administration and within <xx> days of last study drug administration.
Note: TEAEs leading to study termination are TEAEs reported on the Adverse Event CRF with “Led to Study Termination” = ‘yes’.
Note: Severe = severity reported as “severe” or missing.

Note: Reasonable possibility for a causal relationship = drug-event relationship reported as “possible”, “probable”, “certain” or missing.
Note: [TE] Death is defined as a fatal outcome of a [TE](S)AE.

Source: AET001.sas, <CRO>.Run DDMMMYYYY HH:MM Page x/y
Abbott Protocol CCCC-xxx-yyyy

Repeat similar table for **Table 10.1.3.1.1.2: Overall Summary of Adverse Events (by Age Group)**
Repeat similar table for **Table 10.1.3.1.1.3: Overall Summary of Adverse Events (by Geographical Region)**

Table 10.1.3.2.1.2: Summary of Quantitative Safety Laboratory Variable Serum Prolactin (by Gender)

FULL ANALYSIS SUBJECT SAMPLE
SYSTEM: <Variable (Unit)>

Group Visit	Statistics	<Tr Arm 1> (N=xxx)	<Tr Arm 2> (N=xxx)
Male,			
Baseline	n	xxx	xxx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Week 8	n	xxx	xxx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Change from Baseline at Week 8	n	xxx	xxx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
	LS Mean (SE)	xx.x (x.x)	xx.x (x.x)
	95% CI for LS Mean	xx.x, xx.x	xx.x, xx.x
	LS Mean difference (SE)	xx.x (x.x)	
	95% CI for LS Mean difference	xx.x, xx.x	

	p-value	x.xxx	
Female,			
Baseline	n	xxx	xxx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Week 8	n	xxx	xxx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
Change from Baseline at Week 8	n	xxx	xxx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)
	Median	xx.x	xx.x
	Min/Max	xx/xx	xx/xx
	LS Mean (SE)	xx.x (x.x)	xx.x (x.x)
	95% CI for LS Mean	xx.x, xx.x	xx.x, xx.x
	LS Mean difference (SE)	xx.x (x.x)	
	95% CI for LS Mean difference	xx.x, xx.x	
	p-value	x.xxx	

Note 1: Baseline is defined as the last available observation prior to the first study drug administration.

Repeat similar table for **10.1.3.2.1.3 Summary of Quantitative Safety Laboratory Variable Serum Prolactin (by Age Group)**
Repeat similar table for **10.1.3.2.1.4 Summary of Quantitative Safety Laboratory Variable Serum Prolactin (by Geographical Region)**

10.2 Non-Standard Listings

Listing 12.2.4.3.1: H-Pylori and Upper Gastrointestinal Ultrasound

ALL SUBJECTS ALLOCATED TO TREATMENT SUBJECT SAMPLE

		H-Pylori		Upper Gastrointestinal Ultrasound		
Subject Number	Trial Arm</ Unique Treatment>	Date of Assessment	Result	Date of Assessment	Interpretation	Clinical Significance
XXXX-YYYYY	XXXXXXXX</ XXXXXX>	DDMMMYYYY	Negative	DDMMMYYYY	Abnormal	No
XXXX-YYYYY	XXXXXXXX</ XXXXXX>	DDMMMYYYY	Negative	DDMMMYYYY	Normal	

Listing 12.2.4.3.2: Endoscopy

ALL SUBJECTS ALLOCATED TO TREATMENT SUBJECT SAMPLE

Subject Number	Trial Arm</ Unique Treatment>		Endoscopy	
		Date of Assessment	Interpretation	Clinical Significance
XXXX-YYYYY	XXXXXXXX</ XXXXXX>	DDMMMYYYY	Normal	
		DDMMMYYYY	Abnormal	No
XXXX-YYYYY	XXXXXXXX</ XXXXXX>	DDMMMYYYY	Abnormal	Yes

Listing 12.2.4.8: 12-Lead Electrocardiogram and Pregnancy Test

ALL SUBJECTS ALLOCATED TO TREATMENT SUBJECT SAMPLE

		12 Lead Electrocardiogram			Pregnancy Test		
Subject Number	Trial Arm</ Unique Treatment>	Date of Assessment	Interpretation	Clinical Significance	Date of Assessment	Women of Child Bearing Potential	If Yes, Result
XXXX-YYYYY	XXXXXXXX</ XXXXXX>	DDMMMYYYY/XX	Normal	-	DDMMMYYYY/XX	No	-
XXXX-YYYYY	XXXXXXXX</ XXXXXX>	DDMMMYYYY/XX	Normal	-	DDMMMYYYY/XX	Yes	Negative
----							

Source: XXX00X.sas, <CRO>.Run DDMMMYYYY HH:MM
Page x/y
Abbott Protocol CCCC-xxx-yyyy

Listing 12.2.5.1: Drug Exposure, Accountability and Compliance

ALL SUBJECTS AllOCATED TO TREATMENT SUBJECT SAMPLE

Subject Number	Trial Arm </ Unique Treatment>	Visit (Time Point)	Date of Assessment/ Treatment Day	Number of Tablets Dispensed	Number of Tablets Returned	Number of tablets taken	Overall Duration of Treatment Exposure	Overall Compliance/ Category
		Overall	-	xx	xx	xx	xx	xxx.x/ xxxxx
XXXX-YYYYY	XXXXXXXX </XXXXXX>	Visit 2 (Baseline)	DDMMMYYYY/ xx	xx	-	-		
		Visit 3 (Week 4)	DDMMMYYYY/ xx	xx	xx	xx		
		Visit 4 (Week 8)	DDMMMYYYY/ xx	-	xx	xx		

Listing 12.2.6.1.1: Leeds Dyspepsia Questionnaire (LDQ) -Question 1 to 8

ALL SUBJECTS ALLOCATED TO TREATMENT SUBJECT SAMPLE

Subject Number	Trial Arm </Unique Treatment>	Questions	Visit (Time Point)	Date of Assessment	Response (Yes/No)	If Yes, Questions	If Yes, Response
XXXX-YYYYY	XXXXXX <XXXX>	1. Over the last FOUR WEEKS have you had any indigestion (a pain in the upper abdomen)	Visit 1 (Screening)	DDMMMYYYY	Yes	a) How often have you had indigestion over the last FOUR WEEKS?	xxxxxx
						b) How severe has your indigestion been over the last FOUR WEEKS?	xxxxxxx
			Visit 3 (Week 4)	DDMMMYYYY	Yes	a) How often have you had indigestion over the last FOUR WEEKS?	xxxxxx
						b) How severe has your indigestion been over the last FOUR WEEKS?	xxxxxxx
			Visit 4 (Week 8)	DDMMMYYYY	No	-	-

		2. Over the past FOUR WEEKS have you ever experienced heartburn (a burning feeling behind the breast bone)?	Visit 1 (Screening)	DDMMMYYYY	Yes	a) How often have you had heartburn over the last FOUR WEEKS?	xxxxxx
						b) How severe has your heartburn been over the last FOUR WEEKS?	xxxxxxx
			Visit 3 (Week 4)	DDMMMYYYY	Yes	a) How often have you had heartburn over the last FOUR WEEKS?	xxxxxx
						b) How severe has your heartburn been over the last FOUR WEEKS?	xxxxxxx
			Visit 4 (Week 8)	DDMMMYYYY	No	-	-

XXXX-YYYYY	XXXXXXX X</ XXXXXX>	1. Over the last FOUR WEEKS have you had any indigestion (a pain in the upper abdomen)	Visit 1 (Screening)	DDMMMYYYY	Yes	a) How often have you had indigestion over the last FOUR WEEKS?	xxxxxx

				b) How severe has your indigestion been over the last FOUR WEEKS?	xxxxxxx
	Visit 3 (Week 4)	DDMMMYYYY	Yes	a) How often have you had indigestion over the last FOUR WEEKS?	xxxxxx
				b) How severe has your indigestion been over the last FOUR WEEKS?	xxxxxxx
	Visit 4 (Week 8)	DDMMMYYYY	No	-	-

Remarks (not part of the table):
Order by subject number chronologically and within subject by date, treatment day, and trial arm;
Order Question variables within a subject by LDQ questions
Continue the above listings for all LDQ questions and for all subjects

Listing 12.2.6.1.2: Leeds Dyspepsia Questionnaire (LDQ) - Question 9 to 15

ALL SUBJECTS ALLOCATED TO TREATMENT SUBJECT SAMPLE

Subject Number	Trial Arm </Unique Treatment>	Question	Visit (Time Point)	Date of Assessment	Response
XXXX-YYYYY	XXXXXX </XXXX>	9. Which, if any, of these symptoms has been the most trouble-some to you in the last FOUR WEEKS?	Visit 1 (Screening)	DDMMMYYYY	XXXX
			Visit 3 (Week 4)	DDMMMYYYY	Yes
			Visit 4 (Week 8)	DDMMMYYYY	No
		10. Does your indigestion come and go?	Visit 1 (Screening)	DDMMMYYYY	Yes
			Visit 3 (Week 4)	DDMMMYYYY	Yes
			Visit 4	DDMMMYYYY	No

			(Week 8)		

XXXX-YYYYY	XXXXXXX </XXXX>	9. Which, if any, of these symptoms has been the most trouble-some to you in the last FOUR WEEKS?	Visit 1 (Screening)	DDMMMYYYY	Yes
			Visit 3 (Week 4)	DDMMMYYYY	Yes
			Visit 4 (Week 8)	DDMMMYYYY	No

Remarks (not part of the table):
Order by subject number chronologically and within subject by date, treatment day, and trial arm;
Order Question variables within a subject by LDQ questions

Continue the above listings for all LDQ questions and for all subjects

Listing 12.2.6.1.3: Leeds Dyspepsia Questionnaire (LDQ) for Severity Score

ALL SUBJECTS ALLOCATED TO TREATMENT SUBJECT SAMPLE

Subject Number	Trial Arm </ Unique Treatment>	Visit (Time Point)	Date of Assessment/ Treatment Day	Overall LDQ Score	Baseline Value/ Change from Baseline
XXXX-YYYYY	XXXXXXXX </XXXXXX>	Visit 3 (Week 4)	DDMMMYYYY/ XX	XXX	XXXX/ XXXX
		Visit 4 (Week 8)	DDMMMYYYY/ XX	XXX	XXXX/ XXXX

Note: Treatment day is calculated relative to the first administration of a unique treatment and is only presented for those subjects who received at least one dose of the unique treatment.

Source: XXX00X.sas, <CRO>.Run DDMMMYYYY HH:MM Page x/y
Abbott Protocol CCCC-xxx-yyyy

Remarks (not part of the table):
Order by subject number chronologically and within subject by date, treatment day, and trial arm;
Order by Visit within a subject.
Continue the above listings for all subjects and visits.

Listing 12.2.6.2.1: Symptoms Questionnaire by Short Form - Nepean Dyspepsia Index (SF-NDI)

ALL SUBJECTS ALLOCATED TO TREATMENT SUBJECT SAMPLE

Subject Number	Trial Arm </Unique Treatment>	last two weeks, stomach problems	Visit (Time Point)	Date of Assessment	How Often (Frequency)	How Intense (Intensity)	How Bothersomeness
XXXX-YYYYY	XXXXXXX</ XXXXXX>	1. Pain or Ache in Upper Abdomen	Visit 2 (Baseline)	DDMMMYYYY	3-Nine to Twelve Fays	4-Severe	3-Quite a bit
			Visit 4 (Week 8)	DDMMMYYYY	1-One to four days	2-Mild	1-A little bit
		2. Discomfort in Upper Abdomen	Visit 2 (Baseline)	DDMMMYYYY	3-Nine to Twelve Fays	4-Severe	3-Quite a bit
			Visit 4 (Week 8)	DDMMMYYYY	1-One to four days	2-Mild	1-A little bit
		--------					
XXXX-YYYYY	XXXXXXX</ XXXXXX>	1. Pain or Ache in Upper Abdomen	Visit 2 (Baseline)	DDMMMYYYY	3-Nine to Twelve Fays	4-Severe	3-Quite a bit
			Visit 4 (Week 8)	DDMMMYYYY	1-One to four days	2-Mild	1-A little bit
		2. Discomfort in Upper	Visit 2	DDMMMYYYY	3-Nine to Twelve	4-Severe	3-Quite a bit

	Abdomen	(Baseline)		Fays		
		Visit 4 (Week 8)	DDMMMYYYY	1-One to four days	2-Mild	1-A little bit
	---					

Source: XXX00X.sas, <CRO>.Run DDMMMYYYY HH:MM
Abbott Protocol CCCC-xxx-yyyy

Remarks (not part of the table):
Order by subject number chronologically and within subject by date, treatment day, and trial arm;
Order Question variables within a subject by SF-NDI symptoms
Continue the above listings for all SF-NDI symptoms questions for all subjects.

Listing 12.2.6.2.2: All Symptoms & Functional Dyspepsia Scores Assessed by Short Form - Nepean Dyspepsia Index (SF-NDI) Questionnaire

ALL SUBJECTS ALLOCATED TO TREATMENT SUBJECT SAMPLE

Subject Number	Trial Arm </Unique Treatment>	Visit (Time Point)	Date of Assessment/ Treatment Day	All Symptoms Score	All Symptoms Score Baseline Value/ Change from Baseline	Functional Dyspepsia Score	Functional Dyspepsia Baseline Value/ Change from Baseline
XXXX-YYYYY	XXXXXXX </XXXXX>	Visit 4 (Week 8)	DDMMMYYYY/ XX	XXX	XXXX/ XXXX	XXX	XXXX/ XXXX
XXXX-YYYYY	XXXXXXX </XXXXX>	Visit 4 (Week 8)	DDMMMYYYY/ XX	XXX	XXXX/ XXXX	XXX	XXXX/ XXXX

Note: Treatment day is calculated relative to the first administration of a Unique Treatment and is only presented for those subjects who received at least one dose of the Unique Treatment

Remarks (not part of the table):
Order by subject number chronologically and within subject by date, treatment day, and trial arm;
Order by Visit within a subject.
Continue the above listings for all subjects and visits.

Listing 12.2.6.3.1: Quality of Life (QoL) Questionnaire by Short Form - Nepean Dyspepsia Index (SF-NDI)

ALL SUBJECTS ALLOCATED TO TREATMENT SUBJECT SAMPLE

Subject Number	Trial Arm </Unique Treatment>	Domain	Question	Visit (Time Point)	Date of Assessment	Response
XXXX-YYYYY	XXXXXXX X</ XXXXXX>	Tension	1. Has your general emotional well-being been disturbed by your stomach problems in the last 2 weeks?	Visit 2 (Baseline)	DDMMMYYYY	4-Quite a lot
				Visit 4 (Week 8)	DDMMMYYYY	1-A little
			2. Have you been irritable, tense or frustrated in the last 2 weeks because of your stomach problems?	Visit 2 (Baseline)	DDMMMYYYY	3-Moderately
				Visit 4 (Week 8)	DDMMMYYYY	1-A little
		Interference With daily Activities	3. Has your general emotional well-being been disturbed by your stomach problems in the last 2 weeks?	Visit 2 (Baseline)	DDMMMYYYY	4-Quite a lot
				Visit 4 (Week 8)	DDMMMYYYY	1-A little
			4. Have you been irritable, tense or frustrated in the last 2 weeks	Visit 2 (Baseline)	DDMMMYYYY	3-Moderately

			because of your stomach problems?			
				Visit 4 (Week 8)	DDMMMYYYY	1-A little
		--------	--------			
XXXX-YYYYY	XXXXXXX X</ XXXXXX>	Tension	1. Has your general emotional well-being been disturbed by your stomach problems in the last 2 weeks?	Visit 2 (Baseline)	DDMMMYYYY	4-Quite a lot
				Visit 4 (Week 8)	DDMMMYYYY	1-A little
			2. Have you been irritable, tense or frustrated in the last 2 weeks because of your stomach problems?	Visit 2 (Baseline)	DDMMMYYYY	3-Moderately
				Visit 4 (Week 8)	DDMMMYYYY	1-A little
				Visit 4 (Week 8)	DDMMMYYYY	1-One to four days
		--------	--------			

Remarks (not part of the table):
Order by subject number chronologically and within subject by date, treatment day, and trial arm;
Order Question variables within a subject by SF-NDI symptoms
Continue the above listings for all SF-NDI symptoms questions for all subjects.

Listing 12.2.6.3.2: Raw and Transformed Scale scores of Quality of Life (QoL) Assessed by Short Form - Nepean Dyspepsia Index (SF-NDI) Questionnaire

ALL SUBJECTS ALLOCATED TO TREATMENT SUBJECT SAMPLE

Subject Number	Trial Arm</ Unique Treatment>	Date of Visit	Date of Assessment/ Treatment Day	Raw Score	Raw Score Baseline Value/ Change from Baseline	Transformed Score	Transformed Score Baseline Value/ Change from Baseline
XXXX-YYYYY	XXXXXXXX</ XXXXXX>	Visit 4 (Week 8)	DDMMMYYYY/XX	XXX	XXXX/XXXX	XXX	XXXX/XXXX
XXXX-YYYYY	XXXXXXXX</ XXXXXX>	Visit 4 (Week 8)	DDMMMYYYY/XX	XXX	XXXX/XXXX	XXX	XXXX/XXXX

Note: Treatment day is calculated relative to the first administration of a Unique Treatment and is only presented for those subjects who received at least one dose of the Unique Treatment

Source: XXX00X.sas, <CRO>.Run DDMMMYYYY HH:MM Page x/y
Abbott Protocol CCCC-xxx-yyyy

Remarks (not part of the table):
Order by subject number chronologically and within subject by date, treatment day, and trial arm;
Order by Visit within a subject.
Continue the above listings for all subjects and visits.

Listing 12.2.6.4.1: Numerical Rating Scale (NRS 11) Questionnaire

ALL SUBJECTS ALLOCATED TO TREATMENT SUBJECT SAMPLE

Subject Number	Trial Arm </Unique Treatment>	Symptoms	Visit (Time Point)	Date of Assessment	Result
XXXX-YYYYY	XXXXXXXX</ XXXXXX>	Bloating Sensation	Visit 2 (Baseline)	DDMMMYYYY	9-Unbearable
			Visit 3 (Week 4)	DDMMMYYYY	6-Intense
			Visit 4 (Week 8)	DDMMMYYYY	3-Tolerable
		Early Satiety	Visit 2 (Baseline)	DDMMMYYYY	9-Unbearable
			Visit 3 (Week 4)	DDMMMYYYY	6-Intense
			Visit 4 (Week 8)	DDMMMYYYY	3-Tolerable

XXXX-YYYYY	XXXXXXXX</ XXXXXX>	Bloating Sensation	Visit 2 (Baseline)	DDMMMYYYY	9-Unbearable
			Visit 3 (Week 4)	DDMMMYYYY	6-Intense
			Visit 4 (Week 8)	DDMMMYYYY	3-Tolerable

Source: XXX00X.sas, <CRO>.Run DDMMMYYYY HH:MM Page x/y
Abbott Protocol CCCC-xxx-yyyy

Remarks (not part of the table):
Order by subject number chronologically and within subject by date, treatment day, and trial arm;
Order Question variables within a subject by SF-NDI symptoms
Continue the above listings for all SF-NDI symptoms questions for all subjects.

Listing 12.2.6.5.1: Treatment Acceptance and Ease of Use Assessment

ALL SUBJECTS ALLOCATED TO TREATMENT SUBJECT SAMPLE

Subject Number	Trial Arm </Unique Treatment>	Visit (Time Point)	Date of Assessment	Satisfied with the schedule of dosing treatment
XXXX-YYYYY	XXXXXXXX </XXXXXX>	Visit 4 (Week 8)	DDMMMYYYY	4-Very Satisfied
XXXX-YYYYY	XXXXXXXX </XXXXXX>	Visit 4 (Week 8)	DDMMMYYYY	5-Extremely Satisfied
XXXX-YYYYY	XXXXXXXX </XXXXXX>	Visit 4 (Week 8)	DDMMMYYYY	2-Slightly Satisfied
XXXX-YYYYY	XXXXXXXX </XXXXXX>	Visit 4 (Week 8)	DDMMMYYYY	3-Neutral
XXXX-YYYYY	XXXXXXXX </XXXXXX>	Visit 4 (Week 8)	DDMMMYYYY	3-Neutral

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Remarks (not part of the table):
Order by subject number chronologically and within subject by date, and trial arm;
Continue the above listings for all subject..