Statistical Analysis Plan for Interventional Studies

Sponsor Name: Arch Biopartners Inc.

Protocol Title: A phase I double-blind, placebo-controlled, randomized, single and multiple ascending dose finding study to evaluate the safety and pharmacokinetic profile of LSALT peptide in healthy participants

Protocol Number: AB001

Protocol Version and Date: V3, 30-Jan-2020

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Revision History

Version #	**Date** (DD-Mmm-YYYY)	**Document Owner**	**Revision Summary**
v1.0	22-Dec-2019	Konstantine Dres	
v2.0	2-Apr-2020	Konstantine Dres	Additional Cohort added to the MAD portion

I confirm that I have reviewed this document and agree with the content.

Approvals

Syneos Health Approval

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Table of Contents

1. Glossary of Abbreviations

Abbreviation	Description
AE	Adverse event
ATC	Anatomical Therapeutic Chemical
AUC	Area under the curve
BMI	Body mass index
BLQ	Below the quantification limit
CI	Confidence interval
CRF	Case Report Form
CV	Coefficient of variation
ECG	Electrocardiogram
eCRF	Electronic case report form
ITT	Intent-to-Treat
MAD	Multiple ascending dose
MedDRA	Medical Dictionary for Regulatory Activities
OLS	Ordinary least squares
PD	Pharmacodynamic
PK	Pharmacokinetic
PT	Preferred term
RTF	Rich text format
SAD	Single ascending dose
SAE	Serious adverse event
SAP	Statistical analysis plan
SAS	Statistical Analysis System
SD	Standard deviation
SOC	System organ class
SOP	Standard Operating Procedure
SRC	Safety Review Committee
TEAE	Treatment Emergent Adverse Event
TLF	Tables, Listings and Figures
WHO	World Health Organization

2. Purpose

The purpose of this statistical analysis plan (SAP) is to ensure that the data listings, summary tables and figures which will be produced, and the statistical methodologies that will be used, are complete and appropriate to allow valid conclusions regarding the study objectives.

This SAP is based on the following documents:

- Protocol V3, dated 30-Jan-2020.
- Addendum to Clinical Protocol (version 29MAY2019_v2), dated 31-Mar-2020
- Electronic Case Report Form (eCRF) version 4.00, dated 19-Mar-2020.

2.1. Responsibilities

Syneos Health will perform the statistical analyses and are responsible for the production and quality control of all tables, listings, figures (TLFs) and Pharmacokinetic (PK) analysis.

2.2. Timings of Analyses

Interim Analysis:

Interim PK analysis may be performed by the pharmacokineticist after the completion of individual cohorts.

Final Analysis:

The primary analysis of safety and PK is planned after all subjects complete the final study visit or terminate early from the study.

3. Study Objectives

3.1. Primary Objective

The primary objective of this study is:

- To determine the safety and tolerability of 4 single and multiple ascending doses of LSALT peptide in healthy participants.

3.2. Secondary Objective

The secondary objective of this study is:

- To evaluate the pharmacokinetics and pharmacodynamics of LSALT peptide in healthy participants.

3.3. Brief Description

This is a double-blind, placebo-controlled, randomized, adaptive design single and multiple ascending dose study to evaluate the safety and pharmacokinetics of LSALT peptide in healthy participants.

To establish a safe starting dose of LSALT peptide, unblinded low dose escalation will first be performed in a small cohort of participants. 0.01 mg of LSALT peptide will be administered intravenously (IV) once. If no adverse effects are observed following 72 hours, subsequent single (n=1) participants will be administered escalating doses of 0.1 mg, 0.3 mg and 0.5 mg every 72 hours. If no adverse effects are observed at the 0.5 mg dose, then the study will proceed to the first cohort of 8 participants (6 active treatment, 2 placebo per dose level) who will receive 1.0 mg of LSALT peptide in a double-blinded fashion. Safety, tolerability, PK and PD will be assessed before escalating to the next cohort. Dosing will be completed in two sequential cohorts of 8 participants using doses of 2.5 mg and 5.0 mg. The first 2 participants in each blinded cohort will act as sentinels (1 treatment, 1 placebo) who must show no adverse effects before continuing the study under the current design.

Once safety, PK and PD data are completed in the single ascending dose (SAD) cohort, and the LSALT peptide is determined to be safe and well-tolerated by the Safety Review Committee (SRC), the multiple ascending dose arm of the study will proceed. The multiple ascending dose arm will consist of 3 cohorts of 8 participants receiving 3 independent doses of the LSALT peptide or placebo once or twice daily for 3 consecutive days. The doses for this arm of the study will consist of the 3 highest doses determined by the SRC to be safe in the SAD cohort. The first cohort will receive drug in a double-blinded fashion. Safety, tolerability, PK, and PD will be assessed before escalating to the next cohort. Each cohort will consist of 6 active treatment, 2 placebo per dose level. The first 2 participants in each cohort will act as sentinels (1 treatment, 1 placebo) who must show no adverse effects before continuing the study under the current design.

3.4. Subject Selection

Approximately 52 healthy male and female subjects, aged 18-55 years, are planned to be enrolled into the study.

3.5. Determination of Sample Size

No prospective calculations of statistical power have been made. The sample sizes of 4 subjects (low dose cohort), 24 subjects for the SAD portion and 24 subjects for the MAD portion of this study have been selected to provide information on safety, tolerability, PK and PD following single and multiple doses of LSALT peptide.

3.6. Treatment Assignment

All subjects enrolled in this study will receive either LSALT peptide or placebo. The planned dose levels are as follows.

Low Dose (unblinded):

Cohort	Dose	Number of Subjects Receiving LSALT	Number of Subjects Receiving Placebo
Low Dose	0.01 mg	1	0
Low Dose	0.1 mg	1	0
Low Dose	0.3 mg	1	0
Low Dose	0.5 mg	1	0

SAD (blinded):

Cohort Number	Dose	Number of Subjects Receiving LSALT	Number of Subjects Receiving Placebo
1 (sentinel group)	1.0 mg	1	1
1	1.0 mg	5	1
2 (sentinel group)	2.5 mg	1	1
2	2.5 mg	5	1
3 (sentinel group)	5.0 mg	1	1
3	5.0 mg	5	1

MAD (blinded):

Cohort Number	Dose	Number of Subjects Receiving LSALT	Number of Subjects Receiving Placebo
4 (sentinel group)	1.0 mg	1	1
4	1.0 mg	5	1
5 (sentinel group)	2.5 mg	1	1
5	2.5 mg	5	1
6 (sentinel group)	5.0 mg	1	1
6	5.0 mg	5	1

TBD = to be determined.

3.7. Randomization and Blinding

Randomization:

Computer generated randomization schedules will be prepared prior to the start of the study. The schedules will be generated through the statistical analysis system (SAS) software, version 9.4. Block randomization will be used.

Low Dose Subjects will reveive only LSALT peptide. SAD and MAD subjects will be randomly assigned to receive either LSALT peptide or matching placebo in a ratio of 3:1 (active: placebo). A Randomization Plan will be created (which includes provisions for replacement subjects), and the randomization of eligible study participants will be managed as per the plan.

In the event of participant drop-out, participants from the reserve pool will be enrolled in the study and randomized. For subjects who are replaced the replacements should take the same treatment assignment as the original subject to ensure that the planned treatment allocation ratio is retained.

Blinding:

Participants and the study investigators/personnel will be blinded except for initial low doses of LSALT in single subjects which will be open-label. This is a third-party blinded study whereupon the pharmacist (or designate) preparing the LSALT peptide or placebo for infusion will be unblinded.

4. Endpoints

4.1. Safety Endpoints (Primary)

The primary safety endpoints are:

- Incidence of AEs.
- Clinical laboratory test results (hematology, chemistry, coagulaton and urinalysis).
- Vital sign measurements
- 12 lead electrocardiogram (ECG) readings

4.2. Pharmacokinetic Endpoints (Secondary)

The secondary PK endpoints are:

- Plasma LSALT concentrations.
- Plasma LSALT PK parameters.

5. Analysis Populations

All subjects' inclusion status into each analysis population will be determined after database lock and prior to unblinding for the final analysis.

5.1. Intent-to-Treat Population

The Intent-to-Treat (ITT) Population will comprise all randomized subjects and will be based on the randomized treatment, regardless of which treatment the subject actually received. The ITT Population will be used for all summaries of baseline and demographic data. In addition, all listings will be produced for the ITT Population.

5.2. Safety Population

The Safety Population will comprise all randomized subjects who receive any amount of study drug and will be based on the actual treatment received, if this differs from that to which the subject was randomized. The Safety Population will be used for the summaries of all safety and tolerability.

5.3. Pharmacokinetic Concentration Population

The PK Concentration Population will comprise all subjects who receive any amount of LSALT, who have at least one quantifiable PK concentration and will be based on the actual treatment received, if this differs from that to which the subject was randomized. Subjects who receive only placebo will be excluded from the PK Concentration Population. The PK Concentration Population will be used for the summaries of all PK concentration data.

5.4. Pharmacokinetic Parameters Population

The PK Population will comprise all randomized subjects who receive any amount of LSALT, have sufficient concentration data to support accurate estimation of at least 1 PK parameter (determined at the discretion of the pharmacokineticist in consultation with the Sponsor) and will be based on the actual treatment received, if this differs from that to which the subject was randomized. Subjects who receive only placebo will be excluded from the PK Parameters Population. The PK Parameters Population will be used for the summaries/analyses of all PK parameter data.

5.5. Protocol Deviations

Subject data will be examined for evidence of protocol deviations in order to assess how well the protocol was followed. Possible protocol deviations will be independently reviewed and acknowledged by Arch Biopartners Inc.

All protocol deviations will be detailed in the listings.

6. General Aspects for Statistical Analysis

6.1. General Methods

SAS® for Windows, Release 9.4 (SAS® Institute Inc., Cary, NC, USA) software will be used to perform all data analyses.

All data in the database will be presented in the data listings. Unless otherwise stated, all listings will be sorted by cohort, randomized treatment group, subject number and assessment date/time. For the purposes of the summary tables, all subjects randomized to placebo will be combined into a single placebo group.

All listings and summaries/analyses will be presented separately for each study part. Unless otherwise stated, the descriptions of the analyses which follow, apply to both SAD/MAD study parts (Low Dose subjects' results will be listed only).

The following labels for treatment will be used on all tabulations where the results are displayed by treatment, in the following order:

SAD:

- All Placebo
- LSALT 1.0 mg
- LSALT 2.5 mg
- LSALT 5.0 mg

MAD:

- All Placebo
- LSALT 1.0 mg
- LSALT 2.5 mg
- LSALT 5.0 mg

Summary Statistics:

Unless otherwise stated, continuous variables will be summarized using the number of observations (n), and the statistics mean, median, standard deviation (SD), minimum and maximum. The minimum and maximum values will be presented to the same number of decimal places as recorded in the case report form (CRF), mean and median will be presented to one more decimal place than the raw data and the SD will be presented to two more decimal places than the raw data. Summaries of change-from-baseline variables will include only subjects who have both a baseline value and corresponding value at the timepoint of interest. Categorical variables will be summarized with frequency counts and percentages. Percentages will be rounded to one decimal place, with the denominator being the number of subjects in the relevant population, unless otherwise stated.

For the plasma PK data, the data will be rounded to two decimal places in the listings. Summary statistics will also include the geometric mean (three decimal places) and geometric coefficient of variation (CV) (%) (four decimal places). The geometric mean and CV(%) will not be calculated for T_{max}, $t_{1/2}$, $\%AUC_{exp}$ and λ_z.

Only data from nominal protocol scheduled visits will be included in the summary tables. Data from unscheduled visits will not be included in the summary tables (unless they were used as baseline) but will be included in the listings and figures.

6.2. Key Definitions

Baseline:

In general, baseline will be defined for each subject and will be defined as the last available, non-missing assessment results obtained prior to first study drug administration. Unknown, Not Done, Not Applicable and other classifications of missing data will not be considered when calculating baseline observations. However, valid categorical observations will be considered for baseline calculations.

Study Day:

Study day will be calculated using first study drug administration date as the reference date. If the date of interest occurs on or after the first study drug administration date, study day will be calculated as (date of interest – first study drug administration date) + 1. If the date of interest occurs prior to the first study drug administration date, study day will be calculated as (date of interest – first study drug administration date). There will be no study day 0.

6.3. Missing Data

All withdrawals will be included in all summaries up to the time of withdrawal.

There will be no imputation for missing data, unless otherwise specified.

6.4. Visit Windows

All assessments will be included in the listings. No visit windows will be applied to assessments.

7. Demographic and Baseline Characteristics

7.1. Subject Disposition and Withdrawals

Subject enrollment and disposition, including reasons for early withdrawal from the study, will be summarized by randomized treatment.

All subject disposition parameters will be presented for individual subjects in the listings.

7.2. Demographic and Baseline Characteristics

Demographic and baseline characteristics (including gender, child bearing potential, age, race, ethnicity, height, weight and body mass index [BMI]) will be summarized by randomized treatment and overall.

All demographic and baseline characteristics (and other screening data) will be listed.

7.3. Medical History

Medical history, urine drug screen and alcohol breath test will be listed only.

8. Analysis Of Pharmacokinetics

All plasma concentration summaries will be conducted on the PK Concentration Population. All plasma PK parameter summaries/analyses will be conducted on the PK Parameters Population.

8.1. PK Sampling Schedule

SAD:

PK blood samples: 5 ml of blood will be drawn at 30 minutes pre (+/- 5 minutes) and 15 minutes (+/- 5 minutes), 30 minutes (+/- 5 minutes), 45 minutes (+/- 5 minutes), 1h (+/- 5 minutes), 2h (+/- 5 minutes), 4h (+/- 10 minutes), 6h (+/- 10 minutes), 8h (+/- 10 minutes), and 12h (+/- 30 minutes) after the LSALT infusion has completed; followed by 24h and 72h samples.

MAD:

Day 1 PK blood samples: 5 ml of blood will be drawn at 30 minutes pre start of infusion (+/- 5 minutes) and 15 minutes (+/- 5 minutes), 30 minutes (+/- 5minutes), 45 minutes (+/- 5 minutes), 1h (+/- 5 minutes), 2h (+/- 5 minutes), 4h (+/- 10 minutes), 6h (+/- 10 minutes), 8h (+/- 10 minutes), and 12h (+/- 30minutes) after the LSALT infusion has completed; followed by 24h sample.

Day 3 PK blood samples: 5 ml of blood will be drawn at 15 minutes (+/- 5 minutes), 30 minutes (+/- 5 minutes), 45 minutes (+/- 5 minutes), 1h (+/- 5 minutes), 2h (+/- 5 minutes), 4h (+/- 10 minutes), 6h (+/- 10 minutes), 8h (+/- 10 minutes), and 12h (+/- 30 minutes) after the 3rd LSALT infusion has completed; followed by 72h and 92h samples.

8.2. Derived PK Parameters

SAD:

The following plasma PK parameters will be derived for the SAD study portion.

Parameter	Definition	Method of Determination
AUC_{0-24}	Area under the plasma concentration-time curve, from time 0 to 24 hours.	Linear trapezoidal method
AUC_{0-12}	Area under the plasma concentration-time curve, from time 0 to 12 hours.	Linear trapezoidal method
AUC_{0-t}	Area under the plasma concentration-time curve, from time 0 to the last measurable concentration.	Linear trapezoidal method
AUC_{0-inf}	Area under the plasma concentration-time curve, from time 0 extrapolated to infinity.	$AUC_{0-t} + C_{last}/\lambda_z$, where C_{last} is the last measurable concentration.
$\%AUC_{exp}$	Percentage of AUC_{0-inf} due to extrapolation from the time of last concentration to infinity.	$(1 - AUC_{0-t}/AUC_{0-inf})*100$

Parameter	Definition	Method of Determination
C_{max}	Maximum observed plasma concentration.	Observed directly from data
T_{max}	Time to reach C_{max}. If the maximum value occurs at more than 1 timepoint, T_{max} is defined as the first timepoint with this value.	Observed directly from data
$t_{1/2}$	Apparent first-order terminal elimination half-life.	$\ln(2)/\lambda_z$
λ_z	Apparent first-order terminal elimination rate constant.	Estimated by linear regression of the terminal elimination phase of the log-linear drug concentration-time curve
Cl/F	Apparent total body clearance.	Estimated as Dose/$AUC_{0\text{-inf}}$
V_z/F	Apparent volume of distribution.	Estimated as Dose/(λ_z × $AUC_{0\text{-inf}}$)

MAD:

The following plasma PK parameters will be derived for the MAD study portion, for Day 1 and Day 3.

Parameter	Definition	Method of Determination
$AUC_{0\text{-24}}$	Area under the plasma concentration-time curve, from time 0 to 24 hours. (Day 1)	Linear trapezoidal method
$AUC_{0\text{-12}}$	Area under the plasma concentration-time curve, from time 0 to 12 hours. (Day 1)	Linear trapezoidal method
$AUC_{0\text{-tau}}$	Area under the curve over a dosing interval at steady state (Day 3 only)	Linear trapezoidal method
$AUC_{0\text{-t}}$	Area under the plasma concentration-time curve, from time 0 to the last measurable concentration.	Linear trapezoidal method
$AUC_{0\text{-inf}}$	Area under the plasma concentration-time curve, from time 0 extrapolated to infinity.	$AUC_{0\text{-t}} + C_{last}/\lambda_z$, where C_{last} is the last measurable concentration.
$\%AUC_{exp}$	Percentage of $AUC_{0\text{-inf}}$ due to extrapolation from the time of last concentration to	$(1 - AUC_{0\text{-t}}/AUC_{0\text{-inf}})*100$

Parameter	Definition	Method of Determination
	infinity.	
C_{max}	Maximum observed plasma concentration on.	Observed directly from data
T_{max}	Time to reach C_{max}. If the maximum value occurs at more than 1 timepoint, T_{max} is defined as the first timepoint with this value.	Observed directly from data
$t_{1/2}$	Apparent first-order terminal elimination half-life.	$ln(2)/\lambda_z$
λ_z	Apparent first-order terminal elimination rate constant.	Estimated by linear regression of the terminal elimination phase of the log-linear drug concentration-time curve.
Cl/F	Apparent total body clearance.	Estimated as $Dose/AUC_{0-inf}$
V_z/F	Apparent volume of distribution.	Estimated as $Dose/(\lambda_z \times AUC_{0-inf})$
RAUC	Accumulation Ratio for AUC.	AUC_{0-12} or AUC_{0-24} Day 3/ AUC_{0-12} or AUC_{0-24} Day 1
RC_{max}	Accumulation Ratio for C_{max}.	C_{max} Day 3/C_{max} Day 1

Note: λ_z will be the negative of the estimated slope of the linear regression of the log-transformed concentration (natural logarithm) versus time profile in the terminal elimination phase. At least three concentration points will be used in estimating λ_z. The time point where log-linear λ_z calculation begins ($\lambda_{z\ Lower}$), and the actual sampling time of the last quantifiable concentration used to estimate the λ_z ($\lambda_{z\ Upper}$) will be reported with the correlation coefficient from the linear regression to calculate λ_z.

Note: tau is the dosing interval for steady-state data.

8.3. Summary of PK Variables

Concentration:

Plasma concentrations will be listed and summarized, by nominal sampling time, and cohort/actual treatment. Concentrations below the quantification limit (BLQ) will be set to zero in summary tables. BLQ will be displayed in listings.

Individual subject and mean ± SD profiles of the plasma concentration-time data will be plotted by dose level/cohort using actual and nominal times, respectively. These profiles will be presented on both linear-linear and log-linear scales.

For individual plots the BLQ values that occur in a profile before the first measurable concentration will be set to zero, and the BLQ values that occur after first measurable concentration will be set to missing. For mean plots, BLQ will be set to zero.

Parameters:

Plasma PK parameters will be listed and summarized descriptively by dose level/cohort.

For derivation of plasma pharmacokinetic parameters, the BLQ values that occur in a profile before the first measurable concentration will be set to zero. The BLQ values that occur after first measurable concentration will be set to missing.

8.4. Assessment of Dose Proportionality

SAD and MAD:

For the SAD and MAD portions, an exploratory assessment of dose proportionality will be undertaken for the PK parameters $AUC_{0\text{-}t}$, $AUC_{0\text{-}inf}$, and C_{max} (SAD) and $AUC_{0\text{-}24}$ (Day 1), C_{max}, $AUC_{0\text{-}t}$, $AUC_{0\text{-}inf}$ (Days 1 and 3) and $AUC_{0\text{-}tau}$ (Day 3) (MAD). The power model will be used, and will include the PK parameter as the response variable and dose (mg) as the explanatory variable. For this model, the variable dose will be treated as a continuous variable. Cohorts that will be considered for the analysis include LSALT dose levels ≥ 1.0 mg (where a minimum of three different dose levels are required in order to conduct the analysis). The form of the model is as follows:

$$\text{PK Parameter} = e^{\alpha} \times \text{Dose}^{\beta} \times e^{\epsilon}, \quad \text{where Dose} \geq 0, \text{ and } e^{\epsilon} \text{ represents the associated error.}$$

Thus, perfect dose proportionality is met when β=1 (ignoring error). This becomes a linear relationship following a natural-log transformation, to which a linear regression will be fit by ordinary least squares (OLS):

$$\ln(\text{PK Parameter}) = \alpha + \beta \times \ln(\text{Dose}) + \epsilon, \quad \text{where Dose} > 0, \text{ and } \epsilon \text{ represents the associated error.}$$

The estimate of β together with a 90% confidence interval (CI) will be provided (for each PK parameter model), and this will be used to quantify dose proportionality. According to Hummel et al. (2009), the following criterion may be used for exploratory dose proportionality evaluations: If the (two-sided) 90% CI for β is wholly contained within the interval, [1+ln(0.5)/ln(ρ), 1+ln(2)/ln(ρ)], then dose proportionality is suggested across the investigated dose range. Here, ρ is defined as the ratio of the highest to lowest dose. This interval criterion will be reported along with the corresponding 90% CI estimate for β (presented to three decimal places).

The SAS code for the analysis model will follow the format given below (using the Mixed procedure to fit the linear regression). The input variables (or datasets) are depicted in slanted red text and have been given generic names.

```
proc mixed data=dataset order=data;
  model ln_pk_parameter = ln_dose / solution;
  estimate 'Beta Estimate' ln_dose 1 / cl alpha=0.1;
  ods output estimates = estimates;
run;
```

The PK parameter values estimated from the power model will be plotted against dose. This plot will also include individual subject values ± SD (separately by dose level).

9. Anti Drug Antibodies

Analysis of anti drug antibody data is outside the scope of this SAP. The sample collection dates and times will be listed.

10. Safety

Summaries of safety and tolerability data will be based on the Safety Population.

10.1. Exposure

Study drug administration will be listed. For the MAD portion only, the exposure to each dose will be summarized by actual treatment and overall.

10.2. Adverse Events

Adverse events will be coded using the Medical Dictionary for Regulatory Activities (MedDRA) version 21.0 or higher. AEs will be grouped by system organ class (SOC) and preferred term (PT) and summarized by actual treatment. The summary tables will present the number and percentage of total subjects and number of events by SOC and by PT.

All AE summaries will be restricted to treatment emergent AEs (TEAEs) only. Treatment emergent AEs are defined as AEs that commence on or after the time of first study drug administration. Adverse events without an onset date or time or AEs with an onset date of the date of first study drug administration but without an onset time will be defined as treatment emergent, except if an incomplete date (e.g., month and year) clearly indicates that the event started prior to administration of first study drug or if the AE stop date indicates that the event started and stopped prior to administration of first study drug.

Treatment-emergent AEs will be summarized by actual treatment. The number and percentage of subjects experiencing AEs and the number of TEAEs will be tabulated. Subjects who experience the same AE (in terms of MedDRA preferred term) more than once will only be counted once for that event, however, the total number of events will also be counted per category. This also applies to sub-categories displayed in the summaries.

The following summaries will be presented:

- Overall summary of TEAEs
- TEAEs by SOC and PT
- TEAEs by SOC, PT, and severity
- TEAEs by SOC, PT, and relationship to study drug
- Serious TEAEs by SOC and PT

All AEs will be listed. This will include a separate listing of serious adverse events (SAEs), and Non-TEAEs.

10.3. Laboratory Evaluations

Laboratory data (hematology, chemistry and coagulation) will be summarized at each protocol-scheduled visit, by actual treatment. Actual values and actual changes from baseline will be presented.

In addition, a shift table representing the categorical change in laboratory results interpretation (normal, abnormal not clinically significant, or abnormal clinically significant) from baseline to each post baseline visit will be presented.

Urinalysis results evaluation will be summarized at each protocol-scheduled timepoint, by actual treatment, using frequency tabulations.

High and low/abnormal results will be flagged in the listings.

10.4. Vital Signs

Vital sign measurements will be summarized at each protocol-scheduled timepoint, by actual treatment. Actual values and actual changes from baseline will be presented.

In addition, a shift table representing the categorical change in vital signs interpretation (normal, abnormal not clinically significant, or abnormal clinically significant) from baseline to each post baseline visit will be presented.

Abnormal results will be flagged in the listings.

10.5. 12-Lead ECG

ECG values will be summarised at each protocol-scheduled visit, by actual treatment. Actual values and actual changes from baseline will be presented.

In addition, a shift table representing the categorical change in overall ECG interpretation (normal, abnormal not clinically significant, or abnormal clinically significant) from baseline to each post baseline visit will be presented.

Abnormal results will be flagged in the listings.

10.6. Medication

Concomitant medications will be coded using the latest version of the World Health Organisation (WHO) Drug coding dictionary. The version will be presented in the table/listing footnotes.

Prior and concomitant medications will be grouped by Anatomical Therapeutic Chemical (ATC) level 2 class and PT. The summary tables will show the number and percentage of subjects by ATC class, PT and by actual treatment. Prior medications are those medications that were stopped prior to first study drug administration. Concomitant medications are medications taken at least once after first study drug administration. Medications stopped on the same day as study treatment will be considered as concomitant medications. Concomitant medications will be summarized by actual treatment and class. Prior medications will be listed only. For the summaries of concomitant medications, subjects who take the same medication (in terms of PT and ATC) more than once will only be counted once for that medication.

10.7. Other Safety

Physical examination, chest X-ray, serology, follicle stimulating hormone and pregnancy data will be listed only.

11. Interim Analyses

An interim analysis may be performed by the pharmacokineticist after each cohort. The bioanalytical concentration data will be provided to the pharmacokineticist for the calculation of the PK parameters described in section 8.2 using the scheduled sampling times. Descriptive statistics will be calculated on the PK variables as described in section 8.3. These results will be provided as Phoenix WinNonlin outputs in Word format. Blinded listings of data may be provided. No inferential statistical analysis will be performed before the finalization of this SAP.

12. Changes from Analysis Planned in Protocol

None.

13. Reference List

Hummel J., McKendrick S., Brindley C. and French, R. Exploratory assessment of dose proportionality: review of current approaches and proposal for a practical criterion. Pharmaceut. Statist. 2009; 8: 38-49.

14. Programming Considerations

All TLFs, and statistical analyses will be generated using SAS® for Windows, Release 9.4 (SAS® Institute Inc., Cary, NC, USA). Computer-generated table, listing and figure output will adhere to the following specifications.

For all PK analyses, Phoenix® WinNonlin® version 8.0 (Certara USA, Inc., Princeton, NJ) will be used.

14.1. General Considerations

- One SAS program can create several outputs.
- Each output will be stored in a separate file.
- Output files will be delivered in rich text format (RTF) that can be manipulated in MS Word.
- Numbering of TLFs will follow ICH E3 guidance.

14.2. Table, Listing, and Figure Format

14.2.1. General

- All TLFs will be produced in landscape format, unless otherwise specified.
- All TLFs will be produced using the Courier New font, size 9
- The data displays for all TLFs will have a minimum 1-inch margin on all 4 sides.
- Headers and footers for figures will be in Courier New font, size 9.
- Legends will be used for all figures with more than 1 variable, group, or item displayed.
- TLFs will be in black and white (no color), unless otherwise specified
- Specialized text styles, such as bolding, italics, borders, shading, and superscripted and subscripted text, will not be used in the TLFs, unless otherwise specified. On some occasions, superscripts 1, 2, or 3 may be used (see below).
- Only standard keyboard characters will be used in the TLFs. Special characters, such as non-printable control characters, printer-specific, or font-specific characters, will not be used. Hexadecimal-derived characters will be used, where possible, if they are appropriate to help display math symbols (e.g., µ). Certain subscripts and superscripts (e.g., cm2, Cmax) will be employed on a case-by-case basis.
- Mixed case will be used for all titles, footnotes, column headers, and programmer-supplied formats, as appropriate.

14.2.2. Headers

- All output should have the following header at the top left of each page:
- Arch Biopartners Inc. (Syneos Health study number 7001012)

- All output should have Page n of N at the top or bottom right corner of each page. TLFs are internally paginated in relation to the total length (i.e., the page number should appear sequentially as page n of N, where N is the total number of pages in the table).

- The date output was generated should appear along with the program name as a footer on each page.

14.2.3. Display Titles

- Each TLF are identified by the designation and a numeral. (i.e., Table 14.1.1). ICH E3 numbering is strongly recommended, but sponsor preferences are obtained before final determination A decimal system (x.y and x.y.z) are used to identify TLFs with related contents. The title is centered. The analysis set are identified on the line immediately following the title. The title and table designation are single spaced. A solid line spanning the margins will separate the display titles from the column headers. There will be 1 blank line between the last title and the solid line.

Table x.y.z
First Line of Title
Second Line of Title if Needed

14.2.4. Column Headers

- Column headings are displayed immediately below the solid line described above in initial upper-case characters.

- In the case of efficacy tables, the variable (or characteristic) column will be on the far left followed by the treatment group columns and total column (if applicable). P-values may be presented under the total column or in separate p-value column (if applicable). Within-treatment comparisons may have p-values presented in a row beneath the summary statistics for that treatment.

- For numeric variables, include “unit” in column or row heading when appropriate.

- Analysis set sizes will be presented for each treatment group in the column heading as (N=xx) (or in the row headings, if applicable). This is distinct from the ‘n’ used for the descriptive statistics representing the number of subjects in the analysis set.

- The order of treatments in the tables and listings will be Placebo first in the case of placebo controlled studies and Active comparators first in the case of active comparator trials, followed by a total column (if applicable).

14.2.5. Body of the Data Display

14.2.5.1. *General Conventions*

Data in columns of a table or listing are formatted as follows:

- Alphanumeric values are left-justified;

- Whole numbers (e.g., counts) are right-justified; and

- Numbers containing fractional portions are decimal aligned.

14.2.5.2. *Table Conventions*

- Units will be included where available
- If the categories of a parameter are ordered, then all categories between the maximum and minimum category are presented in the table, even if n=0 for all treatment groups in a given category that is between the minimum and maximum level for that parameter. For example, the frequency distribution for symptom severity would appear as:

Severity Rating	N
severe	0
moderate	8
mild	3

Where percentages are presented in these tables, zero percentages will not be presented and so counts of 0 will be presented as 0 and not as 0 (0%).

- If the categories are not ordered (e.g., Medical History, Reasons for Discontinuation from the Study, etc.), then only those categories for which there is at least 1 subject represented in 1 or more groups are included.
- An Unknown or Missing category are added to each parameter for which information is not available for 1 or more subjects.
- Unless otherwise specified, the estimated mean and median for a set of values are printed out to one more decimal places than the original values, and standard deviations are printed out to two more decimal places than the original values. The minimum and maximum should report the same significant digits as the original values. For example, for systolic blood pressure:

N	XX
Mean	XXX.X
Std Dev	X.XX
Median	XXX.X
Minimum	XXX
Maximum	XXX

- P-values are output in the format: “0.xxx”, where xxx is the value rounded to 3 decimal places. Every p-value less than 0.001 will be presented as <0.001. If the p-value is returned as >0.999, then present as >0.999
- Percentage values are printed to one decimal place, in parentheses with no spaces, one space after the count (e.g., 7 (12.8%), 13 (5.4%)). Pre-determine how to display values that round down to 0.0. A common convention is to display as '<0.1', or as appropriate with additional decimal places. Unless otherwise noted, for all percentages, the number of subjects in the analysis set for the treatment group who have an observation will be the denominator. Percentages after zero counts should not be displayed and percentages equating to 100% are presented as 100%, without decimal places.

- Tabular display of data for medical history, prior/concomitant medications, and all tabular displays of adverse event data are presented by the body system, treatment class, or SOC with the highest occurrence in the active treatment group in decreasing order, assuming all terms are coded. Within the body system, drug class and SOC, medical history (by preferred term), drugs (by ATC1 code), and adverse events (by preferred term) are displayed in decreasing order. If incidence for more than 1 term is identical, they should then be sorted alphabetically. Missing descriptive statistics or p-values which cannot be estimated are reported as "-".

- The percentage of subjects is normally calculated as a proportion of the number of subjects assessed in the relevant treatment group (or overall) for the analysis set presented. However, careful consideration is required in many instances due to the complicated nature of selecting the denominator, usually the appropriate number of subjects exposed. Describe details of this in footnotes or programming notes.

- For categorical summaries (number and percentage of subjects) where a subject can be included in more than one category, describe in a footnote or programming note if the subject are included in the summary statistics for all relevant categories or just 1 category and the criteria for selecting the criteria.

- Where a category with a subheading (such as system organ class) has to be split over more than one page, output the subheading followed by "(cont)" at the top of each subsequent page. The overall summary statistics for the subheading should only be output on the first relevant page.

14.2.5.3. *Listing Conventions*

- Listings will be sorted for presentation in order of treatment groups as above, subject number, visit/collection day, and visit/collection time.

- Missing data are represented on subject listings as either a hyphen ("-") with a corresponding footnote ("- = unknown or not evaluated"), or as "N/A", with the footnote "N/A = not applicable", whichever is appropriate.

- Dates are printed in SAS DATE9.format ("ddMMMyyyy": 01JUL2000). Missing portions of dates are represented on subject listings as dashes (--JUL2000). Dates that are missing because they are not applicable for the subject are output as "N/A", unless otherwise specified.

- All observed time values are to be presented using a 24-hour clock HH:MM or HH:MM:SS format (e.g., 11:26:45, or 11:26). Time will only be reported if it was measured as part of the study.

- Units will be included where available

14.2.5.4. *Figure Conventions*

- Unless otherwise specified, for all figures, study visits will be displayed on the X-axis and endpoint (e.g., treatment mean change from Baseline) values will be displayed on the Y-axis.

14.2.6. Footnotes

- A solid line spanning the margins will separate the body of the data display from the footnotes.

- All footnotes will be left justified with single-line spacing immediately below the solid line underneath the data display.
- Footnotes should always begin with “Note:” if an informational footnote, or 1, 2, 3, etc. if a reference footnote. Each new footnote should start on a new line, where possible.
- Subject specific footnotes are avoided, where possible.
- Footnotes will be used sparingly and add value to the table, figure, or data listing. If more than six lines of footnotes are planned, then a cover page may be used to display footnotes, and only those essential to comprehension of the data will be repeated on each page.
- The last line of the footnote section will be a standard source line that indicates the name of the program used to produce the data display and date the program was run (i.e., ‘Program : myprogram.sas’).

15. Quality Control

SAS programs are developed to produce output such as analysis data sets, summary tables, data listings, figures or statistical analyses. These will be developed and undergo quality control as per SOPs 2800 and 2801.

16. Tables, Listings and Figures Shells

Tables, Listings and Figures Shells for Statistical Analysis of AB001

A phase I double-blind, placebo-controlled, randomized, single and multiple ascending dose finding study to evaluate the safety and pharmacokinetic profile of LSALT peptide in healthy participants

Prepared for:

Arch Biopartners Inc.

Prepared by:

Version Number:	v2.0
Author:	Konstantine Dres
Date:	2-Apr-2020

List of Tables, Listings and Figures

For the SAD study, The following labels for treatment group will be used on all tabulations, in the following order:

- All Placebo
- LSALT 1.0 mg
- LSALT 2.5 mg
- LSALT 5.0 mg

For the MAD study, The following labels for treatment group will be used on all tabulations, in the following order:

- All Placebo
- LSALT TBD mg
- LSALT TBD mg

All listings will be separated by study part, and sorted by cohort, treatment group, subject number and assessment date/time, in the following order:

Low Dose

- LSALT 0.01 mg
- LSALT 0.1 mg
- LSALT 0.3 mg
- LSALT 0.5 mg

SAD

- Cohort 1/Placebo
- Cohort 1/LSALT 1.0 mg
- Cohort 2/Placebo
- Cohort 2/LSALT 2.5 mg
- etc.

MAD

- Cohort 1/Placebo
- Cohort 1/LSALT TBD mg
- Cohort 2/Placebo
- Cohort 2/LSALT TBD mg
- etc.

Note that the nominal doses as planned in the protocol are listed above. However, should the actual doses differ from the planned nominal doses, the actual doses will be displayed in the appropriate tabulations.

For descriptive statistical representation, columns detailing Parameter/Visit/Timepoint/Statistics may be combined to ensure that all treatment groups can be displayed on the same page.

For singular columns that are represented over multiple pages (Visits), an additional column may be added to the output to reflect the by parameter detail across each page. In some cases a statement describing the continuation (e.g. System Organ Classes with multiple Preferred Terms) of a field can be added to the first row of a page to ensure clarity.

Due to the number of groups, it may not be possible to fit all groups on one page in some of the summary tables. Therefore, the summary tables will be split across multiple pages.

For results that are not applicable to a specified visit ‘N/A’ (Not Applicable) will be noted. As an example, changes from baseline will be noted as ‘N/A’ for pre-baseline visits.

For the final production tables, the listing source for each table and figure will be displayed in the footer.

Table 14.1.1.2 Enrolment and Disposition - SAD (Intent-to-Treat Population)

	All Placebo (N=xxx)	etc. (N=xxx)
Intent-to-Treat Population	xx	xx
Safety Population	xx (xx.x%)	xx (xx.x%)
Pharmacokinetic Concentration Population	xx (xx.x%)	xx (xx.x%)
Pharmacodynamic Parameters Population	xx (xx.x%)	xx (xx.x%)
Completed the Study		
Yes	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)
Primary Reason For Eary Discontinuation		
Adverse Event	xx (xx.x%)	xx (xx.x%)
Protocol Violation	xx (xx.x%)	xx (xx.x%)
Withdrawal of Consent	xx (xx.x%)	xx (xx.x%)
Death	xx (xx.x%)	xx (xx.x%)
Lost to Follow-Up	xx (xx.x%)	xx (xx.x%)
Other	xx (xx.x%)	xx (xx.x%)

Table 14.1.1.3 Enrolment and Disposition – MAD (Intent-to-Treat Population)

	All Placebo (N=xxx)	etc. (N=xxx)
Intent-to-Treat Population	xx	xx
Safety Population	xx (xx.x%)	xx (xx.x%)
Pharmacokinetic Population	xx (xx.x%)	xx (xx.x%)
Pharmacodynamic Population	xx (xx.x%)	xx (xx.x%)
Completed the Study		
Yes	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)
Primary Reason For Eary Discontinuation		
Adverse Event	xx (xx.x%)	xx (xx.x%)
Protocol Violation	xx (xx.x%)	xx (xx.x%)
Withdrawal of Consent	xx (xx.x%)	xx (xx.x%)
Death	xx (xx.x%)	xx (xx.x%)
Lost to Follow-Up	xx (xx.x%)	xx (xx.x%)
Other	xx (xx.x%)	xx (xx.x%)

Table 14.1.2.2 Demographic Characteristics – SAD (Intent-to-Treat Population)

	All Placebo (N=xxx)	etc. (N=xxx)
Gender		
Male	xx (xx.x%)	xx (xx.x%)
Female	xx (xx.x%)	xx (xx.x%)
Child Bearing Potential		
Yes	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)
Post-menopausal	xx (xx.x%)	xx (xx.x%)
Surgically sterile	xx (xx.x%)	xx (xx.x%)
Other	xx (xx.x%)	xx (xx.x%)
Race		
Asian	xx (xx.x%)	xx (xx.x%)
Black	xx (xx.x%)	xx (xx.x%)
White	xx (xx.x%)	xx (xx.x%)
Pacific Islander	xx (xx.x%)	xx (xx.x%)
Australian Aborigine/Torres Strait Islander	xx (xx.x%)	xx (xx.x%)
Other	xx (xx.x%)	xx (xx.x%)
Ethnicity		
Hispanic or Latino	xx (xx.x%)	xx (xx.x%)
Not Hispanic or Latino	xx (xx.x%)	xx (xx.x%)

[1] Age (years) = integer value ((Date Signed Informed Consent – Date of Birth + 1) / 365.25).
[2] BMI = Body Weight, in kg / ((Height, in m)^2).
Note: For the child bearing potential summary, percentages will be based on number of females.
Note: For the child bearing potential summary, subcategory percentages will be based on number subjects within the corresponding category.
Programming Note: Also include a Total column.

Table 14.1.2.2 Demographic Characteristics – SAD (Intent-to-Treat Population)

	All Placebo (N=xxx)	etc. (N=xxx)
Age (years)[1]		
n	xx	xx
Mean (SD)	xx.xx (xx.xxx)	xx.xx (xx.xxx)
Median	xx.xx	xx.xx
Min, Max	xx.x, xx.x	xx.x, xx.x
Height (cm)		
n	xx	xx
Mean (SD)	xx.xx (xx.xxx)	xx.xx (xx.xxx)
Median	xx.xx	xx.xx
Min, Max	xx.x, xx.x	xx.x, xx.x
Body Weight (kg)		
n	xx	xx
Mean (SD)	xx.xx (xx.xxx)	xx.xx (xx.xxx)
Median	xx.xx	xx.xx
Min, Max	xx.x, xx.x	xx.x, xx.x
BMI (kg/m^2)[2]		
n	xx	xx
Mean (SD)	xx.xx (xx.xxx)	xx.xx (xx.xxx)
Median	xx.xx	xx.xx
Min, Max	xx.x, xx.x	xx.x, xx.x

[1] Age (years) = integer value ((Date Signed Informed Consent – Date of Birth + 1) / 365.25).
[2] BMI = Body Weight, in kg / ((Height, in $m)^2$).
Note: For the child bearing potential summary, percentages will be based on number of females.
Note: For the child bearing potential summary, subcategory percentages will be based on number subjects within the corresponding category.
Programming Note: Also include a Total column.

Table 14.1.2.3 Demographic Characteristics – MAD (Intent-to-Treat Population)

	All Placebo (N=xxx)	etc. (N=xxx)
Gender		
Male	xx (xx.x%)	xx (xx.x%)
Female	xx (xx.x%)	xx (xx.x%)
Child Bearing Potential		
Yes	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)
Post-menopausal	xx (xx.x%)	xx (xx.x%)
Surgically sterile	xx (xx.x%)	xx (xx.x%)
Other	xx (xx.x%)	xx (xx.x%)
Race		
Asian	xx (xx.x%)	xx (xx.x%)
Black	xx (xx.x%)	xx (xx.x%)
White	xx (xx.x%)	xx (xx.x%)
Pacific Islander	xx (xx.x%)	xx (xx.x%)
Australian Aborigine/Torres Strait Islander	xx (xx.x%)	xx (xx.x%)
Other	xx (xx.x%)	xx (xx.x%)
Ethnicity		
Hispanic or Latino	xx (xx.x%)	xx (xx.x%)
Not Hispanic or Latino	xx (xx.x%)	xx (xx.x%)

[1] Age (years) = integer value ((Date Signed Informed Consent – Date of Birth + 1) / 365.25).
[2] BMI = Body Weight, in kg / ((Height, in m)^2).
Note: For the child bearing potential summary, percentages will be based on number of females.
Note: For the child bearing potential summary, subcategory percentages will be based on number subjects within the corresponding category.
Programming Note: Also include a Total column.

Table 14.1.2.3 Demographic Characteristics – MAD (Intent-to-Treat Population)

	All Placebo (N=xxx)	etc. (N=xxx)
Age (years)[1]		
n	xx	xx
Mean (SD)	xx.xx (xx.xxx)	xx.xx (xx.xxx)
Median	xx.xx	xx.xx
Min, Max	xx.x, xx.x	xx.x, xx.x
Height (cm)		
n	xx	xx
Mean (SD)	xx.xx (xx.xxx)	xx.xx (xx.xxx)
Median	xx.xx	xx.xx
Min, Max	xx.x, xx.x	xx.x, xx.x
Body Weight (kg)		
n	xx	xx
Mean (SD)	xx.xx (xx.xxx)	xx.xx (xx.xxx)
Median	xx.xx	xx.xx
Min, Max	xx.x, xx.x	xx.x, xx.x
BMI (kg/m^2)[2]		
n	xx	xx
Mean (SD)	xx.xx (xx.xxx)	xx.xx (xx.xxx)
Median	xx.xx	xx.xx
Min, Max	xx.x, xx.x	xx.x, xx.x

[1] Age (years) = integer value ((Date Signed Informed Consent – Date of Birth + 1) / 365.25).
[2] BMI = Body Weight, in kg / ((Height, in $m)^2$).
Note: For the child bearing potential summary, percentages will be based on number of females.
Note: For the child bearing potential summary, subcategory percentages will be based on number subjects within the corresponding category.
Programming Note: Also include a Total column.

Table 14.1.3.2 Concomitant Medications – SAD (Safety Population)

ATC2 Class Preferred Term	All Placebo (N=xxx)	etc. (N=xxx)
Subjects with at Least One Concomitant Medication	xx (xx.x%)	xx (xx.x%)
ATC2 A	xx (xx.x%)	xx (xx.x%)
Preferred Drug Name 1	xx (xx.x%)	xx (xx.x%)
Preferred Drug Name 2	xx (xx.x%)	xx (xx.x%)
ATC2 B	xx (xx.x%)	xx (xx.x%)
Preferred Drug Name 1	xx (xx.x%)	xx (xx.x%)
Preferred Drug Name 2	xx (xx.x%)	xx (xx.x%)
etc.		

Concomitant medications coded using WHO Drug Version X.X.
Concomitant medications are medications taken at least once on or after first study drug administration. Medications stopping on the same day as study drug administration are considered as concomitant medications.
ATC = Anatomic Therapeutic Chemical, WHO DD = World Health Organization Drug Dictionary (WHO DD) Version.

Table 14.1.3.3 Concomitant Medications – MAD (Safety Population)

ATC2 Class Preferred Term	All Placebo (N=xxx)	etc. (N=xxx)
Subjects with at Least One Concomitant Medication	xx (xx.x%)	xx (xx.x%)
ATC2 A	xx (xx.x%)	xx (xx.x%)
Preferred Drug Name 1	xx (xx.x%)	xx (xx.x%)
Preferred Drug Name 2	xx (xx.x%)	xx (xx.x%)
ATC2 B	xx (xx.x%)	xx (xx.x%)
Preferred Drug Name 1	xx (xx.x%)	xx (xx.x%)
Preferred Drug Name 2	xx (xx.x%)	xx (xx.x%)
etc.		

Concomitant medications coded using WHO Drug Version X.X.
Concomitant medications are medications taken at least once on or after first study drug administration. Medications stopping on the same day as study drug administration are considered as concomitant medications.
ATC = Anatomic Therapeutic Chemical, WHO DD = World Health Organization Drug Dictionary (WHO DD) Version.

Table 14.1.4.3 Exposure – MAD (Safety Population)

Administered Dose	All Placebo (N=xxx)	etc. (N=xxx)
Day 1 Dose	xx (xx.x%)	xx (xx.x%)
Day 2 Dose	xx (xx.x%)	xx (xx.x%)
Day 3 Dose	xx (xx.x%)	xx (xx.x%)

Programming Note: Also include a Total column.

Table 14.2.1.1.1.2 Plasma Pharmacokinetic Concentrations – SAD (Pharmacokinetic Concentration Population)

Concentration (unit) Visit Scheduled Timepoint	LSALT 1.0 mg (N=xxx)	etc. (N=xxx)
Concentration (unit)		
Day 1		
XX Hours Pre-dose		
n	xx	xx
Mean (SD)	xx.xx (xx.xxx)	xx.xx (xx.xxx)
Median	xx.xx	xx.xx
Min, Max	xx.x, xx.x	xx.x, xx.x
Geometric Mean	xx.xx	xx.xx
CV% Geometric Mean	xx.xxx	xx.xxx
etc.		

Programming Note: Continue for all protocol scheduled visits/timepoints.

Table 14.2.1.1.1.3 Plasma Pharmacokinetic Concentrations – MAD (Pharmacokinetic Concentration Population)

Concentration (unit) Visit Scheduled Timepoint	LSALT XX mg (N=xxx)	etc. (N=xxx)
Concentration (unit)		
Day 1		
XX Hours Pre-dose		
n	xx	xx
Mean (SD)	xx.xx (xx.xxx)	xx.xx (xx.xxx)
Median	xx.xx	xx.xx
Min, Max	xx.x, xx.x	xx.x, xx.x
Geometric Mean	xx.xx	xx.xx
CV% Geometric Mean	xx.xxx	xx.xxx
etc.		

Programming Note: Continue for all protocol scheduled visits/timepoints.

Figure 14.2.1.1.2.2 Individual Plasma Pharmacokinetic Concentrations by Treatment Group – SAD (Pharmacokinetic Concentration Population)

Plots of individual plasma concentrations over time, by treatment group for each subject

Figure Description: The individual plasma concentration over time will be presented, by treatment group for each subject. The figure will display on a single page values for all subjects within each treatment group. Straight lines will connect the values for each subject. Different symbols and line types will be used to distinguish between each subject.

For each figure, the X axis will be the actual timepoint. The Y axis will be the concentration, in units.

The X axis title: Timepoint
The Y axis title: Concentration (units)

Figure 14.2.1.1.2.3 Individual Plasma Pharmacokinetic Concentrations by Treatment Group – MAD (Pharmacokinetic Concentration Population)

Plots of individual plasma concentrations over time, by treatment group for each subject

Figure Description: The individual plasma concentration over time will be presented, by treatment group (including days 1 and 3 on juxtaposed figures) for each subject. The figure will display on a single page values for all subjects within each treatment group. Straight lines will connect the values for each subject. Different symbols and line types will be used to distinguish between each subject.

For each figure, the X axis will be the actual timepoint. The Y axis will be the concentration, in units.

The X axis title: Timepoint
The Y axis title: Concentration (units)

Figure 14.2.1.1.3.2 Individual Plasma Pharmacokinetic Concentrations (Log-Scale) by Treatment Group – SAD (Pharmacokinetic Concentration Population)

Plots of individual plasma concentrations (log-scale) over time, by treatment group for each subject

Figure Description: The individual plasma concentration (log-scale) over time will be presented, by treatment group and visit for each subject. The figure will display on a single page values for all subjects within each treatment group. Straight lines will connect the values for each subject. Different symbols and line types will be used to distinguish between each subject.

For each figure, the X axis will be the actual timepoint. The Y axis will be the concentration, in units.

The X axis title: Timepoint
The Y axis title: Concentration (units)

Figure 14.2.1.1.3.3 Individual Plasma Pharmacokinetic Concentrations (Log-Scale) by Treatment Group – MAD (Pharmacokinetic Concentration Population)

Plots of individual plasma concentrations (log-scale) over time, by treatment group for each subject

Figure Description: The individual plasma concentration (log-scale) over time will be presented, by treatment group (including days 1 and 3 on juxtaposed figures) for each subject. The figure will display on a single page values for all subjects within each treatment group. Straight lines will connect the values for each subject. Different symbols and line types will be used to distinguish between each subject.

For each figure, the X axis will be the actual timepoint. The Y axis will be the concentration, in units.

The X axis title: Timepoint
The Y axis title: Concentration (units)

Figure 14.2.1.1.4.2 Mean Plasma Pharmacokinetic Concentrations – SAD (Pharmacokinetic Concentration Population)

Plot of mean plasma concentrations over time

Figure Description: The mean plasma concentration over time (±SD) will be presented. The figure will display on a single page values for all treatment groups. Straight lines will connect the values within each treatment group. Different symbols and line types will be used to distinguish between each treatment group. The SD at each point will be added.

For each figure, the X axis will be the scheduled timepoint. The Y axis will be the concentration, in units.

The X axis title: Timepoint
The Y axis title: Concentration (units)

Figure 14.2.1.1.4.3 Mean Plasma Pharmacokinetic Concentrations – MAD (Pharmacokinetic Concentration Population)

Plot of mean plasma concentrations over time

Figure Description: The mean plasma concentration over time (±SD) will be presented (including days 1 and 3 overlayed). The figure will display on a single page values for all treatment groups. Straight lines will connect the values within each treatment group. Different symbols and line types will be used to distinguish between each treatment group. The SD at each point will be added.

For each figure, the X axis will be the scheduled timepoint. The Y axis will be the concentration, in units.

The X axis title: Timepoint
The Y axis title: Concentration (units)

Figure 14.2.1.1.5.2 Mean Plasma Pharmacokinetic Concentrations (Log-Scale) – SAD (Pharmacokinetic Concentration Population)

Plot of mean plasma concentrations (log-scale) over time

Figure Description: The mean plasma concentration (log-scale) over time will be presented. The figure will display on a single page values for all treatment groups. Straight lines will connect the values within each treatment group. Different symbols and line types will be used to distinguish between each treatment group.

For each figure, the X axis will be the scheduled timepoint. The Y axis will be the concentration, in units.

The X axis title: Timepoint
The Y axis title: Concentration (units)

Figure 14.2.1.1.5.3 Mean Plasma Pharmacokinetic Concentrations (Log-Scale) – MAD (Pharmacokinetic Concentration Population)

Plot of mean plasma concentrations (log-scale) over time

Figure Description: The mean plasma concentration (log-scale) over time will be presented (including days 1 and 3 overlayed). The figure will display on a single page values for all treatment groups (including days 1 and 7 overlayed). Straight lines will connect the values within each treatment group. Different symbols and line types will be used to distinguish between each treatment group.

For each figure, the X axis will be the scheduled timepoint. The Y axis will be the concentration, in units.

The X axis title: Timepoint
The Y axis title: Concentration (units)

Table 14.2.1.2.1.2 Plasma Pharmacokinetic Parameters – SAD (Pharmacokinetic Parameters Population)

Parameter (unit)	LSALT 1.0 mg (N=xxx)	etc. (N=xxx)
AUC_{0-t} (unit)		
n	xx	xx
Mean (SD)	xx.xx (xx.xxx)	xx.xx (xx.xxx)
Median	xx.xx	xx.xx
Min, Max	xx.x, xx.x	xx.x, xx.x
Geometric Mean	xx.xx	xx.xx
CV% Geometric Mean	xx.xxx	xx.xxx
etc.		

Programming Note: Continue for all plasma pharmacokinetic parameters.

Table 14.2.1.2.1.3 Plasma Pharmacokinetic Parameters – MAD (Pharmacokinetic Parameters Population)

Day 1 Plasma PK Parameters

Parameter (unit)	LSALT XX mg (N=xxx)	etc. (N=xxx)
AUC_{0-t} (unit)		
n	xx	xx
Mean (SD)	xx.xx (xx.xxx)	xx.xx (xx.xxx)
Median	xx.xx	xx.xx
Min, Max	xx.x, xx.x	xx.x, xx.x
Geometric Mean	xx.xx	xx.xx
CV% Geometric Mean	xx.xxx	xx.xxx
etc.		

Programming Note: Continue for all plasma pharmacokinetic parameters, and Day 7 PK Parameters

Table 14.2.1.2.2.2 Analysis of Dose Proportionality – SAD (Pharmacokinetic Parameters Population)

Dose Levels Included	PK Parameter (unit)	Number of Subjects Included in the Analysis	Power Model Analysis			
			Slope Estimate	90% CI for the Slope	Interval Criterion	Criterion Satisfied[1]
XX mg, XX mg, XX mg	AUC_{0-t} (unit)	xx	xx.xxx	(xx.xxx, xx.xxx)	(0.xxx, 1.xxx)	Yes
	AUC_{0-inf} (unit)	xx	xx.xxx	(xx.xxx, xx.xxx)	(0.xxx, 1.xxx)	Yes
	C_{max} (unit)	xx	xx.xxx	(xx.xxx, xx.xxx)	(0.xxx, 1.xxx)	No

[1] If the reported 90% confidence interval is entirely contained within the interval criterion of (0.xxx, 1.xxx), then dose proportionality is supported across the investigated dose range.

Table 14.2.1.2.2.3 Analysis of Dose Proportionality – SAD (Pharmacokinetic Parameters Population)

Day 1 PK Parameters

Dose Levels Included	PK Parameter (unit)	Number of Subjects Included in the Analysis	Power Model Analysis			
			Slope Estimate	90% CI for the Slope	Interval Criterion	Criterion Satisfied[1]
XX mg, XX mg, XX mg	AUC_{0-t} (unit)	xx	xx.xxx	(xx.xxx, xx.xxx)	(0.xxx, 1.xxx)	Yes
	AUC_{0-inf} (unit)	xx	xx.xxx	(xx.xxx, xx.xxx)	(0.xxx, 1.xxx)	Yes
	C_{max} (unit)	xx	xx.xxx	(xx.xxx, xx.xxx)	(0.xxx, 1.xxx)	No
	etc.					

[1] If the reported 90% confidence interval is entirely contained within the interval criterion of (0.xxx, 1.xxx), then dose proportionality is supported across the investigated dose range, for the particular dosing regimen.

Figure 14.2.1.2.3.2 Estimated Pharmacokinetic Parameters (Power Model) – SAD (Pharmacokinetic Parameters Population)

Plot of estimated PK parameters against dose level

Figure Description: PK parameters, as estimated from the power model, will be plotted against dose (mg). The figure will include individual subject values and the means(±SD) for each dose level. The figure will display on a single page values for all dose levels, and all individual subjects.

For each figure, the X axis will be the dose level. The Y axis will be the PK parameter, in units.

The X axis title: Dose (mg)
The Y axis title: PK Parameter (unit)

Figure 14.2.1.2.3.3 Estimated Pharmacokinetic Parameters (Power Model) – SAD (Pharmacokinetic Parameters Population)

Plot of estimated PK parameters against dose level

Figure Description: PK parameters, as estimated from the power model, will be plotted against dose (mg). The figure will include individual subject values and the means(±SD) for each dose level. The figure will display on a single page values for all dose levels, and all individual subjects.

For each figure, the X axis will be the dose level. The Y axis will be the PK parameter, in units.

The X axis title: Dose (mg)
The Y axis title: PK Parameter (unit)

Table 14.3.1.1.2 Treatment Emergent Adverse Events Overall Summary – SAD (Safety Population)

	All Placebo (N=xxx) S(%)E	LSALT 1.0 mg (N=xxx) S(%)E	etc. (N=xxx) S(%)E
At Least One TEAE	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
At Least One Severe or Life-threatening TEAE	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
At Least One Study Drug-related[1] TEAE	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
At Least One Serious TEAE	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
At Least One Serious Study Drug-related[1] TEAE	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Discontinuation Due to TEAE	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Death	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx

S = Subjects, E = Events.

TEAE = Treatment Emergent Adverse Event.

[1] Drug-related is defined as Missing, Possibly, Probably or Related.

Table 14.3.1.1.3 Treatment Emergent Adverse Events Overall Summary - MAD (Safety Population)

	All Placebo (N=xxx) S(%)E	LSALT XX mg (N=xxx) S(%)E	etc. (N=xxx) S(%)E
At Least One TEAE	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
At Least One Severe or Life-threatening TEAE	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
At Least One Study Drug-related[1] TEAE	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
At Least One Serious TEAE	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
At Least One Serious Study Drug-related[1] TEAE	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Discontinuation Due to TEAE	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Death	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx

S = Subjects, E = Events.

TEAE = Treatment Emergent Adverse Event.

[1] Drug-related is defined as Missing, Possibly, Probably or Related.

Table 14.3.1.2.2 Treatment Emergent Adverse Events – SAD (Safety Population)

System Organ Class Preferred Term	All Placebo (N=xxx) S (%) E	LSALT 1.0 mg (N=xxx) S (%) E	etc. (N=xxx) S (%) E
Subjects with at Least One TEAE	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
System Organ Class 1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Preferred Term 1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Preferred Term 2	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
System Organ Class 2	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Preferred Term 1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Preferred Term 2	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
etc.			

S = Subjects, E = Events.

TEAE = Treatment Emergent Adverse Event.

Note: Subjects are counted once if the same event occurred more than one time.
Note: This table presents the number of subjects with an event, the percentage of total subjects with an event and the number of events. Percentages are based on the total number of treated subjects.
Note: Adverse events coded according to MedDRA Version XX.

Table 14.3.1.2.3 Treatment Emergent Adverse Events – MAD (Safety Population)

System Organ Class Preferred Term	All Placebo (N=xxx) S (%) E	LSALT XX mg (N=xxx) S (%) E	etc. (N=xxx) S (%) E
Subjects with at least one TEAE	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
System Organ Class 1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Preferred Term 1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Preferred Term 2	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
System Organ Class 2	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Preferred Term 1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Preferred Term 2	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
etc.			

S = Subjects, E = Events.

TEAE = Treatment Emergent Adverse Event.

Note: Subjects are counted once if the same event occurred more than one time.
Note: This table presents the number of subjects with an event, the percentage of total subjects with an event and the number of events. Percentages are based on the total number of treated subjects.

Note: Adverse events coded according to MedDRA Version XX.

Table 14.3.1.3.2 Treatment Emergent Adverse Events by Severity – SAD (Safety Population)

System Organ Class Preferred Term Severity	All Placebo (N=xxx) S (%) E	LSALT 1.0 mg (N=xxx) S (%) E	etc. (N=xxx) S (%) E
Subjects with at Least One TEAE	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Mild	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Moderate	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Severe	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Life-threatening consequences	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Missing	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
System Organ Class 1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Preferred Term 1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Mild	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Moderate	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Severe	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Life-threatening consequences	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Missing	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
etc.			

S = Subjects, E = Events.

TEAE = Treatment Emergent Adverse Event.

Note: Subjects are counted once if the same event occurred more than one time.

Note: This table presents the number of subjects with an event, the percentage of total subjects with an event and the number of events. Percentages are based on the total number of treated subjects.
Note: Adverse events coded according to MedDRA Version XX.

Table 14.3.1.3.3 Treatment Emergent Adverse Events by Severity – MAD (Safety Population)

System Organ Class Preferred Term Severity	All Placebo (N=xxx) S (%) E	LSALT XX mg (N=xxx) S (%) E	etc. (N=xxx) S (%) E
Subjects with at Least One TEAE	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Mild	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Moderate	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Severe	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Life-threatening consequences	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Missing	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
System Organ Class 1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Preferred Term 1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Mild	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Moderate	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Severe	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Life-threatening consequences	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Missing	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
etc.			

S = Subjects, E = Events.

TEAE = Treatment Emergent Adverse Event.

Note: Subjects are counted once if the same event occurred more than one time.

Note: This table presents the number of subjects with an event, the percentage of total subjects with an event and the number of events. Percentages are based on the total number of treated subjects.
Note: Adverse events coded according to MedDRA Version XX.

Table 14.3.1.4.2 Treatment Emergent Adverse Events by Relationship to Study Drug – SAD (Safety Population)

System Organ Class Preferred Term Relationship to Study Drug	All Placebo (N=xxx) S (%) E	LSALT 1.0 mg (N=xxx) S (%) E	etc. (N=xxx) S (%) E
Subjects with at Least One TEAE	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Unrelated	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Unlikely Related	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Possibly Related	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Probably Related	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Related	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Missing	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
System Organ Class 1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Preferred Term 1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Unrelated	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Unlikely Related	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Possibly Related	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Probably Related	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Related	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Missing	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
etc.			

S = Subjects, E = Events.

TEAE = Treatment Emergent Adverse Event.

Note: Subjects are counted once if the same event occurred more than one time.

Note: This table presents the number of subjects with an event, the percentage of total subjects with an event and the number of events. Percentages are based on the total number of treated subjects.
Note: Adverse events coded according to MedDRA Version XX.

Table 14.3.1.4.3 Treatment Emergent Adverse Events by Relationship to Study Drug – MAD (Safety Population)

System Organ Class Preferred Term Relationship to Study Drug	All Placebo (N=xxx) S (%) E	LSALT XX mg (N=xxx) S (%) E	etc. (N=xxx) S (%) E
Subjects with at Least One TEAE	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Unrelated	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Unlikely Related	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Possibly Related	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Probably Related	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Related	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Missing	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
System Organ Class 1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Preferred Term 1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Unrelated	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Unlikely Related	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Possibly Related	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Probably Related	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Related	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Missing	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
etc.			

S = Subjects, E = Events.

TEAE = Treatment Emergent Adverse Event.

Note: Subjects are counted once if the same event occurred more than one time.

Note: This table presents the number of subjects with an event, the percentage of total subjects with an event and the number of events. Percentages are based on the total number of treated subjects.
Note: Adverse events coded according to MedDRA Version XX.

Table 14.3.1.5.2 Serious Treatment Emergent Adverse Events – SAD (Safety Population)

System Organ Class Preferred Term	All Placebo (N=xxx) S (%) E	LSALT 1.0 mg (N=xxx) S (%) E	etc. (N=xxx) S (%) E
Subjects with at Least One Serious TEAE	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
System Organ Class 1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Preferred Term 1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Preferred Term 2	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
System Organ Class 2	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Preferred Term 1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Preferred Term 2	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
etc.			

S = Subjects, E = Events.

TEAE = Treatment Emergent Adverse Event.

Note: Subjects are counted once if the same event occurred more than one time.
Note: This table presents the number of subjects with an event, the percentage of total subjects with an event and the number of events. Percentages are based on the total number of treated subjects.
Note: Adverse events coded according to MedDRA Version XX.

Table 14.3.1.5.3 Serious Treatment Emergent Adverse Events – MAD (Safety Population)

System Organ Class Preferred Term	All Placebo (N=xxx) S (%) E	LSALT XX mg (N=xxx) S (%) E	etc. (N=xxx) S (%) E
Subjects with at Least One Serious TEAE	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
System Organ Class 1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Preferred Term 1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Preferred Term 2	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
System Organ Class 2	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Preferred Term 1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Preferred Term 2	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
etc.			

S = Subjects, E = Events.

TEAE = Treatment Emergent Adverse Event.

Note: Subjects are counted once if the same event occurred more than one time.
Note: This table presents the number of subjects with an event, the percentage of total subjects with an event and the number of events. Percentages are based on the total number of treated subjects.
Note: Adverse events coded according to MedDRA Version XX.

Table 14.3.4.1.1.2 Hematology – SAD (Safety Population)

Parameter (unit) Visit	All Placebo (N=xxx)	etc. (N=xxx)
Hemoglobin (g/L)		
Baseline[1]		
Actual Value		
n	xx	xx
Mean (SD)	xx.xx (xx.xxx)	xx.xx (xx.xxx)
Median	xx.xx	xx.xx
Min, Max	xx.x, xx.x	xx.x, xx.x

[1] Baseline is defined as the last available, non-missing assessment on or prior to first study drug administration.

Table 14.3.4.1.1.2 Hematology – SAD (Safety Population)

Parameter (unit) Visit	All Placebo (N=xxx)	etc. (N=xxx)
Hemoglobin (g/L)		
Day XX		
Actual Value		
n	xx	xx
Mean (SD)	xx.xx (xx.xxx)	xx.xx (xx.xxx)
Median	xx.xx	xx.xx
Min, Max	xx.x, xx.x	xx.x, xx.x
Actual Change from Baseline[1]		
n	xx	xx
Mean (SD)	xx.xx (xx.xxx)	xx.xx (xx.xxx)
Median	xx.xx	xx.xx
Min, Max	xx.x, xx.x	xx.x, xx.x
etc.		

[1] Baseline is defined as the last available, non-missing assessment on or prior to first study drug administration.

Programming Note: Continue for all protocol scheduled visits and all hematology parameters.

Table 14.3.4.1.1.3 Hematology – MAD (Safety Population)

Parameter (unit) Visit	All Placebo (N=xxx)	etc. (N=xxx)
Hemoglobin (g/L)		
Baseline[1]		
Actual Value		
n	xx	xx
Mean (SD)	xx.xx (xx.xxx)	xx.xx (xx.xxx)
Median	xx.xx	xx.xx
Min, Max	xx.x, xx.x	xx.x, xx.x

[1] Baseline is defined as the last available, non-missing assessment on or prior to first study drug administration.

Table 14.3.4.1.1.3 Hematology – MAD (Safety Population)

Parameter (unit) Visit	All Placebo (N=xxx)	etc. (N=xxx)
Hemoglobin (g/L)		
Day XX		
Actual Value		
n	xx	xx
Mean (SD)	xx.xx (xx.xxx)	xx.xx (xx.xxx)
Median	xx.xx	xx.xx
Min, Max	xx.x, xx.x	xx.x, xx.x
Actual Change from Baseline[1]		
n	xx	xx
Mean (SD)	xx.xx (xx.xxx)	xx.xx (xx.xxx)
Median	xx.xx	xx.xx
Min, Max	xx.x, xx.x	xx.x, xx.x
etc.		

[1] Baseline is defined as the last available, non-missing assessment on or prior to first study drug administration.

Programming Note: Continue for all protocol scheduled visits and all hematology parameters.

Table 14.3.4.1.2.2 Hematology Shifts From Baseline – SAD (Safety Population)

Treatment Group: All Placebo (N=xxx)

Parameter (unit)	Visit	Baseline[1]	Post Baseline[1]			
			Normal	Abnormal NCS	Abnormal CS	Missing
Hemoglobin (g/L)	Day XX	Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		Abnormal NCS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		Abnormal CS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		Missing	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Day XX	Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		Abnormal NCS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		Abnormal CS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		Missing	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

etc.

[1] Baseline is defined as the last available, non-missing assessment on or prior to first study drug administration.
NCS = Not Clinically Signifcant, CS = Clinically Significant.

Programming Note: Continue for all protocol scheduled visits/time points and all hematology parameters.

Table 14.3.4.1.2.3 Hematology Shifts From Baseline – MAD (Safety Population)

Treatment Group: All Placebo (N=xxx)

Parameter (unit)	Visit	Baseline[1]	Post Baseline[1]			
			Normal	Abnormal NCS	Abnormal CS	Missing
Hemoglobin (g/L)	Day XX	Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		Abnormal NCS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		Abnormal CS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		Missing	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Day XX	Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		Abnormal NCS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		Abnormal CS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		Missing	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

etc.

[1] Baseline is defined as the last available, non-missing assessment on or prior to first study drug administration.
NCS = Not Clinically Signifcant, CS = Clinically Significant.

Programming Note: Continue for all protocol scheduled visits/time points and all hematology parameters.

Table 14.3.4.1.3.2 Chemistry - SAD (Safety Population)

Parameter (unit) Visit	All Placebo (N=xxx)	etc. (N=xxx)
Albumin (g/L)		
Baseline[1]		
Actual Value		
n	xx	xx
Mean (SD)	xx.xx (xx.xxx)	xx.xx (xx.xxx)
Median	xx.xx	xx.xx
Min, Max	xx.x, xx.x	xx.x, xx.x

[1] Baseline is defined as the last available, non-missing assessment on or prior to first study drug administration.

Table 14.3.4.1.3.2 Chemistry – SAD (Safety Population)

Parameter (unit) Visit	All Placebo (N=xxx)	etc. (N=xxx)
Albumin (g/L)		
Day XX		
Actual Value		
n	xx	xx
Mean (SD)	xx.xx (xx.xxx)	xx.xx (xx.xxx)
Median	xx.xx	xx.xx
Min, Max	xx.x, xx.x	xx.x, xx.x
Actual Change from Baseline[1]		
n	xx	xx
Mean (SD)	xx.xx (xx.xxx)	xx.xx (xx.xxx)
Median	xx.xx	xx.xx
Min, Max	xx.x, xx.x	xx.x, xx.x
etc.		

[1] Baseline is defined as the last available, non-missing assessment on or prior to first study drug administration.

Programming Note: Continue for all protocol scheduled visits and all chemistry parameters.

Table 14.3.4.1.3.3 Chemistry - MAD (Safety Population)

Parameter (unit) Visit	All Placebo (N=xxx)	etc. (N=xxx)
Albumin (g/L)		
Baseline[1]		
Actual Value		
n	xx	xx
Mean (SD)	xx.xx (xx.xxx)	xx.xx (xx.xxx)
Median	xx.xx	xx.xx
Min, Max	xx.x, xx.x	xx.x, xx.x

[1] Baseline is defined as the last available, non-missing assessment on or prior to first study drug administration.

Table 14.3.4.1.3.3 Chemistry – MAD (Safety Population)

Parameter (unit) Visit	All Placebo (N=xxx)	etc. (N=xxx)
Albumin (g/L)		
Day XX		
Actual Value		
n	xx	xx
Mean (SD)	xx.xx (xx.xxx)	xx.xx (xx.xxx)
Median	xx.xx	xx.xx
Min, Max	xx.x, xx.x	xx.x, xx.x
Actual Change from Baseline[1]		
n	xx	xx
Mean (SD)	xx.xx (xx.xxx)	xx.xx (xx.xxx)
Median	xx.xx	xx.xx
Min, Max	xx.x, xx.x	xx.x, xx.x
etc.		

[1] Baseline is defined as the last available, non-missing assessment on or prior to first study drug administration.

Programming Note: Continue for all protocol scheduled visits and all chemistry parameters.

Table 14.3.4.1.4.2 Chemistry Shifts From Baseline – SAD (Safety Population)

Treatment Group: All Placebo (N=xxx)

Parameter (unit)	Visit	Baseline[1]	Post Baseline[1]			
			Normal	Abnormal NCS	Abnormal CS	Missing
Albumin (g/L)	Day XX	Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		Abnormal NCS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		Abnormal CS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		Missing	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Day XX	Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		Abnormal NCS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		Abnormal CS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		Missing	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

etc.

[1] Baseline is defined as the last available, non-missing assessment on or prior to first study drug administration.
NCS = Not Clinically Signifcant, CS = Clinically Significant.

Programming Note: Continue for all protocol scheduled visits/time points and all chemistry parameters.

Table 14.3.4.1.4.3 Chemistry Shifts From Baseline – MAD (Safety Population)

Treatment Group: All Placebo (N=xxx)

Parameter (unit)	Visit	Baseline[1]	Post Baseline[1]			
			Normal	Abnormal NCS	Abnormal CS	Missing
Albumin (g/L)	Day XX	Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		Abnormal NCS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		Abnormal CS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		Missing	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Day XX	Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		Abnormal NCS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		Abnormal CS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		Missing	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

etc.

[1] Baseline is defined as the last available, non-missing assessment on or prior to first study drug administration.
NCS = Not Clinically Signifcant, CS = Clinically Significant.

Programming Note: Continue for all protocol scheduled visits/time points and all chemistry parameters.

Table 14.3.4.1.3.2 Coagulation – SAD (Safety Population)

Parameter (unit) Visit	All Placebo (N=xxx)	etc. (N=xxx)
INR (unit)		
Baseline[1]		
Actual Value		
n	xx	xx
Mean (SD)	xx.xx (xx.xxx)	xx.xx (xx.xxx)
Median	xx.xx	xx.xx
Min, Max	xx.x, xx.x	xx.x, xx.x

[1] Baseline is defined as the last available, non-missing assessment on or prior to first study drug administration.

Table 14.3.4.1.5.2 Coagulation – SAD (Safety Population)

Parameter (unit) Visit	All Placebo (N=xxx)	etc. (N=xxx)
INR (unit)		
Day XX		
Actual Value		
n	xx	xx
Mean (SD)	xx.xx (xx.xxx)	xx.xx (xx.xxx)
Median	xx.xx	xx.xx
Min, Max	xx.x, xx.x	xx.x, xx.x
Actual Change from Baseline[1]		
n	xx	xx
Mean (SD)	xx.xx (xx.xxx)	xx.xx (xx.xxx)
Median	xx.xx	xx.xx
Min, Max	xx.x, xx.x	xx.x, xx.x
etc.		

[1] Baseline is defined as the last available, non-missing assessment on or prior to first study drug administration.

Programming Note: Continue for all protocol scheduled visits and all chemistry parameters.

Table 14.3.4.1.5.3 Coagulation – MAD (Safety Population)

Parameter (unit) Visit	All Placebo (N=xxx)	etc. (N=xxx)
INR (unit)		
Baseline[1]		
Actual Value		
n	xx	xx
Mean (SD)	xx.xx (xx.xxx)	xx.xx (xx.xxx)
Median	xx.xx	xx.xx
Min, Max	xx.x, xx.x	xx.x, xx.x

[1] Baseline is defined as the last available, non-missing assessment on or prior to first study drug administration.

Table 14.3.4.1.5.3 Coagulation - MAD (Safety Population)

Parameter (unit) Visit	All Placebo (N=xxx)	etc. (N=xxx)
INR (unit)		
Day XX		
Actual Value		
n	xx	xx
Mean (SD)	xx.xx (xx.xxx)	xx.xx (xx.xxx)
Median	xx.xx	xx.xx
Min, Max	xx.x, xx.x	xx.x, xx.x
Actual Change from Baseline[1]		
n	xx	xx
Mean (SD)	xx.xx (xx.xxx)	xx.xx (xx.xxx)
Median	xx.xx	xx.xx
Min, Max	xx.x, xx.x	xx.x, xx.x
etc.		

[1] Baseline is defined as the last available, non-missing assessment on or prior to first study drug administration.

Programming Note: Continue for all protocol scheduled visits and all chemistry parameters.

Table 14.3.4.1.6.2 Coagulation Shifts From Baseline – SAD (Safety Population)

Treatment Group: All Placebo (N=xxx)

Parameter (unit)	Visit	Baseline[1]	Post Baseline[1]			
			Normal	Abnormal NCS	Abnormal CS	Missing
INR (unit)	Day XX	Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		Abnormal NCS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		Abnormal CS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		Missing	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Day XX	Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		Abnormal NCS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		Abnormal CS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		Missing	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
etc.						

[1] Baseline is defined as the last available, non-missing assessment on or prior to first study drug administration.
NCS = Not Clinically Signifcant, CS = Clinically Significant.

Programming Note: Continue for all protocol scheduled visits/time points and all chemistry parameters.

Table 14.3.4.1.6.3 Coagulation Shifts From Baseline – MAD (Safety Population)

Treatment Group: All Placebo (N=xxx)

Parameter (unit)	Visit	Baseline[1]	Post Baseline[1]			
			Normal	Abnormal NCS	Abnormal CS	Missing
INR (unit)	Day XX	Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		Abnormal NCS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		Abnormal CS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		Missing	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Day XX	Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		Abnormal NCS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		Abnormal CS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		Missing	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

etc.

[1] Baseline is defined as the last available, non-missing assessment on or prior to first study drug administration.
NCS = Not Clinically Signifcant, CS = Clinically Significant.

Programming Note: Continue for all protocol scheduled visits/time points and all chemistry parameters.

Table 14.3.4.1.7.2 Urinalysis Results Evaluation – SAD (Safety Population)

Parameter (unit)	Visit	Result	All Placebo (N=xxx)	etc. (N=xxx)
Glucose (mmol/L)	Baseline[1]	Positive	xx (xx.x%)	xx (xx.x%)
		Negative	xx (xx.x%)	xx (xx.x%)
	Day XX	Positive	xx (xx.x%)	xx (xx.x%)
		Negative	xx (xx.x%)	xx (xx.x%)
etc.				

[1] Baseline is defined as the last available, non-missing assessment prior to first study drug administration.

Programming Note: Continue for all protocol scheduled visits and all urinalysis parameters.

Table 14.3.4.1.7.3 Urinalysis Results Evaluation – MAD (Safety Population)

Parameter (unit)	Visit	Result	All Placebo (N=xxx)	etc. (N=xxx)
Glucose (mmol/L)	Baseline[1]	Positive	xx (xx.x%)	xx (xx.x%)
		Negative	xx (xx.x%)	xx (xx.x%)
	Day XX	Positive	xx (xx.x%)	xx (xx.x%)
		Negative	xx (xx.x%)	xx (xx.x%)
etc.				

[1] Baseline is defined as the last available, non-missing assessment prior to first study drug administration.

Programming Note: Continue for all protocol scheduled visits and all urinalysis parameters.

Table 14.3.4.2.1.2 Vital Signs – SAD (Safety Population)

Parameter (unit) Visit Scheduled Timepoint	All Placebo (N=xxx)	etc. (N=xxx)
Pulse Rate (beats/min)		
Baseline[1]		
Actual Value		
n	xx	xx
Mean (SD)	xx.xx (xx.xxx)	xx.xx (xx.xxx)
Median	xx.xx	xx.xx
Min, Max	xx.x, xx.x	xx.x, xx.x

[1] Baseline is defined as the last available, non-missing assessment on or prior to first study drug administration.

Table 14.3.4.2.1.2 Vital Signs – SAD (Safety Population)

Parameter (unit) Visit Scheduled Timepoint	All Placebo (N=xxx)	etc. (N=xxx)
Pulse Rate (beats/min)		
Day XX		
XX hours postdose		
Actual Value		
n	xx	xx
Mean (SD)	xx.xx (xx.xxx)	xx.xx (xx.xxx)
Median	xx.xx	xx.xx
Min, Max	xx.x, xx.x	xx.x, xx.x
Actual Change from Baseline[1]		
n	xx	xx
Mean (SD)	xx.xx (xx.xxx)	xx.xx (xx.xxx)
Median	xx.xx	xx.xx
Min, Max	xx.x, xx.x	xx.x, xx.x
etc.		

[1] Baseline is defined as the last available, non-missing assessment on or prior to first study drug administration.

Programming Note: Continue for all scheduled visits/timepoints and all vital signs parameters.

Table 14.3.4.2.1.3 Vital Signs – MAD (Safety Population)

Parameter (unit) Visit Scheduled Timepoint	All Placebo (N=xxx)	etc. (N=xxx)
Pulse Rate (beats/min)		
Baseline[1]		
Actual Value		
n	xx	xx
Mean (SD)	xx.xx (xx.xxx)	xx.xx (xx.xxx)
Median	xx.xx	xx.xx
Min, Max	xx.x, xx.x	xx.x, xx.x

[1] Baseline is defined as the last available, non-missing assessment on or prior to first study drug administration.

Table 14.3.4.2.1.3 Vital Signs – MAD (Safety Population)

Parameter (unit) Visit Scheduled Timepoint	All Placebo (N=xxx)	etc. (N=xxx)
Pulse Rate (beats/min)		
Day XX		
XX hours postdose		
Actual Value		
n	xx	xx
Mean (SD)	xx.xx (xx.xxx)	xx.xx (xx.xxx)
Median	xx.xx	xx.xx
Min, Max	xx.x, xx.x	xx.x, xx.x
Actual Change from Baseline[1]		
n	xx	xx
Mean (SD)	xx.xx (xx.xxx)	xx.xx (xx.xxx)
Median	xx.xx	xx.xx
Min, Max	xx.x, xx.x	xx.x, xx.x
etc.		

[1] Baseline is defined as the last available, non-missing assessment on or prior to first study drug administration.

Programming Note: Continue for all scheduled visits/timepoints and all vital signs parameters.

Table 14.3.4.2.2.2 Vital Signs Shifts from Baseline – SAD (Safety Population)

Treatment Group: All Placebo

Parameter (unit)	Visit	Scheduled Timepoint	Baseline[1]	Post Baseline[1] Normal	Abnormal NCS	Abnormal CS	Missing
Pulse Rate (beats/min)	Day XX	XX hours postdose	Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
			Abnormal NCS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
			Abnormal CS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
			Missing	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		XX hours postdose	Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
			Abnormal NCS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
			Abnormal CS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
			Missing	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[1] Baseline is defined as the last available, non-missing assessment on or prior to first study drug administration.
NCS=Not Clinically Significant, CS=Clinically Significant.

Programming Note: Continue for all protocol scheduled visits/timepoints, readings and all groups.

Table 14.3.4.2.2.3 Vital Signs Shifts from Baseline – MAD (Safety Population)

Treatment Group: All Placebo

Parameter (unit)	Visit	Scheduled Timepoint	Baseline[1]	Post Baseline[1] Normal	Abnormal NCS	Abnormal CS	Missing
Pulse Rate (beats/min)	Day XX	XX hours postdose	Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
			Abnormal NCS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
			Abnormal CS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
			Missing	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		XX hours postdose	Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
			Abnormal NCS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
			Abnormal CS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
			Missing	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[1] Baseline is defined as the last available, non-missing assessment on or prior to first study drug administration.
NCS=Not Clinically Significant, CS=Clinically Significant.

Programming Note: Continue for all protocol scheduled visits/timepoints, readings and all groups.

Table 14.3.4.3.1.2 12-Lead Electrocardiogram – SAD (Safety Population)

Parameter (unit) Visit Scheduled Timepoint	All Placebo (N=xxx)	etc. (N=xxx)
RR Interval (msec)		
Baseline[1]		
Actual Value		
n	xx	xx
Mean (SD)	xx.xx (xx.xxx)	xx.xx (xx.xxx)
Median	xx.xx	xx.xx
Min, Max	xx.x, xx.x	xx.x, xx.x

[1] Baseline is defined as the last available, non-missing assessment on or prior to first study drug administration.

Table 14.3.4.3.1.2 12-Lead Electrocardiogram – SAD (Safety Population)

Parameter (unit) Visit Scheduled Timepoint	All Placebo (N=xxx)	etc. (N=xxx)
RR Interval (msec)		
Day XX		
XX Hours Postdose		
Actual Value		
n	xx	xx
Mean (SD)	xx.xx (xx.xxx)	xx.xx (xx.xxx)
Median	xx.xx	xx.xx
Min, Max	xx.x, xx.x	xx.x, xx.x
Actual Change from Baseline[1]		
n	xx	xx
Mean (SD)	xx.xx (xx.xxx)	xx.xx (xx.xxx)
Median	xx.xx	xx.xx
Min, Max	xx.x, xx.x	xx.x, xx.x
etc.		

[1] Baseline is defined as the last available, non-missing assessment on or prior to first study drug administration.

Programming Note: Continue for all scheduled visits/timepoints, readings and all ECG parameters.

Table 14.3.4.3.1.3 12-Lead Electrocardiogram – MAD (Safety Population)

Parameter (unit) Visit Scheduled Timepoint	All Placebo (N=xxx)	etc. (N=xxx)
RR Interval (msec)		
Baseline[1]		
Actual Value		
n	xx	xx
Mean (SD)	xx.xx (xx.xxx)	xx.xx (xx.xxx)
Median	xx.xx	xx.xx
Min, Max	xx.x, xx.x	xx.x, xx.x

[1] Baseline is defined as the last available, non-missing assessment on or prior to first study drug administration.

Table 14.3.4.3.1.3 12-Lead Electrocardiogram – MAD (Safety Population)

Parameter (unit) Visit Scheduled Timepoint	All Placebo (N=xxx)	etc. (N=xxx)
RR Interval (msec)		
Day XX		
XX Hours Postdose		
Actual Value		
n	xx	xx
Mean (SD)	xx.xx (xx.xxx)	xx.xx (xx.xxx)
Median	xx.xx	xx.xx
Min, Max	xx.x, xx.x	xx.x, xx.x
Actual Change from Baseline[1]		
n	xx	xx
Mean (SD)	xx.xx (xx.xxx)	xx.xx (xx.xxx)
Median	xx.xx	xx.xx
Min, Max	xx.x, xx.x	xx.x, xx.x
etc.		

[1] Baseline is defined as the last available, non-missing assessment on or prior to first study drug administration.

Programming Note: Continue for all scheduled visits/timepoints, readings and all ECG parameters.

Table 14.3.4.3.2.2 12-Lead Electrocardiogram Shifts from Baseline – SAD (Safety Population)

Treatment Group: All Placebo

Parameter (unit)	Visit	Scheduled Timepoint	Baseline[1]	Post Baseline[1] Normal	Abnormal NCS	Abnormal CS	Missing
RR Interval (msec)	Day XX	XX hours postdose	Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
			Abnormal NCS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
			Abnormal CS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
			Missing	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		XX hours postdose	Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
			Abnormal NCS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
			Abnormal CS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
			Missing	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[1] Baseline is defined as the last available, non-missing assessment on or prior to first study drug administration.
NCS=Not Clinically Significant, CS=Clinically Significant.

Programming Note: Continue for all protocol scheduled visits/timepoints, readings and all groups.

Table 14.3.4.3.2.3 12-Lead Electrocardiogram Shifts from Baseline – MAD (Safety Population)

Treatment Group: All Placebo

Parameter (unit)	Visit	Scheduled Timepoint	Baseline[1]	Post Baseline[1] Normal	Abnormal NCS	Abnormal CS	Missing
RR Interval (msec)	Day XX	XX hours postdose	Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
			Abnormal NCS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
			Abnormal CS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
			Missing	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		XX hours postdose	Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
			Abnormal NCS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
			Abnormal CS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
			Missing	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[1] Baseline is defined as the last available, non-missing assessment on or prior to first study drug administration.
NCS=Not Clinically Significant, CS=Clinically Significant.

Programming Note: Continue for all protocol scheduled visits/timepoints, readings and all groups.

Table 14.3.4.4.1.3 Anti-Drug Antibodies – MAD (Safety Population)

Parameter (unit)	Visit	Result	All Placebo (N=xxx)	etc. (N=xxx)
ADA	Day 14	Positive	xx (xx.x%)	xx (xx.x%)
		Negative	xx (xx.x%)	xx (xx.x%)
etc.				

Listing 16.2.1.1.1 Subject Enrollment – Low Dose (Intent-to-Treat Population)

Treatment Group: LSALT 0.01 mg

Subject Number	Date of Informed Consent	Informed Consent Version	Protocol Version	Date/ Time of Study Drug Administration	Included in Intent-to-Treat Population	Included in Safety Population	Included in Pharmacokinetic Concentration Population	Included in Pharmacokinetic Parameters Population
xxxxx	DDMONYYYY	x	x	DDMONYYYY/ HH:MM	Yes	Yes	Yes	Yes
xxxxx	DDMONYYYY	x	x	DDMONYYYY/ HH:MM	Yes	Yes	Yes	Yes
etc.								

Listing 16.2.1.1.2 Subject Enrollment – SAD (Intent-to-Treat Population)

Cohort/Treatment Group: Cohort 1/Placebo

Subject Number	Date of Informed Consent	Informed Consent Version	Protocol Version	Date/ Time of Study Drug Administration	Included in Intent-to-Treat Population	Included in Safety Population	Included in Pharmacokinetic Concentration Population	Included in Pharmacokinetic Parameters Population
xxxxx	DDMONYYYY	x	x	DDMONYYYY/ HH:MM	Yes	Yes	Yes	Yes
xxxxx	DDMONYYYY	x	x	DDMONYYYY/ HH:MM	Yes	Yes	Yes	Yes
etc.								

Listing 16.2.1.1.3 Subject Enrollment – MAD (Intent-to-Treat Population)

Cohort/Treatment Group: Cohort 4/Placebo

Subject Number	Date of Informed Consent	Informed Consent Version	Protocol Version	Date/ Time of First Study Drug Administration	Included in Intent-to-Treat Population	Included in Safety Population	Included in Pharmacokinetic Concentration Population	Included in Pharmacokinetic Parameters Population
xxxxx	DDMONYYYY	x	x	DDMONYYYY/ HH:MM	Yes	Yes	Yes	Yes
xxxxx	DDMONYYYY	x	x	DDMONYYYY/ HH:MM	Yes	Yes	Yes	Yes
etc.								

Listing 16.2.1.2.1 Subject Disposition – Low Dose (Intent-to-Treat Population)

Treatment Group: LSALT 0.01 mg

Subject Number	Subject Completed the Study per Protocol	Date of Completion or Early Discontinuation	Primary Reason for Early Discontinuation/ If AE, Number
xxxxx	No	DDMONYYYY	Withdrawal of Consent

Listing 16.2.1.2.2 Subject Disposition - SAD (Intent-to-Treat Population)

Cohort/Treatment Group: Cohort 1/Placebo

Subject Number	Subject Completed the Study per Protocol	Date of Completion or Early Discontinuation	Primary Reason for Early Discontinuation/ If AE, Number
xxxxx	No	DDMONYYYY	Withdrawal of Consent
xxxxx	Yes	DDMONYYYY	
xxxxx	No	DDMONYYYY	Other - xxxxxxxxxxxxxxxxxxxxxxxxxxxxx
etc.			

Listing 16.2.1.2.3 Subject Disposition – MAD (Intent-to-Treat Population)

Cohort/Treatment Group: Cohort 4/Placebo

Subject Number	Subject Completed the Study per Protocol	Date of Completion or Early Discontinuation	Primary Reason for Early Discontinuation/ If AE, Number
xxxxx	No	DDMONYYYY	Withdrawal of Consent
xxxxx	Yes	DDMONYYYY	
xxxxx	No	DDMONYYYY	Other - xxxxxxxxxxxxxxxxxxxxxxxxxxxx
etc.			

Listing 16.2.2.1 Protocol Deviations – Low Dose (Intent-to-Treat Population)

Treatment Group: LSALT 0.01 mg

Subject Number	Visit	Date of Deviation	Deviation Category	Assessment Type	Protocol Deviation Classification	Deviation Description
xxxxx	Screening	DDMONYYYY	Missed Visit	Medical History	Minor	xxxxxxxxxxxxxxxxx
	Day 1	DDMONYYYY	Other - xxxxxxxxxx	Demographics	Major	xxxxxxxxxxxxxxxxx
	etc.		etc.	etc.	etc.	etc.

Note: The form of this listing may change depending upon the data collected for protocol deviations.

Listing 16.2.2.2 Protocol Deviations – SAD (Intent-to-Treat Population)

Cohort/Treatment Group: Cohort 1/Placebo

Subject Number	Visit	Date of Deviation	Deviation Category	Assessment Type	Protocol Deviation Classification	Deviation Description
xxxxx	Screening	DDMONYYYY	Missed Visit	Medical History	Minor	xxxxxxxxxxxxxxxxx
	Day 1	DDMONYYYY	Other - xxxxxxxxxx	Demographics	Major	xxxxxxxxxxxxxxxxx
	etc.		etc.	etc.	etc.	etc.
etc.						

Note: The form of this listing may change depending upon the data collected for protocol deviations.

Listing 16.2.2.3 Protocol Deviations – MAD (Intent-to-Treat Population)

Cohort/Treatment Group: Cohort 1/Placebo

Subject Number	Visit	Date of Deviation	Deviation Category	Assessment Type	Protocol Deviation Classification	Deviation Description
xxxxx	Screening	DDMONYYYY	Missed Visit	Medical History	Minor	xxxxxxxxxxxxxxxxx
	Day 1	DDMONYYYY	Other - xxxxxxxxxx	Demographics	Major	xxxxxxxxxxxxxxxxx
	etc.		etc.	etc.	etc.	etc.
etc.						

Note: The form of this listing may change depending upon the data collected for protocol deviations.

Lising 16.2.3.1.1 Eligibility Criteria – Low Dose (Intent-to-Treat Population)

Treatment Group: LSALT 0.01 mg

Subject Number	Visit	Subject Met All Eligibility Criteria/ If No, Criteria Not Met	If Eligibilty Not Met, Exemption Granted
xxxxx	Screening	Yes	
	Day -1	No/ Inclusion - 1	No

Lising 16.2.3.1.2 Eligibility Criteria – SAD (Intent-to-Treat Population)

Cohort/Treatment Group: Cohort 1/Placebo

Subject Number	Visit	Subject Met All Eligibility Criteria/ If No, Criteria Not Met	If Eligibilty Not Met, Exemption Granted
xxxxx	Screening	Yes	
	Day -1	No/ Inclusion - 1	No
etc.			

Lising 16.2.3.1.3 Eligibility Criteria – MAD (Intent-to-Treat Population)

Cohort/Treatment Group: Cohort 4/Placebo

Subject Number	Visit	Subject Met All Eligibility Criteria/ If No, Criteria Not Met	If Eligibilty Not Met, Exemption Granted
xxxxx	Screening	Yes	
	Day -1	No/ Inclusion - 1	No
etc.			

Listing 16.2.4.1.1 Demographic Characteristics – Low Dose (Intent-to-Treat Population)

Treatment Group: LSALT 0.01 mg

Subject Number	Date of Informed Consent	Date of Birth	Age (years)[1]	Gender	Child Bearing Potential/ If No, Reason	Race	Ethnicity	Height (cm) at Screening	Weight (kg) at Screening	BMI (kg/m^2)[2] at Screening
xxxxx	DDMONYYYY	DDMONYYYY	xx	Female	Yes	xxxxxxx	xxxxxxx	xx.x	xx.x	xx.x

[1] Age is calculated as integer value ((Date Signed Informed Consent – Date of Birth + 1) / 365.25)
[2] BMI = Body Weight, in kg/((Height, in $m)^2$).

Listing 16.2.4.1.2 Demographic Characteristics – SAD (Intent-to-Treat Population)

Cohort/Treatment Group: Cohort 1/Placebo

Subject Number	Date of Informed Consent	Date of Birth	Age (years)[1]	Gender	Child Bearing Potential/ If No, Reason	Race	Ethnicity	Height (cm) at Screening	Weight (kg) at Screening	BMI (kg/m^2)[2] at Screening
xxxxx	DDMONYYYY	DDMONYYYY	xx	Female	Yes	xxxxxxx	xxxxxxx	xx.x	xx.x	xx.x
xxxxx	DDMONYYYY	DDMONYYYY	xx	Male	N/A	xxxxxxx	xxxxxxx	xx.x	xx.x	xx.x
xxxxx	DDMONYYYY	DDMONYYYY	xx	Female	No	Other - xxxxx	xxxxxxx	xx.x	xx.x	xx.x
etc.										

[1] Age is calculated as integer value ((Date Signed Informed Consent – Date of Birth + 1) / 365.25)
[2] BMI = Body Weight, in kg/((Height, in $m)^2$).

Listing 16.2.4.1.3 Demographic Characteristics – MAD (Intent-to-Treat Population)

Cohort/Treatment Group: Cohort 4/Placebo

Subject Number	Date of Informed Consent	Date of Birth	Age (years)[1]	Gender	Child Bearing Potential/ If No, Reason	Race	Ethnicity	Height (cm) at Screening	Weight (kg) at Screening	BMI (kg/m^2)[2] at Screening
xxxxx	DDMONYYYY	DDMONYYYY	xx	Female	Yes	xxxxxxx	xxxxxxx	xx.x	xx.x	xx.x
xxxxx	DDMONYYYY	DDMONYYYY	xx	Male	N/A	xxxxxxx	xxxxxxx	xx.x	xx.x	xx.x
xxxxx	DDMONYYYY	DDMONYYYY	xx	Female	No	Other - xxxxx	xxxxxxx	xx.x	xx.x	xx.x
etc.										

[1] Age is calculated as integer value ((Date Signed Informed Consent – Date of Birth + 1) / 365.25)
[2] BMI = Body Weight, in kg/((Height, in $m)^2$).

Listing 16.2.4.2.1 Medical History – Low Dose (Intent-to-Treat Population)

Treatment Group: LSALT 0.01 mg

Subject Number	Medical Condition/ Surgery	Onset Date	End Date
xxxxx	xxxxxxxxxx	DDMONYYYY	Ongoing
	xxxxxxxxxx	DDMONYYYY	DDMONYYYY

Note: Medications coded using MedDRA Version X.X.

Listing 16.2.4.2.2 Medical History - SAD (Intent-to-Treat Population)

Cohort/Treatment Group: Cohort 1/Placebo

Subject Number	Medical Condition/ Surgery	Onset Date	End Date
xxxxx	xxxxxxxxxx	DDMONYYYY	Ongoing
	xxxxxxxxxx	DDMONYYYY	DDMONYYYY
xxxxx	xxxxxxxxxx	DDMONYYYY	DDMONYYYY
etc.			

Note: Medications coded using MedDRA Version X.X.

Listing 16.2.4.2.3 Medical History - MAD (Intent-to-Treat Population)

Cohort/Treatment Group: Cohort 4/Placebo

Subject Number	Medical Condition/ Surgery	Onset Date	End Date
xxxxx	xxxxxxxxxx	DDMONYYYY	Ongoing
	xxxxxxxxxx	DDMONYYYY	DDMONYYYY
xxxxx	xxxxxxxxxx	DDMONYYYY	DDMONYYYY
etc.			

Note: Medications coded using MedDRA Version X.X.

Listing 16.2.4.3.1 Alcohol Breath Test – Low Dose (Intent-to-Treat Population)

Treatment Group: LSALT 0.01 mg

Subject Number	Visit	Test Performed/ If No, Reason	Date/ Time of Sample Collection	Result
xxxxx	Screening	Yes	DDMONYYYY/ HH:MM	Negative
	Day -1	No/ xxxxxx		

Listing 16.2.4.3.2 Alcohol Breath Test – SAD (Intent-to-Treat Population)

Cohort/Treatment Group: Cohort 1/Placebo

Subject Number	Visit	Test Performed/ If No, Reason	Date/ Time of Sample Collection	Result
xxxxx	Screening	Yes	DDMONYYYY/ HH:MM	Negative
	Day -1	No/ xxxxxx		
etc.				

Listing 16.2.4.3.3 Alcohol Breath Test – MAD (Intent-to-Treat Population)

Cohort/Treatment Group: Cohort 4/Placebo

Subject Number	Visit	Test Performed/ If No, Reason	Date/ Time of Sample Collection	Result
xxxxx	Screening	Yes	DDMONYYYY/ HH:MM	Negative
	Day -1	No/ xxxxxx		
etc.				

Listing 16.2.4.4.1 Urine Drug Screen – Low Dose (Intent-to-Treat Population)

Treatment Group: LSALT 0.01 mg

Subject Number	Visit	Test Performed	Date/Time of Sample Collection	Result
xxxxx	Screening	Yes	DDMONYYYY/ HH:MM	Negative
	Day -1	Yes	DDMONYYYY/ HH:MM	Positive

Listing 16.2.4.4.2 Urine Drug Screen – SAD (Intent-to-Treat Population)

Cohort/Treatment Group: Cohort 1/Placebo

Subject Number	Visit	Test Performed	Date/Time of Sample Collection	Result
xxxxx	Screening	Yes	DDMONYYYY/ HH:MM	Negative
	Day -1	Yes	DDMONYYYY/ HH:MM	Positive
xxxxx	Screening	No		
	Day -1	Yes	DDMONYYYY/ HH:MM	Negative
etc.				

Listing 16.2.4.4.3 Urine Drug Screen – MAD (Intent-to-Treat Population)

Cohort/Treatment Group: Cohort 4/Placebo

Subject Number	Visit	Test Performed	Date/Time of Sample Collection	Result
xxxxx	Screening	Yes	DDMONYYYY/ HH:MM	Negative
	Day -1	Yes	DDMONYYYY/ HH:MM	Positive
xxxxx	Screening	No		
	Day -1	Yes	DDMONYYYY/ HH:MM	Negative
etc.				

Listing 16.2.4.5.1 Serology - Low Dose (Intent-to-Treat Population)

Treatment Group: LSALT 0.01 mg

Subject Number	Visit	Test	Sample Collected/ If No, Reason	Date/ Time of Sample Collection	Result
xxxxx	Screening	HIV Type 1	Yes	DDMONYYYY/ HH:MM	Negative
		HIV Type 2	Yes	DDMONYYYY/ HH:MM	Negative
		Hepatitis B surface antigen	Yes	DDMONYYYY/ HH:MM	Negative
		Hepatitis C surface antibody	Yes	DDMONYYYY/ HH:MM	Negative

Listing 16.2.4.5.2 Serology – SAD (Intent-to-Treat Population)

Cohort/Treatment Group: Cohort 1/Placebo

Subject Number	Visit	Test	Sample Collected/ If No, Reason	Date/ Time of Sample Collection	Result
xxxxx	Screening	HIV Type 1	Yes	DDMONYYYY/ HH:MM	Negative
		HIV Type 2	Yes	DDMONYYYY/ HH:MM	Negative
		Hepatitis B surface antigen	Yes	DDMONYYYY/ HH:MM	Negative
		Hepatitis C surface antibody	Yes	DDMONYYYY/ HH:MM	Negative
etc.					

Listing 16.2.4.5.3 Serology – MAD (Intent-to-Treat Population)

Cohort/Treatment Group: Cohort 4/Placebo

Subject Number	Visit	Test	Sample Collected/ If No, Reason	Date/ Time of Sample Collection	Result
xxxxx	Screening	HIV Type 1	Yes	DDMONYYYY/ HH:MM	Negative
		HIV Type 2	Yes	DDMONYYYY/ HH:MM	Negative
		Hepatitis B surface antigen	Yes	DDMONYYYY/ HH:MM	Negative
		Hepatitis C surface antibody	Yes	DDMONYYYY/ HH:MM	Negative
etc.					

Listing 16.2.4.6.1 Serum Follicle Stimulating Hormone – Low Dose (Intent-to-Treat Population)

Cohort/Treatment Group: Cohort 1/Placebo

Subject Number	Visit	Sample Collected/ If No, Reason	Date/ Time of Sample Collection	Result
xxxxx	Screening	Yes	DDMONYYYY/ HH:MM	Negative

Listing 16.2.4.6.2 Serum Follicle Stimulating Hormone – SAD (Intent-to-Treat Population)

Cohort/Treatment Group: Cohort 1/Placebo

Subject Number	Visit	Sample Collected/ If No, Reason	Date/ Time of Sample Collection	Result
xxxxx	Screening	Yes	DDMONYYYY/ HH:MM	Negative
etc.				

Listing 16.2.4.6.3 Serum Follicle Stimulating Hormone – MAD (Intent-to-Treat Population)

Cohort/Treatment Group: Cohort 4/Placebo

Subject Number	Visit	Sample Collected/ If No, Reason	Date/ Time of Sample Collection	Result
xxxxx	Screening	Yes	DDMONYYYY/ HH:MM	Negative
etc.				

Listing 16.2.4.7.1 Pregnancy - Low Dose (Intent-to-Treat Population)

Treatment Group: LSALT 0.01 mg

Subject Number	Visit	Panel	Test Performed/ If No, Reason	Date/Time of Sample Collection	Result
xxxxx	Screening	Urine	Yes	DDMONYYYY/ HH:MM	Negative
		Serum	Yes	DDMONYYYY/ HH:MM	Positive
	etc.				

Listing 16.2.4.7.2 Pregnancy – SAD (Intent-to-Treat Population)

Cohort/Treatment Group: Cohort 1/Placebo

Subject Number	Visit	Panel	Test Performed/ If No, Reason	Date/Time of Sample Collection	Result
xxxxx	Screening	Urine	Yes	DDMONYYYY/ HH:MM	Negative
		Serum	Yes	DDMONYYYY/ HH:MM	Positive
	etc.				
etc.					

Listing 16.2.4.7.3 Pregnancy – MAD (Intent-to-Treat Population)

Cohort/Treatment Group: Cohort 4/Placebo

Subject Number	Visit	Panel	Test Performed/ If No, Reason	Date/Time of Sample Collection	Result
xxxxx	Screening	Urine	Yes	DDMONYYYY/ HH:MM	Negative
		Serum	Yes	DDMONYYYY/ HH:MM	Positive
	etc.				
etc.					

Listing 16.2.4.8.1 Prior and Concomitant Medications – Low Dose (Intent-to-Treat Population)

Treatment Group: LSALT 0.01 mg

Subject Number	Date/ Time of Study Drug Administrtation	ATC2 Class/ Preferred Term/ Medication	Indication/ If Adverse Event or Medical History, Specify	Dose/ Unit	Frequency	Route	Start Date/ Study Day	End Date/ Study Day	Prior or Concomitant
xxxxx	DDMONYYYY/ HH:MM	ZZZZZZZZZZZZZZ/ XXXXXXXXXXXXXX/ YYYYYYYYYYYYYY	xxxxxxxxxxxxxx	1000 mg	QD	Oral	DDMONYYYY/ XX	DDMONYYYY/ XX	Prior
		ZZZZZZZZZZZZZZ/ XXXXXXXXXXXXXX/ YYYYYYYYYYYYYY	xxxxxxxxxxxxxxx/ yyyyyyyyyyyyyy	10 mg	BID	Oral	DDMONYYYY/ XX	Ongoing	Concomitant
		ZZZZZZZZZZZZZZ/ XXXXXXXXXXXXXX/ YYYYYYYYYYYYYY	xxxxxxxxxxxxxx	100 mg	QID	Other – xxxxxx	DDMONYYYY/ XX	DDMONYYYY/ XX	Concomitant

Prior and concomitant medications coded using WHO Drug Version X.X.

Concomitant medications are medications taken at least once on or after first study drug administration. Prior medications are medications stopped prior to first study drug administration. Medications stopping on the same day as first study drug administration are considered as concomitant medications.
ATC = Anatomic Therapeutic Chemical, WHO DD = World Health Organization Drug (WHO DD) Version.

Listing 16.2.4.8.2 Prior and Concomitant Medications - SAD (Intent-to-Treat Population)

Cohort/Treatment Group: Cohort 1/Placebo

Subject Number	Date/ Time of Study Drug Administrtation	ATC2 Class/ Preferred Term/ Medication	Indication/ If Adverse Event or Medical History, Specify	Dose/ Unit	Frequency	Route	Start Date/ Study Day	End Date/ Study Day	Prior or Concomitant
xxxxx	DDMONYYYY/ HH:MM	ZZZZZZZZZZZZZZ/ XXXXXXXXXXXXXX/ YYYYYYYYYYYYYY	xxxxxxxxxxxxxx	1000 mg	QD	Oral	DDMONYYYY/ XX	DDMONYYYY/ XX	Prior
		ZZZZZZZZZZZZZZ/ XXXXXXXXXXXXXX/ YYYYYYYYYYYYYY	xxxxxxxxxxxxxx/ yyyyyyyyyyyyyy	10 mg	BID	Oral	DDMONYYYY/ XX	Ongoing	Concomitant
		ZZZZZZZZZZZZZZ/ XXXXXXXXXXXXXX/ YYYYYYYYYYYYYY	xxxxxxxxxxxxxx	100 mg	QID	Other - xxxxxx	DDMONYYYY/ XX	DDMONYYYY/ XX	Concomitant
etc.									

Prior and concomitant medications coded using WHO Drug Version X.X.

Concomitant medications are medications taken at least once on or after first study drug administration. Prior medications are medications stopped prior to first study drug administration. Medications stopping on the same day as first study drug administration are considered as concomitant medications.
ATC = Anatomic Therapeutic Chemical, WHO DD = World Health Organization Drug (WHO DD) Version.

Listing 16.2.4.9.3 Prior and Concomitant Medications - MAD (Intent-to-Treat Population)

Cohort/Treatment Group: Cohort 4/Placebo

Subject Number	Date/ Time of Study Drug Administrtation	ATC2 Class/ Preferred Term/ Medication	Indication/ If Adverse Event or Medical History, Specify	Dose/ Unit	Frequency	Route	Start Date/ Study Day	End Date/ Study Day	Prior or Concomitant
xxxxx	DDMONYYYY/ HH:MM	ZZZZZZZZZZZZZZ/ XXXXXXXXXXXXXX/ YYYYYYYYYYYYYY	xxxxxxxxxxxxxx	1000 mg	QD	Oral	DDMONYYYY/ XX	DDMONYYYY/ XX	Prior
		ZZZZZZZZZZZZZZ/ XXXXXXXXXXXXXX/ YYYYYYYYYYYYYY	xxxxxxxxxxxxxx/ yyyyyyyyyyyyyy	10 mg	BID	Oral	DDMONYYYY/ XX	Ongoing	Concomitant
		ZZZZZZZZZZZZZZ/ XXXXXXXXXXXXXX/ YYYYYYYYYYYYYY	xxxxxxxxxxxxxx	100 mg	QID	Other - xxxxxx	DDMONYYYY/ XX	DDMONYYYY/ XX	Concomitant
etc.									

Prior and concomitant medications coded using WHO Drug Version X.X.

Concomitant medications are medications taken at least once on or after first study drug administration. Prior medications are medications stopped prior to first study drug administration. Medications stopping on the same day as first study drug administration are considered as concomitant medications.
ATC = Anatomic Therapeutic Chemical, WHO DD = World Health Organization Drug (WHO DD) Version.

Listing 16.2.5.1.1 Study Drug Administration – Low Dose (Intent-to-Treat Population)

Treatment Group: LSALT 0.01 mg

Subject Number	Visit	Study Drug Administered/ If No, Reason	Administration Date/ Time	Dose Level (mg)	Volume Prepared (mL)	Total Volum Administered (mL)	Infusion Interrupted/ If Yes, Specify
xxxxx	Day 1	Yes	DDMONYYYY/HH:MM	xx.xx	xxx	xxx	No

Listing 16.2.5.1.2 Study Drug Administration – SAD (Intent-to-Treat Population)

Cohort/Treatment Group: Cohort 1/Placebo

Subject Number	Visit	Study Drug Administered/ If No, Reason	Administration Date/ Time	Dose Level (mg)	Volume Prepared (mL)	Total Volum Administered (mL)	Infusion Interrupted/ If Yes, Specify
xxxxx	Day 1	Yes	DDMONYYYY/HH:MM	xx.xx	xxx	xxx	No
etc.							

Listing 16.2.5.1.3 Study Drug Administration – MAD (Intent-to-Treat Population)

Cohort/Treatment Group: Cohort 4/Placebo

Subject Number	Visit	Study Drug Administered/ If No, Reason	Administration Date/ Time	Dose Level (mg)	Volume Prepared (mL)	Total Volum Administered (mL)	Infusion Interrupted/ If Yes, Specify
xxxxx	Day 1	Yes	DDMONYYYY/HH:MM	xx.xx	xxx	xxx	No
	Day 2	Yes	DDMONYYYY/HH:MM	xx.xx	xxx	xxx	No
	etc.						
etc.							

Listing 16.2.5.2.1 Randomization – Low Dose (Intent-to-Treat Population)

Subject Number	Subject Eligible for Randomization	Randomization Date/ Time	Randomization Number	Treatment Group
xxxxx	Yes	DDMONYYYY/ HH:MM	xxxxx	LSALT 0.01 mg
xxxxx	Yes	DDMONYYYY/ HH:MM	xxxxx	LSALT 0.1 mg
xxxxx	Yes	DDMONYYYY/ HH:MM	xxxxx	LSALT 0.3 mg
xxxxx	Yes	DDMONYYYY/ HH:MM	xxxxx	LSALT 0.5 mg

Listing 16.2.5.2.2 Randomization – SAD (Intent-to-Treat Population)

Subject Number	Subject Eligible for Randomization	Randomization Date/ Time	Randomization Number	Cohort: Treatment Group
xxxxx	Yes	DDMONYYYY/ HH:MM	xxxxx	Cohort 1: Placebo
etc.				

Listing 16.2.5.2.3 Randomization – MAD (Intent-to-Treat Population)

Subject Number	Subject Eligible for Randomization	Randomization Date/ Time	Randomization Number	Cohort: Treatment Group
xxxxx	Yes	DDMONYYYY/ HH:MM	xxxxx	Cohort 4: Placebo
etc.				

Listing 16.2.7.1.1 Adverse Events – Low Dose (Intent-to-Treat Population)

Treatment Group: LSALT 0.01 mg

Subject Number	Date/ Time of Study Drug Administration	System Organ Class/ Preferred Term/ Adverse Event	SAE	Onset Date/ Time/ Study Day	Resolution Date/ Time Study Day	Severity	Relationship to Study Drug	Outcome	Action Taken with Study Drug	Concomitant Medication Administered	TEAE[1]
xxxxx	DDMONYYYY/ HH:MM	XXXXXXXXXXX/ YYYYYYYYYYY/ ZZZZZZZZZZZZZ	No	DDMONYYYY/ HH:MM/ XX	DDMONYYYY/ HH:MM/ XX	Mild	Related	Recovering /Resolving	Study Drug Stopped	No	Yes
		XXXXXXXXXXX/ YYYYYYYYYYY/ ZZZZZZZZZZZZZ	Yes	DDMONYYYY/ HH:MM/ XX	DDMONYYYY/ HH:MM/ XX	Moderate	Unrelated	Unknown	Unkown	Yes	Yes

Adverse Events coded using MedDRA Version X.X.

[1] TEAE = Treatment Emergent Adverse Event.

Listing 16.2.7.1.2 Adverse Events – SAD (Intent-to-Treat Population)

Cohort/Treatment Group: Cohort 1/Placebo

Subject Number	Date/ Time of Study Drug Administration	System Organ Class/ Preferred Term/ Adverse Event	SAE	Onset Date/ Time/ Study Day	Resolution Date/ Time Study Day	Severity	Relationship to Study Drug	Outcome	Action Taken with Study Drug	Concomitant Medication Administered	TEAE[1]
xxxxx	DDMONYYYY/ HH:MM	XXXXXXXXXXX/ YYYYYYYYYYY/ ZZZZZZZZZZZZZ	No	DDMONYYYY/ HH:MM/ XX	DDMONYYYY/ HH:MM/ XX	Mild	Related	Recovering /Resolving	Study Drug Stopped	No	Yes
		XXXXXXXXXXX/ YYYYYYYYYYY/ ZZZZZZZZZZZZZ	Yes	DDMONYYYY/ HH:MM/ XX	DDMONYYYY/ HH:MM/ XX	Moderate	Unrelated	Unknown	Unkown	Yes	Yes
etc.											

Adverse Events coded using MedDRA Version X.X.
[1] TEAE = Treatment Emergent Adverse Event.

Listing 16.2.7.1.3 Adverse Events – MAD (Intent-to-Treat Population)

Cohort/Treatment Group: Cohort 4/Placebo

Subject Number	Date/ Time of Study Drug Administration	System Organ Class/ Preferred Term/ Adverse Event	SAE	Onset Date/ Time/ Study Day	Resolution Date/ Time Study Day	Severity	Relationship to Study Drug	Outcome	Action Taken with Study Drug	Concomitant Medication Administered	TEAE[1]
xxxxx	DDMONYYYY/ HH:MM	XXXXXXXXXXX/ YYYYYYYYYYY/ ZZZZZZZZZZZZZ	No	DDMONYYYY/ HH:MM/ XX	DDMONYYYY/ HH:MM/ XX	Mild	Related	Recovering /Resolving	Study Drug Stopped	No	Yes
		XXXXXXXXXXX/ YYYYYYYYYYY/ ZZZZZZZZZZZZZ	Yes	DDMONYYYY/ HH:MM/ XX	DDMONYYYY/ HH:MM/ XX	Moderate	Unrelated	Unknown	Unkown	Yes	Yes
etc.											

Adverse Events coded using MedDRA Version X.X.
[1] TEAE = Treatment Emergent Adverse Event.

Listing 16.2.7.2.1 Serious Adverse Events – Low Dose (Intent-to-Treat Population)

Treatment Group: LSALT 0.01 mg

Subject Number	Date/ Time of Study Drug Administration	System Organ Class/ Preferred Term/ Adverse Event	SAE Reason	Onset Date/ Time/ Study Day	Resolution Date/ Time Study Day	Severity	Relationship to Study Drug	Outcome	Action Taken with Study Drug	Concomitant Medication Administered	TEAE[1]
xxxxx	DDMONYYYY/ HH:MM	XXXXXXXXXXX/ YYYYYYYYYYY/ ZZZZZZZZZZZZZ	xxxxxx	DDMONYYYY/ HH:MM/ XX	DDMONYYYY/ HH:MM/ XX	Mild	Related	Recovering /Resolving	Study Drug Stopped	No	Yes
		XXXXXXXXXXX/ YYYYYYYYYYY/ ZZZZZZZZZZZZZ	xxxxxx	DDMONYYYY/ HH:MM/ XX	DDMONYYYY/ HH:MM/ XX	Moderate	Unrelated	Unknown	Unkown	Yes	Yes

Adverse Events coded using MedDRA Version X.X.
[1] TEAE = Treatment Emergent Adverse Event.

Listing 16.2.7.2.2 Serious Adverse Events – SAD (Intent-to-Treat Population)

Cohort/Treatment Group: Cohort 1/Placebo

Subject Number	Date/ Time of Study Drug Administration	System Organ Class/ Preferred Term/ Adverse Event	SAE Reason	Onset Date/ Time/ Study Day	Resolution Date/ Time Study Day	Severity	Relationship to Study Drug	Outcome	Action Taken with Study Drug	Concomitant Medication Administered	TEAE[1]
xxxxx	DDMONYYYY/ HH:MM	XXXXXXXXXXX/ YYYYYYYYYYY/ ZZZZZZZZZZZZZ	xxxxxx	DDMONYYYY/ HH:MM/ XX	DDMONYYYY/ HH:MM/ XX	Mild	Related	Recovering /Resolving	Study Drug Stopped	No	Yes
		XXXXXXXXXXX/ YYYYYYYYYYY/ ZZZZZZZZZZZZZ	xxxxxx	DDMONYYYY/ HH:MM/ XX	DDMONYYYY/ HH:MM/ XX	Moderate	Unrelated	Unknown	Unkown	Yes	Yes
etc.											

Adverse Events coded using MedDRA Version X.X.

[1] TEAE = Treatment Emergent Adverse Event.

Listing 16.2.7.2.3 Serious Adverse Events – MAD (Intent-to-Treat Population)

Cohort/Treatment Group: Cohort 4/Placebo

Subject Number	Date/ Time of Study Drug Administration	System Organ Class/ Preferred Term/ Adverse Event	SAE Reason	Onset Date/ Time/ Study Day	Resolution Date/ Time Study Day	Severity	Relationship to Study Drug	Outcome	Action Taken with Study Drug	Concomitant Medication Administered	TEAE[1]
xxxxx	DDMONYYYY/ HH:MM	XXXXXXXXXXX/ YYYYYYYYYYY/ ZZZZZZZZZZZZZ	xxxxxx	DDMONYYYY/ HH:MM/ XX	DDMONYYYY/ HH:MM/ XX	Mild	Related	Recovering /Resolving	Study Drug Stopped	No	Yes
		XXXXXXXXXXX/ YYYYYYYYYYY/ ZZZZZZZZZZZZZ	xxxxxx	DDMONYYYY/ HH:MM/ XX	DDMONYYYY/ HH:MM/ XX	Moderate	Unrelated	Unknown	Unkown	Yes	Yes
etc.											

Adverse Events coded using MedDRA Version X.X.
[1] TEAE = Treatment Emergent Adverse Event.

Listing 16.2.7.3.1 Non-Treatment-Emergent Adverse Events – Low Dose (Intent-to-Treat Population)

Treatment Group: LSALT 0.01 mg

Subject Number	Date/ Time of Study Drug Administration	System Organ Class/ Preferred Term/ Adverse Event	Onset Date/ Time/ Study Day	Resolution Date/ Time Study Day	Severity	Outcome	Concomitant Medication Administered
xxxxx	DDMONYYYY/ HH:MM	XXXXXXXXXXX/ YYYYYYYYYY/ ZZZZZZZZZZZZ	DDMONYYYY/ HH:MM/ XX	DDMONYYYY/ HH:MM/ XX	Mild	Recovering/ Resolving	No
		XXXXXXXXXXX/ YYYYYYYYYY/ ZZZZZZZZZZZZ	DDMONYYYY/ HH:MM/ XX	DDMONYYYY/ HH:MM/ XX	Moderate	Unknown	Yes

Adverse Events coded using MedDRA Version X.X.
[1] TEAE = Treatment Emergent Adverse Event.

Listing 16.2.7.3.2 Non-Treatment-Emergent Adverse Events – SAD (Intent-to-Treat Population)

Cohort/Treatment Group: Cohort 1/Placebo

Subject Number	Date/ Time of Study Drug Administration	System Organ Class/ Preferred Term/ Adverse Event	Onset Date/ Time/ Study Day	Resolution Date/ Time Study Day	Severity	Outcome	Concomitant Medication Administered
xxxxx	DDMONYYYY/ HH:MM	XXXXXXXXXXX/ YYYYYYYYYY/ ZZZZZZZZZZZZ	DDMONYYYY/ HH:MM/ XX	DDMONYYYY/ HH:MM/ XX	Mild	Recovering/ Resolving	No
		XXXXXXXXXXX/ YYYYYYYYYY/ ZZZZZZZZZZZZ	DDMONYYYY/ HH:MM/ XX	DDMONYYYY/ HH:MM/ XX	Moderate	Unknown	Yes

Adverse Events coded using MedDRA Version X.X.

[1] TEAE = Treatment Emergent Adverse Event.

Listing 16.2.7.3.3 Non-Treatment-Emergent Adverse Events – MAD (Intent-to-Treat Population)

Cohort/Treatment Group: Cohort 4/Placebo

Subject Number	Date/ Time of Study Drug Administration	System Organ Class/ Preferred Term/ Adverse Event	Onset Date/ Time/ Study Day	Resolution Date/ Time Study Day	Severity	Outcome	Concomitant Medication Administered
xxxxx	DDMONYYYY/ HH:MM	XXXXXXXXXXX/ YYYYYYYYYY/ ZZZZZZZZZZZZ	DDMONYYYY/ HH:MM/ XX	DDMONYYYY/ HH:MM/ XX	Mild	Recovering/ Resolving	No
		XXXXXXXXXXX/ YYYYYYYYYY/ ZZZZZZZZZZZZ	DDMONYYYY/ HH:MM/ XX	DDMONYYYY/ HH:MM/ XX	Moderate	Unknown	Yes

Adverse Events coded using MedDRA Version X.X.

[1] TEAE = Treatment Emergent Adverse Event.

Listing 16.2.8.1.1.1 Hematology – Low Dose (Intent-to-Treat Population)

Treatment Group: LSALT 0.01 mg

Subject Number	Parameter (unit)	Visit	Hematology Sample Collected/ If No, Reason	Sample Collection Date/ Time	Actual Value	Actual Change from Baseline[1]	Normal Range (Low, High)	Flag[2]
xxxxx	Hemoglobin (g/L)	Screening	Yes	DDMONYYYY/ HH:MM	xxx.x	N/A	(xxx.x, xxx.x)	
		Day -1[1]	Yes	DDMONYYYY/ HH:MM	xxx.x	N/A	(xxx.x, xxx.x)	L, NCS
		Day XX	Yes	DDMONYYYY/ HH:MM	xxx.x	xxx.x	(xxx.x, xxx.x)	L, NCS
		Day XX	Yes	DDMONYYYY/ HH:MM	xxx.x	xxx.x	(xxx.x, xxx.x)	H, CS
	Parameter (unit)	Screening	Yes	DDMONYYYY/ HH:MM	xxx.x	N/A	(xxx.x, xxx.x)	H, CS
		Day -1[1]	Yes	DDMONYYYY/ HH:MM	xxx.x	N/A	(xxx.x, xxx.x)	L, NCS
		Day XX	Yes	DDMONYYYY/ HH:MM	xxx.x	xxx.x	(xxx.x, xxx.x)	
		Day XX	Yes	DDMONYYYY/ HH:MM	xxx.x	xxx.x	(xxx.x, xxx.x)	L, NCS

[1] Baseline value. Baseline is defined as the last available, non-missing assessment on or prior to first study drug administration.

[2] H = Above High Range, L = Below Low Range, NCS = Not Clinically Significant, CS = Clinically Significant.

Listing 16.2.8.1.1.2 Hematology – SAD (Intent-to-Treat Population)

Cohort/Treatment Group: Cohort 1/Placebo

Subject Number	Parameter (unit)	Visit	Hematology Sample Collected/ If No, Reason	Sample Collection Date/ Time	Actual Value	Actual Change from Baseline[1]	Normal Range (Low, High)	Flag[2]
xxxxx	Hemoglobin (g/L)	Screening	Yes	DDMONYYYY/ HH:MM	xxx.x	N/A	(xxx.x, xxx.x)	
		Day -1[1]	Yes	DDMONYYYY/ HH:MM	xxx.x	N/A	(xxx.x, xxx.x)	L, NCS
		Day XX	Yes	DDMONYYYY/ HH:MM	xxx.x	xxx.x	(xxx.x, xxx.x)	L, NCS
		Day XX	Yes	DDMONYYYY/ HH:MM	xxx.x	xxx.x	(xxx.x, xxx.x)	H, CS
	Parameter (unit)	Screening	Yes	DDMONYYYY/ HH:MM	xxx.x	N/A	(xxx.x, xxx.x)	H, CS
		Day -1[1]	Yes	DDMONYYYY/ HH:MM	xxx.x	N/A	(xxx.x, xxx.x)	L, NCS
		Day XX	Yes	DDMONYYYY/ HH:MM	xxx.x	xxx.x	(xxx.x, xxx.x)	
		Day XX	Yes	DDMONYYYY/ HH:MM	xxx.x	xxx.x	(xxx.x, xxx.x)	L, NCS

etc.

[1] Baseline value. Baseline is defined as the last available, non-missing assessment on or prior to first study drug administration.

[2] H = Above High Range, L = Below Low Range, NCS = Not Clinically Significant, CS = Clinically Significant.

Listing 16.2.8.1.1.3 Hematology – MAD (Intent-to-Treat Population)

Cohort/Treatment Group: Cohort 4/Placebo

Subject Number	Parameter (unit)	Visit	Hematology Sample Collected/ If No, Reason	Sample Collection Date/ Time	Actual Value	Actual Change from Baseline[1]	Normal Range (Low, High)	Flag[2]
xxxxx	Hemoglobin (g/L)	Screening	Yes	DDMONYYYY/ HH:MM	xxx.x	N/A	(xxx.x, xxx.x)	
		Day -1[1]	Yes	DDMONYYYY/ HH:MM	xxx.x	N/A	(xxx.x, xxx.x)	L, NCS
		Day XX	Yes	DDMONYYYY/ HH:MM	xxx.x	xxx.x	(xxx.x, xxx.x)	L, NCS
		Day XX	Yes	DDMONYYYY/ HH:MM	xxx.x	xxx.x	(xxx.x, xxx.x)	H, CS
	Parameter (unit)	Screening	Yes	DDMONYYYY/ HH:MM	xxx.x	N/A	(xxx.x, xxx.x)	H, CS
		Day -1[1]	Yes	DDMONYYYY/ HH:MM	xxx.x	N/A	(xxx.x, xxx.x)	L, NCS
		Day XX	Yes	DDMONYYYY/ HH:MM	xxx.x	xxx.x	(xxx.x, xxx.x)	
		Day XX	Yes	DDMONYYYY/ HH:MM	xxx.x	xxx.x	(xxx.x, xxx.x)	L, NCS

etc.

[1] Baseline value. Baseline is defined as the last available, non-missing assessment on or prior to first study drug administration.

[2] H = Above High Range, L = Below Low Range, NCS = Not Clinically Significant, CS = Clinically Significant.

Listing 16.2.8.1.2.1 Chemistry – Low Dose (Intent-to-Treat Population)

Treatment Group: LSALT 0.01 mg

Subject Number	Parameter (unit)	Visit	Chemistry Sample Collected/ If No, Reason	Sample Collection Date/ Time	Actual Value	Actual Change from Baseline[1]	Normal Range (Low, High)	Flag[2]
xxxxx	Albumin (g/L)	Screening	Yes	DDMONYYYY/ HH:MM	xxx.x	N/A	(xxx.x, xxx.x)	
		Day -1[1]	Yes	DDMONYYYY/ HH:MM	xxx.x	N/A	(xxx.x, xxx.x)	L, NCS
		Day XX	Yes	DDMONYYYY/ HH:MM	xxx.x	xxx.x	(xxx.x, xxx.x)	L, NCS
		Day XX	Yes	DDMONYYYY/ HH:MM	xxx.x	xxx.x	(xxx.x, xxx.x)	H, CS
	Parameter (unit)	Screening	Yes	DDMONYYYY/ HH:MM	xxx.x	N/A	(xxx.x, xxx.x)	H, CS
		Day -1[1]	Yes	DDMONYYYY/ HH:MM	xxx.x	N/A	(xxx.x, xxx.x)	L, NCS
		Day XX	Yes	DDMONYYYY/ HH:MM	xxx.x	xxx.x	(xxx.x, xxx.x)	
		Day XX	Yes	DDMONYYYY/ HH:MM	xxx.x	xxx.x	(xxx.x, xxx.x)	L, NCS

[1] Baseline value. Baseline is defined as the last available, non-missing assessment on or prior to first study drug administration.
[2] H = Above High Range, L = Below Low Range, NCS = Not Clinically Significant, CS = Clinically Significant.

Listing 16.2.8.1.2.2 Chemistry – SAD (Intent-to-Treat Population)

Cohort/Treatment Group: Cohort 1/Placebo

Subject Number	Parameter (unit)	Visit	Chemistry Sample Collected/ If No, Reason	Sample Collection Date/ Time	Actual Value	Actual Change from Baseline[1]	Normal Range (Low, High)	Flag[2]
xxxxx	Albumin (g/L)	Screening	Yes	DDMONYYYY/ HH:MM	xxx.x	N/A	(xxx.x, xxx.x)	
		Day -1[1]	Yes	DDMONYYYY/ HH:MM	xxx.x	N/A	(xxx.x, xxx.x)	L, NCS
		Day XX	Yes	DDMONYYYY/ HH:MM	xxx.x	xxx.x	(xxx.x, xxx.x)	L, NCS
		Day XX	Yes	DDMONYYYY/ HH:MM	xxx.x	xxx.x	(xxx.x, xxx.x)	H, CS
	Parameter (unit)	Screening	Yes	DDMONYYYY/ HH:MM	xxx.x	N/A	(xxx.x, xxx.x)	H, CS
		Day -1[1]	Yes	DDMONYYYY/ HH:MM	xxx.x	N/A	(xxx.x, xxx.x)	L, NCS
		Day XX	Yes	DDMONYYYY/ HH:MM	xxx.x	xxx.x	(xxx.x, xxx.x)	
		Day XX	Yes	DDMONYYYY/ HH:MM	xxx.x	xxx.x	(xxx.x, xxx.x)	L, NCS
etc.								

[1] Baseline value. Baseline is defined as the last available, non-missing assessment on or prior to first study drug administration.

[2] H = Above High Range, L = Below Low Range, NCS = Not Clinically Significant, CS = Clinically Significant.

Listing 16.2.8.1.2.3 Chemistry – MAD (Intent-to-Treat Population)

Cohort/Treatment Group: Cohort 4/Placebo

Subject Number	Parameter (unit)	Visit	Chemistry Sample Collected/ If No, Reason	Sample Collection Date/ Time	Actual Value	Actual Change from Baseline[1]	Normal Range (Low, High)	Flag[2]
xxxxx	Albumin (g/L)	Screening	Yes	DDMONYYYY/ HH:MM	xxx.x	N/A	(xxx.x, xxx.x)	
		Day -1[1]	Yes	DDMONYYYY/ HH:MM	xxx.x	N/A	(xxx.x, xxx.x)	L, NCS
		Day XX	Yes	DDMONYYYY/ HH:MM	xxx.x	xxx.x	(xxx.x, xxx.x)	L, NCS
		Day XX	Yes	DDMONYYYY/ HH:MM	xxx.x	xxx.x	(xxx.x, xxx.x)	H, CS
	Parameter (unit)	Screening	Yes	DDMONYYYY/ HH:MM	xxx.x	N/A	(xxx.x, xxx.x)	H, CS
		Day -1[1]	Yes	DDMONYYYY/ HH:MM	xxx.x	N/A	(xxx.x, xxx.x)	L, NCS
		Day XX	Yes	DDMONYYYY/ HH:MM	xxx.x	xxx.x	(xxx.x, xxx.x)	
		Day XX	Yes	DDMONYYYY/ HH:MM	xxx.x	xxx.x	(xxx.x, xxx.x)	L, NCS
etc.								

[1] Baseline value. Baseline is defined as the last available, non-missing assessment on or prior to first study drug administration.

[2] H = Above High Range, L = Below Low Range, NCS = Not Clinically Significant, CS = Clinically Significant.

Listing 16.2.8.1.3.1 Coagulation – Low Dose (Intent-to-Treat Population)

Treatment Group: LSALT 0.01 mg

Subject Number	Parameter (unit)	Visit	Coagulation Sample Collected/ If No, Reason	Sample Collection Date/ Time	Actual Value	Actual Change from Baseline[1]	Normal Range (Low, High)	Flag[2]
xxxxx	INR (unit)	Screening	Yes	DDMONYYYY/ HH:MM	xxx.x	N/A	(xxx.x, xxx.x)	
		Day -1[1]	Yes	DDMONYYYY/ HH:MM	xxx.x	N/A	(xxx.x, xxx.x)	L, NCS
		Day XX	Yes	DDMONYYYY/ HH:MM	xxx.x	xxx.x	(xxx.x, xxx.x)	L, NCS
		Day XX	Yes	DDMONYYYY/ HH:MM	xxx.x	xxx.x	(xxx.x, xxx.x)	H, CS
	Parameter (unit)	Screening	Yes	DDMONYYYY/ HH:MM	xxx.x	N/A	(xxx.x, xxx.x)	H, CS
		Day -1[1]	Yes	DDMONYYYY/ HH:MM	xxx.x	N/A	(xxx.x, xxx.x)	L, NCS
		Day XX	Yes	DDMONYYYY/ HH:MM	xxx.x	xxx.x	(xxx.x, xxx.x)	
		Day XX	Yes	DDMONYYYY/ HH:MM	xxx.x	xxx.x	(xxx.x, xxx.x)	L, NCS

[1] Baseline value. Baseline is defined as the last available, non-missing assessment on or prior to first study drug administration.
[2] H = Above High Range, L = Below Low Range, NCS = Not Clinically Significant, CS = Clinically Significant.

Listing 16.2.8.1.3.2 Coagulation – SAD (Intent-to-Treat Population)

Cohort/Treatment Group: Cohort 1/Placebo

Subject Number	Parameter (unit)	Visit	Coagulation Sample Collected/ If No, Reason	Sample Collection Date/ Time	Actual Value	Actual Change from Baseline[1]	Normal Range (Low, High)	Flag[2]
xxxxx	INR (unit)	Screening	Yes	DDMONYYYY/ HH:MM	xxx.x	N/A	(xxx.x, xxx.x)	
		Day -1[1]	Yes	DDMONYYYY/ HH:MM	xxx.x	N/A	(xxx.x, xxx.x)	L, NCS
		Day XX	Yes	DDMONYYYY/ HH:MM	xxx.x	xxx.x	(xxx.x, xxx.x)	L, NCS
		Day XX	Yes	DDMONYYYY/ HH:MM	xxx.x	xxx.x	(xxx.x, xxx.x)	H, CS
	Parameter (unit)	Screening	Yes	DDMONYYYY/ HH:MM	xxx.x	N/A	(xxx.x, xxx.x)	H, CS
		Day -1[1]	Yes	DDMONYYYY/ HH:MM	xxx.x	N/A	(xxx.x, xxx.x)	L, NCS
		Day XX	Yes	DDMONYYYY/ HH:MM	xxx.x	xxx.x	(xxx.x, xxx.x)	
		Day XX	Yes	DDMONYYYY/ HH:MM	xxx.x	xxx.x	(xxx.x, xxx.x)	L, NCS

etc.

[1] Baseline value. Baseline is defined as the last available, non-missing assessment on or prior to first study drug administration.

[2] H = Above High Range, L = Below Low Range, NCS = Not Clinically Significant, CS = Clinically Significant.

Listing 16.2.8.1.3.3 Coagulation – MAD (Intent-to-Treat Population)

Cohort/Treatment Group: Cohort 4/Placebo

Subject Number	Parameter (unit)	Visit	Coagulation Sample Collected/ If No, Reason	Sample Collection Date/ Time	Actual Value	Actual Change from Baseline[1]	Normal Range (Low, High)	Flag[2]
xxxxx	INR (unit)	Screening	Yes	DDMONYYYY/ HH:MM	xxx.x	N/A	(xxx.x, xxx.x)	
		Day -1[1]	Yes	DDMONYYYY/ HH:MM	xxx.x	N/A	(xxx.x, xxx.x)	L, NCS
		Day XX	Yes	DDMONYYYY/ HH:MM	xxx.x	xxx.x	(xxx.x, xxx.x)	L, NCS
		Day XX	Yes	DDMONYYYY/ HH:MM	xxx.x	xxx.x	(xxx.x, xxx.x)	H, CS
	Parameter (unit)	Screening	Yes	DDMONYYYY/ HH:MM	xxx.x	N/A	(xxx.x, xxx.x)	H, CS
		Day -1[1]	Yes	DDMONYYYY/ HH:MM	xxx.x	N/A	(xxx.x, xxx.x)	L, NCS
		Day XX	Yes	DDMONYYYY/ HH:MM	xxx.x	xxx.x	(xxx.x, xxx.x)	
		Day XX	Yes	DDMONYYYY/ HH:MM	xxx.x	xxx.x	(xxx.x, xxx.x)	L, NCS

etc.

[1] Baseline value. Baseline is defined as the last available, non-missing assessment on or prior to first study drug administration.

[2] H = Above High Range, L = Below Low Range, NCS = Not Clinically Significant, CS = Clinically Significant.

Listing 16.2.8.1.4.1 Urinalysis – Low Dose (Intent-to-Treat Population)

Treatment Group: LSALT 0.01 mg

Subject Number	Parameter (unit)	Visit	Urinalysis Sample Collected/ If No, Reason	Sample Collection Date/ Time	Actual Value	Normal Range (Low, High)	Flag[2]
xxxxx	Glucose	Screening	Yes	DDMONYYYY/ HH:MM	Negative		
		Day -1[1]	Yes	DDMONYYYY/ HH:MM	Positive		
		Day XX	Yes	DDMONYYYY/ HH:MM	Positive		
		Day XX	Yes	DDMONYYYY/ HH:MM	Positive		
	Parameter (unit)	Screening	Yes	DDMONYYYY/ HH:MM	xxx.x	(xxx.x, xxx.x)	H, NCS
		Day -1[1]	Yes	DDMONYYYY/ HH:MM	xxx.x	(xxx.x, xxx.x)	L, CS
		Day XX	Yes	DDMONYYYY/ HH:MM	xxx.x	(xxx.x, xxx.x)	
		Day XX	Yes	DDMONYYYY/ HH:MM	xxx.x	(xxx.x, xxx.x)	L, NCS

[1] Baseline value. Baseline is defined as the last available, non-missing assessment on or prior to first study drug administration.
[2] H = Above High Range, L = Below Low Range, NCS = Not Clinically Significant, CS = Clinically Significant.

Listing 16.2.8.1.4.2 Urinalysis – SAD (Intent-to-Treat Population)

Cohort/Treatment Group: Cohort 1/Placebo

Subject Number	Parameter (unit)	Visit	Urinalysis Sample Collected/ If No, Reason	Sample Collection Date/ Time	Actual Value	Normal Range (Low, High)	Flag[2]
xxxxx	Glucose	Screening	Yes	DDMONYYYY/ HH:MM	Negative		
		Day -1[1]	Yes	DDMONYYYY/ HH:MM	Positive		
		Day XX	Yes	DDMONYYYY/ HH:MM	Positive		
		Day XX	Yes	DDMONYYYY/ HH:MM	Positive		
	Parameter (unit)	Screening	Yes	DDMONYYYY/ HH:MM	xxx.x	(xxx.x, xxx.x)	H, NCS
		Day -1[1]	Yes	DDMONYYYY/ HH:MM	xxx.x	(xxx.x, xxx.x)	L, CS
		Day XX	Yes	DDMONYYYY/ HH:MM	xxx.x	(xxx.x, xxx.x)	
		Day XX	Yes	DDMONYYYY/ HH:MM	xxx.x	(xxx.x, xxx.x)	L, NCS
etc.							

[1] Baseline value. Baseline is defined as the last available, non-missing assessment on or prior to first study drug administration.
[2] H = Above High Range, L = Below Low Range, NCS = Not Clinically Significant, CS = Clinically Significant.

Listing 16.2.8.1.4.3 Urinalysis – MAD (Intent-to-Treat Population)

Cohort/Treatment Group: Cohort 1/Placebo

Subject Number	Parameter (unit)	Visit	Urinalysis Sample Collected/ If No, Reason	Sample Collection Date/ Time	Actual Value	Normal Range (Low, High)	Flag[2]
xxxxx	Glucose	Screening	Yes	DDMONYYYY/ HH:MM	Negative		
		Day -1[1]	Yes	DDMONYYYY/ HH:MM	Positive		
		Day XX	Yes	DDMONYYYY/ HH:MM	Positive		
		Day XX	Yes	DDMONYYYY/ HH:MM	Positive		
	Parameter (unit)	Screening	Yes	DDMONYYYY/ HH:MM	xxx.x	(xxx.x, xxx.x)	H, NCS
		Day -1[1]	Yes	DDMONYYYY/ HH:MM	xxx.x	(xxx.x, xxx.x)	L, CS
		Day XX	Yes	DDMONYYYY/ HH:MM	xxx.x	(xxx.x, xxx.x)	
		Day XX	Yes	DDMONYYYY/ HH:MM	xxx.x	(xxx.x, xxx.x)	L, NCS
etc.							

[1] Baseline value. Baseline is defined as the last available, non-missing assessment on or prior to first study drug administration.
[2] H = Above High Range, L = Below Low Range, NCS = Not Clinically Significant, CS = Clinically Significant.

Listing 16.2.8.2.1.1 Vital Signs – Low Dose (Intent-to-Treat Population)

Treatment Group: LSALT 0.01 mg

Subject Number	Parameter (unit)	Visit	Scheduled Timepoint	Vital Signs Performed/ If No, Reason	Date/ Time of Assessment	Actual Value	Actual Change from Baseline[1]	Interpretation
xxxxx	Heart Rate (beats/min)	Screening	N/A	Yes	DDMONYYYY/ HH:MM	xxx.x	N/A	Abnormal NCS
		Day -1	N/A	Yes	DDMONYYYY/ HH:MM	xxx.x	N/A	Normal
		Day XX	Pre Dose[1]	Yes	DDMONYYYY/ HH:MM	xxx.x	N/A	Normal
			XX Hrs Post Dose	Yes	DDMONYYYY/ HH:MM	xxx.x	xxx.x	Normal

[1] Baseline value. Baseline is defined as the last available, non-missing assessment on or prior to first study drug administration.
[2] NCS = Not Clinically Significant, CS = Clinically Significant.

Listing 16.2.8.2.1.2 Vital Signs – SAD (Intent-to-Treat Population)

Cohort/Treatment Group: Cohort 1/Placebo

Subject Number	Parameter (unit)	Visit	Scheduled Timepoint	Vital Signs Performed/ If No, Reason	Date/ Time of Assessment	Actual Value	Actual Change from Baseline[1]	Interpretation
xxxxx	Heart Rate (beats/min)	Screening	N/A	Yes	DDMONYYYY/ HH:MM	xxx.x	N/A	Abnormal NCS
		Day -1	N/A	Yes	DDMONYYYY/ HH:MM	xxx.x	N/A	Normal
		Day XX	Pre Dose[1]	Yes	DDMONYYYY/ HH:MM	xxx.x	N/A	Normal
			XX Hrs Post Dose	Yes	DDMONYYYY/ HH:MM	xxx.x	xxx.x	Normal
etc.								

[1] Baseline value. Baseline is defined as the last available, non-missing assessment on or prior to first study drug administration.
[2] NCS = Not Clinically Significant, CS = Clinically Significant.

Listing 16.2.8.2.1.3 Vital Signs – MAD (Intent-to-Treat Population)

Cohort/Treatment Group: Cohort 4/Placebo

Subject Number	Parameter (unit)	Visit	Scheduled Timepoint	Vital Signs Performed/ If No, Reason	Date/ Time of Assessment	Actual Value	Actual Change from Baseline[1]	Interpretation[2]
xxxxx	Heart Rate (beats/min)	Screening	N/A	Yes	DDMONYYYY/ HH:MM	xxx.x	N/A	Abnormal NCS
		Day -1	N/A	Yes	DDMONYYYY/ HH:MM	xxx.x	N/A	Normal
		Day XX	Pre Dose[1]	Yes	DDMONYYYY/ HH:MM	xxx.x	N/A	Normal
			XX Hrs Post Dose	Yes	DDMONYYYY/ HH:MM	xxx.x	xxx.x	Normal
etc.								

[1] Baseline value. Baseline is defined as the last available, non-missing assessment on or prior to first study drug administration.
[2] NCS = Not Clinically Significant, CS = Clinically Significant.

Listing 16.2.8.2.2.1 12-Lead Electrocardiogram – Low Dose (Intent-to-Treat Population)

Treatment Group: LSALT 0.01 mg

Subject Number	Parameter (unit)	Visit	Scheduled Timepoint	ECG Performed/ If No, Reason	Date/Time of Assessment	Actual Value	Actual Change from Baseline[1]	Interpretation [2]	Details
xxxxx	PR Interval (msec)	Screening	N/A	Yes	DDMONYYYY/ HH:MM	xxx.x	N/A	Abnormal NCS	xxxxxxxxx
		Day -1	N/A	Yes	DDMONYYYY/ HH:MM	xxx.x	N/A	Normal	
		Day XX	Pre Dose[1]	Yes	DDMONYYYY/ HH:MM	xxx.x	N/A	Normal	
			XX Hrs Post Dose	Yes	DDMONYYYY/ HH:MM	xxx.x	xxx.x	N/A	xxxxxxxxx
etc.									

[1] Baseline value. Baseline is defined as the last available, non-missing assessment on or prior to first study drug administration.
[2] NCS = Not Clinically Significant, CS = Clinically Significant.

Listing 16.2.8.2.2.2 12-Lead Electrocardiogram – SAD (Intent-to-Treat Population)

Cohort/Treatment Group: Cohort 1/Placebo

Subject Number	Parameter (unit)	Visit	Scheduled Timepoint	ECG Performed/ If No, Reason	Date/Time of Assessment	Actual Value	Actual Change from Baseline[1]	Interpretation [2]	Details
xxxxx	PR Interval (msec)	Screening	N/A	Yes	DDMONYYYY/ HH:MM	xxx.x	N/A	Abnormal NCS	xxxxxxxxx
		Day -1	N/A	Yes	DDMONYYYY/ HH:MM	xxx.x	N/A	Normal	
		Day XX	Pre Dose[1]	Yes	DDMONYYYY/ HH:MM	xxx.x	N/A	Normal	
			XX Hrs Post Dose	Yes	DDMONYYYY/ HH:MM	xxx.x	xxx.x	N/A	xxxxxxxxx

etc.

[1] Baseline value. Baseline is defined as the last available, non-missing assessment on or prior to first study drug administration.
[2] NCS = Not Clinically Significant, CS = Clinically Significant.

Listing 16.2.8.2.2.3 12-Lead Electrocardiogram – MAD (Intent-to-Treat Population)

Cohort/Treatment Group: Cohort 4/Placebo

Subject Number	Parameter (unit)	Visit	Scheduled Timepoint	ECG Performed/ If No, Reason	Date/Time of Assessment	Actual Value	Actual Change from Baseline[1]	Interpretation [2]	Details
xxxxx	PR Interval (msec)	Screening	N/A	Yes	DDMONYYYY/ HH:MM	xxx.x	N/A	Abnormal NCS	xxxxxxxxx
		Day -1	N/A	Yes	DDMONYYYY/ HH:MM	xxx.x	N/A	Normal	
		Day XX	Pre Dose[1]	Yes	DDMONYYYY/ HH:MM	xxx.x	N/A	Normal	
			XX Hrs Post Dose	Yes	DDMONYYYY/ HH:MM	xxx.x	xxx.x	N/A	xxxxxxxxx
etc.									

[1] Baseline value. Baseline is defined as the last available, non-missing assessment on or prior to first study drug administration.
[2] NCS = Not Clinically Significant, CS = Clinically Significant.

Listing 16.2.8.2.3.1 Physical Examination – Low Dose (Intent-to-Treat Population)

Treatment Group: LSALT 0.01 mg

Subject Number	Physical Examination Type/ Visit	Physical Examination Performed/ If No, Reason (Reason Applies to Full Examination)	Change from Previous Examination (Applies to Brief Examination)	Date of Assessment	Body System	Result[1]	Details
xxxxx	Full/ Screening	Yes	N/A	DDMONYYY	General appearance	Normal	
					Skin	Abnormal NCS	xxxxxxxxxxxxxxxxxxx xxx
					Head, ears, eyes, nose, throat	Normal	
					etc.		

[1] NCS = Not Clinically Significant, CS = Clinically Significant.

Listing 16.2.8.2.3.2 Physical Examination – SAD (Intent-to-Treat Population)

Cohort/Treatment Group: Cohort 1/Placebo

Subject Number	Physical Examination Type/ Visit	Physical Examination Performed/ If No, Reason (Reason Applies to Full Examination)	Change from Previous Examination (Applies to Brief Examination)	Date of Assessment	Body System	Result[1]	Details
xxxxx	Full/ Screening	Yes	N/A	DDMONYYY	General appearance	Normal	
					Skin	Abnormal NCS	xxxxxxxxxxxxxxxxxxxxx
					Head, ears, eyes, nose, throat	Normal	
					etc.		
etc.							

[1] NCS = Not Clinically Significant, CS = Clinically Significant.

Listing 16.2.8.2.3.3 Physical Examination – MAD (Intent-to-Treat Population)

Cohort/Treatment Group: Cohort 4/Placebo

Subject Number	Physical Examination Type/ Visit	Physical Examination Performed/ If No, Reason (Reason Applies to Full Examination)	Change from Previous Examination (Applies to Brief Examination)	Date of Assessment	Body System	Result[1]	Details
xxxxx	Full/ Screening	Yes	N/A	DDMONYYY	General appearance	Normal	
					Skin	Abnormal NCS	xxxxxxxxxxxxxxxxxxxxx
					Head, ears, eyes, nose, throat	Normal	
					etc.		
etc.							

[1] NCS = Not Clinically Significant, CS = Clinically Significant.

Listing 16.2.8.2.4.1 Chest X-Ray – Low Dose (Intent-to-Treat Population)

Treatment Group: LSALT 0.01 mg

Subject Number	Visit	Chest X-Ray Performed/ If No, Reason	Test Date	Result[1]	Details
xxxxx	Screening	Yes	DDMONYYYY	Normal	xxxxxxxxxxxxxxxxxxxxxxxxxxxx

[1] NCS = Not Clinically Significant, CS = Clinically Significant.

Listing 16.2.8.2.4.2 Chest X-Ray – SAD (Intent-to-Treat Population)

Cohort/Treatment Group: Cohort 1/Placebo

Subject Number	Visit	Chest X-Ray Performed/ If No, Reason	Test Date	Result[1]	Details
xxxxx	Screening	Yes	DDMONYYYY	Normal	xxxxxxxxxxxxxxxxxxxxxxxxxxxx
etc.					

[1] NCS = Not Clinically Significant, CS = Clinically Significant.

Listing 16.2.8.2.4.3 Chest X-Ray – MAD (Intent-to-Treat Population)

Cohort/Treatment Group: Cohort 4/Placebo

Subject Number	Visit	Chest X-Ray Performed/ If No, Reason	Test Date	Result[1]	Details
xxxxx	Screening	Yes	DDMONYYYY	Normal	xxxxxxxxxxxxxxxxxxxxxxxxxxxx
etc.					

[1] NCS = Not Clinically Significant, CS = Clinically Significant.

Listing 16.2.8.2.5.2 Plasma Pharmacokinetic Concentrations – SAD (Intent-to-Treat Population)

Cohort/Treatment Group: Cohort 1/Placebo

Subject Number	Date/ Time of Study Drug Administration	Visit	Scheduled Timepoint	Blood Sample Collected/ If No, Reason	Date/ Time of Collection	Duration From Study Drug Admistration (hours)	Concentration (unit)
xxxxx	DDMONYYYY/ HH:MM	Day 1	30 mins pre start of Infusion	Yes	DDMONYYY/ HH:MM	xx.xx	xx.xx
			15 mins after end of 1st infusion	Yes	DDMONYYY/ HH:MM	xx.xx	xx.xx
			30 mins after end of 1st infusion	Yes	DDMONYYY/ HH:MM	xx.xx	xx.xx
			etc.				
etc.							

Listing 16.2.8.2.5.3 Plasma Pharmacokinetic Concentrations – MAD (Intent-to-Treat Population)

Cohort/Treatment Group: Cohort 4/Placebo

Subject Number	Date/ Time of First Study Drug Administration	Visit	Scheduled Timepoint	Blood Sample Collected/ If No, Reason	Date/ Time of Collection	Duration From First Study Drug Admistration (hours)	Duration From Study Drug Admistration of Dosing Day (hours)	Concentration (unit)
xxxxx	DDMONYYYY/ HH:MM	Day 1	30 mins pre start of Infusion	Yes	DDMONYYY/ HH:MM	xx.xx	xx.xx	xx.xx
			15 mins after end of 1st infusion	Yes	DDMONYYY/ HH:MM	xx.xx	xx.xx	xx.xx
			30 mins after end of 1st infusion	Yes	DDMONYYY/ HH:MM	xx.xx	xx.xx	xx.xx
			etc.					
etc.								

Listing 16.2.8.2.6.2 Plasma Pharmacokinetic Parameters – SAD (Intent-to-Treat Population)

Cohort/Treatment Group: Cohort 1/Placebo

Subject Number	AUC_{0-t} (unit)	C_{max} (unit)	etc.
xxxxx	xxx.x	xxx.x	xxx.x
xxxxx	xxx.x	xxx.x	xxx.x
xxxxx	xxx.x	xxx.x	xxx.x
xxxxx	xxx.x	xxx.x	xxx.x
xxxxx	xxx.x	xxx.x	xxx.x
xxxxx	xxx.x	xxx.x	xxx.x
etc.			

Programming Note: Include all plasma PK parameters.

Listing 16.2.8.2.6.3 Plasma Pharmacokinetic Parameters – MAD (Intent-to-Treat Population)

Cohort/Treatment Group: Cohort 4/Placebo

Subject Number	Plasma PK Parameter Day	AUC_{0-t} (unit)	C_{max} (unit)	etc.
xxxxx	Day 1	xxx.x	xxx.x	xxx.x
xxxxx	Day 3	xxx.x	xxx.x	xxx.x
xxxxx	Day 1	xxx.x	xxx.x	xxx.x
xxxxx	Day 3	xxx.x	xxx.x	xxx.x
xxxxx	Day 1	xxx.x	xxx.x	xxx.x
xxxxx	Day 3	xxx.x	xxx.x	xxx.x
etc.	etc.			

Programming Note: Include all plasma PK parameters.

Listing 16.2.8.2.7.3 Anti-Drug Antibody – MAD (Intent-to-Treat Population)

Cohort/Treatment Group: Cohort 4/Placebo

Subject Number	Visit	Sample Collected/ If No, Reason	Collection Date/ Time
xxxxx	Day 14	Yes	DDMONYYYY/ HH:MM
etc.			