STATISTICAL ANALYSIS PLAN

Protocol Number:	MTI-109
Study Title:	A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY OF THE EFFICACY, SAFETY, AND TOLERABILITY OF SERLOPITANT FOR THE TREATMENT OF PRURITUS IN ADULTS WITH PLAQUE PSORIASIS
Development Phase of Study:	Phase 2
Sponsor:	Menlo Therapeutics Inc. 200 Cardinal Way, 2nd Floor Redwood City, CA 94063 USA
Sponsor Contact:	[redacted]
Statistical Analysis Plan based on Protocol Version:	Version 2.0 Amendment 1, 15 March 2018
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Authored by:

SIGNATURE: [redacted] DATE: [redacted]

Reviewed by:

SIGNATURE: [redacted] DATE: [redacted]

Approved by:

SIGNATURE: [redacted] DATE: [redacted]

SIGNATURE: [redacted] DATE: [redacted]

Revisions to the Statistical Analysis Plan described herein must be approved through a formal written amendment with the exception of minor editorial changes to tables, figures, or listing shells, and any necessary textual clarifications for programmers that do not affect the stated analysis variables, study endpoints, or statistical methods.

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Revision History:

Version	Date	Summary of Changes	Author
Version 1	18 July 2018	Original document	[redacted]
Version 2	09 November 2018	Clarified p-values to be one-sided. Updates to table and listing shells based on dry run/mock delivery comments.	[redacted]

1. LIST OF ABBREVIATIONS AND DEFINITIONS OF TERMS

AE(s)	adverse event(s)
ANCOVA	analysis of covariance
CMH	Cochran-Mantel-Haenszel
ECG	Electrocardiogram
eDiary	Electronic diary
FAS	Full analysis set
ITT	Intent-to-treat
LOCF	Last observation carried forward
MedDRA	Medical Dictionary for Regulatory Activities
MCMC	Markov Chain Monte Carlo
PGA	Physician Global Assessment
PGIC	Patient Global Impression of Change
PK	Pharmacokinetics
PP	Per-Protocol
PROMIS®	Patient-Reported Outcomes Measurement Information System
PIQ	Patient-Reported Outcomes Measurement Information System Itch Questionnaire
SAE(s)	Serious adverse event(s)
SAS®	Statistical Analysis System (SAS® Institute Inc., Cary, NC)
SD	Standard Deviation
sPGA	Static Patient Global Assessment
TEAE(s)	Treatment-emergent adverse event(s)
WI-NRS	Worst-Itch Numeric Rating Scale

2. INTRODUCTION

Psoriasis is a chronic, non-communicable, immune-mediated inflammatory disease affecting at least 100 million individuals worldwide. The most common clinical variant is plaque psoriasis (also known as “psoriasis vulgaris”), which affects approximately 85-90% of all patients with psoriasis; this typically manifests as raised, well-demarcated erythematous skin plaques with adherent silvery scales, which are a result of a hyperproliferative epidermis with premature maturation of keratinocytes and parakeratosis. Next to scaling of the skin (reported by 92% of patients with plaque psoriasis), the most frequently reported symptom is itching (reported by 72-87%). In a survey of over 3,400 U.S. patients with psoriasis, itching was consistently reported as the most influential factor in determining their perception of psoriasis severity.

Menlo Therapeutics Inc. is pursuing the development of serlopitant for treatment of itch. The MTI-109 study described herein is a double-blind, randomized, placebo-controlled study to assess the efficacy, safety, and tolerability of serlopitant for the treatment of pruritus in adults with plaque psoriasis.

3. STUDY OBJECTIVES

The primary objective of this study is to assess the efficacy of serlopitant for the treatment of pruritus in adults with plaque psoriasis.

The secondary objectives of this study are as follows:

- To assess the safety and tolerability of repeated oral doses of serlopitant in adults with plaque psoriasis.
- To assess the psychometric properties of Worst-Itch Numeric Rating Scale (WI-NRS).

4. STUDY DESIGN

4.1 Overall Study Design

This is a double-blind, randomized, placebo-controlled study to assess the efficacy, safety, and tolerability of serlopitant for the treatment of pruritus in adults with plaque psoriasis. Subjects who meet the study entry criteria will be randomized in a 1:1 ratio to receive daily oral doses of serlopitant 5 mg or placebo for 8 weeks. The study will be conducted at approximately 40 study sites in North America.

The study will consist of three periods, for a total study period of approximately 12 or 14 weeks:

- Screening period: 2 or 4 weeks
- Treatment period: 8 weeks
- Follow-up period: 2 weeks

4.1.1 Schedule of Visits and Assessments

The schedule of assessments can be found in Section 6.5 and Appendix A of the Protocol.

4.1.2 Method of Assigning Subjects to Treatment Groups

Eligible subjects will be randomized to receive serlopitant 5 mg or placebo in a 1:1 ratio. Stratified permuted block randomization will be used. Randomization will be stratified by the subject's reported WI-NRS score for the 24-hour period prior to the initial Screening visit (7-8, 9-10).

An interactive web response sytem will be used to perform the randomization.

4.1.3 Blinding

This study will be conducted as a double-blind study with the treatment assignment concealed from the subjects, the investigators and their staff, the Sponsor, and any designees of the Sponsor as required. The placebo will be formulated to be indistinguishable from the active study product(s). Study materials will be packaged and issued in a manner designed to maintain the blind for subjects and all study personnel involved in the direction and execution of study procedures, study assessments, and collection of data. The randomization code for each subject will be available to the sites for use only in an emergency situation. For details of the procedure for unblinding of individual subjects in cases of emergency see Section 7.6 of the Protocol and the Blinding Plan.

5. EFFICACY AND SAFETY ENDPOINTS

5.1 Efficacy Endpoints

5.1.1 Primary Efficacy Endpoint

The primary efficacy endpoint is the WI-NRS 4-point responder rate at Week 8.

5.1.2 Key Secondary Efficacy Endpoints

The key secondary efficacy endpoints are as follows:

- The WI-NRS 4-point responder rate at Week 4
- Change in WI-NRS from baseline to Day 7
- Change in WI-NRS from baseline to Day 3

5.1.3 Additional Secondary Efficacy Endpoints

Additional secondary efficacy endpoints include the following:

- Change in number of night-time scratching events from baseline to Week 8
- Change in WI-NRS from baseline to Weeks 2, 4, 6 and 8
- The WI-NRS 3-point responder rate at Weeks 4 and 8
- Change in Static Patient Global Assessment of Itch Severity (sPGA)
- Patient Global Impression of Change in Itch Severity (PGIC)

5.2 Safety Endpoints

Safety endpoints include the following:

- Incidence of treatment-emergent adverse events (TEAEs) and serious adverse events (SAEs)
- Changes in clinical laboratory parameters following study drug exposure
- Changes in vital sign and ECG parameters following study drug exposure
- Plasma concentrations of serlopitant and metabolites

5.3 Exploratory Endpoints

Exploratory endpoints include the following:

- Change in Body Surface Area (BSA), and Physician Global Assessment (PGA) of psoriasis
- Change in Patient-Reported Outcomes Measurement Information System Itch Questionnaire (PIQ) score for Itch – General
- Change in Patient-Reported Outcomes Measurement Information System Itch Questionnaire (PIQ) score for Itch – Scratching Behavior
- Change in Patient-Reported Outcomes Measurement Information System Itch Questionnaire (PIQ) score for Itch – Mood and Sleep
- Change in Patient-Reported Outcomes Measurement Information System Itch Questionnaire (PIQ) score for Itch – Activity and Clothing
- Change in sleep efficiency
- Change in mean activity during the sleep period

6. STATISTICAL AND ANALYTICAL PLANS

6.1 General Methodology

All statistical processing will be performed using SAS® unless otherwise stated. No interim analyses are planned. Endpoints will be summarized with descriptive statistics by treatment group and visit. For continuous variables, the following information will be presented: n, mean standard deviation (SD), median, minimum and maximum. For categorical variables, counts and percentages will be used.

Reported adverse events (AEs), medical history terms and prior and concomitant procedures and therapies will be classified on the basis of Medical Dictionary for Regulatory Activities (MedDRA) terminology. Concomitant medications will be classified on the basis of World Health Organization Drug Dictionary (WHO-DDE) terminology.

6.1.1 Statistical Analysis

All summary tables and data listings will be prepared by QST Consultations, Ltd., utilizing SAS® Version 9.3 or later software.

The standard operating procedures of QST Consultations, Ltd. will be followed in the creation and quality control of all data displays.

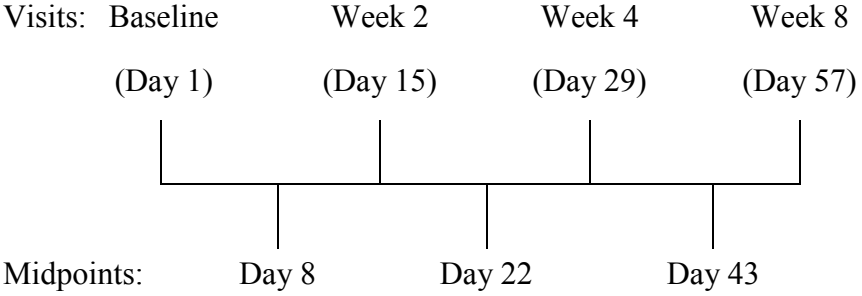
6.1.2 Baseline Definition

Baseline, for measures other than those collected daily, will be the last recorded value prior to the start of treatment. For daily measures, including WI-NRS (eDiary) and actigraphy, baseline will be the average result measured over the 7 days prior to treatment.

6.1.3 Visit Windowing

Data will be summarized based on nominal visit indications unless a subject discontinues early in which case the procedure is described below.

Information collected at early end of treatment visits (information captured within the Week 8 visit/follow-up visit for subjects that discontinued treatment early) will be mapped to the most appropriate visit based on the midpoints between scheduled visits. Follow-up visits occurring after early termination of treatment will remain a follow-up visit; follow-up visits will not be mapped.



For example, if a subject terminates on or after Day 22 but before Day 43, data collected at the early end of treatment visit will be mapped to the Week 4 evaluation for summaries. If the subject has Week 4 values present, the data collected at the early end of treatment visit will not replace the data collected at Week 4. For the sensitivity efficacy analyses, last observation carried forward (LOCF) will be applied subsequent to mapping the information to the appropriate visit.

Additionally the daily measures will be summarized at Weeks 2, 3, 4, 5, 6, 7 and 8 by averaging the daily results for the 7 days prior to each week. The weekly average values will be calculated if a subject has at least one response during the 7 day range, as defined below:

Week/Visit	Study Day Range
Week 2	8-14
Week 3	15-21
Week 4	22-28
Week 5	29-35
Week 6	36-42
Week 7	43-49
Week 8	50-56
Follow-up	Last 7 days (off-treatment) prior to ending the study.

6.1.4 Adjustments for Covariates

Analysis of covariance will include baseline value as a covariate.

6.1.5 Handling of Dropouts or Missing Data

Should a determination of treatment period (on treatment, pre-treatment, post-treatment) be required for AEs or concomitant medication but the corresponding date is missing, or is a partial date, the event/medication will be considered on treatment unless the portions of the date that are available indicate this is not possible.

The primary method of handling missing efficacy data will be Markov Chain Monte Carlo (MCMC) multiple imputation. Imputation will be conducted within each treatment group independently, so the pattern of missing observations in one treatment group cannot influence missing value estimations in another. For each imputation process, 25 imputations will be performed.

Subjects that withdrew from the study due to lack of efficacy will have missing values imputed, however, the responder status will be defined as non-responder. Subjects that used an excluded therapy to treat psoriasis or pruritus will have data values collected after the use of the excluded therapy set to missing and subsequently imputed. These subjects will also have the responder status defined as non-responder.

Missing WI-NRS data will be derived for the analysis using the method of MCMC multiple imputation. The 4-point responder status will be derived from imputed WI-NRS values. Since both primary and key secondary endpoints require WI-NRS, the following steps will be followed:

1. Using the daily eDiary data, calculate Baseline and Week 2 through Week 8 values by averaging available values. If any values are available, these will be used i.e. a minimum of 1 observation is required to compute a week's average.

2. From step 1, create a dataset for each treatment group, of subjects with observed values and those needing estimation by MCMC. The missing WI-NRS values in each dataset will be filled in using the MCMC method to generate 25 datasets. The resulting datasets for each treatment group will be combined into one complete dataset.

Syntax:

```
proc mi data=datain out=dataout seed=&seed. Nimpute=25 <options>;
  where trtpn=(TRT); /* Note TRT = [1, 2]; depending on treatment group */;
  mcmc chain=single;
  var baseline d2 d3 d4 d5 d6 d7 week2 week3 week4 week5 week6 week7 week8;
run;
```

3. From each complete dataset, the dichotomous responder rate will be determined.

Each complete dataset formed by multiply imputed data will be analyzed as specified for the particular analysis. The results from the analyses will be combined into a single inference using SAS® PROC MIANALYZE. In the case of the primary analysis and the secondary responder analyses, the Cochran Mantel Haenszel (CMH) statistics computed in the analyses of WI-NRS responder rates will be converted to z-scores prior to combining them using SAS® PROC MIANALYZE.

A total of 2 random seeds will be needed to impute missing data. Those random seeds have been pre-specified by using a random number generator:

- WI-NRS Serlopitant: Seed= 85162995
- WI-NRS Placebo: Seed= 878201528

6.1.6 Multicenter Studies

The clinical study will be conducted under a common protocol for each investigational site with the intention of pooling all the data for analysis. Every effort will be made to promote consistency in study execution at each study site.

6.1.7 Multiple Comparisons/Multiplicity

The primary and key secondary endpoints will be analyzed. However, the statistical significance of the key secondary endpoints will only be considered should statistical significance be reached for the primary endpoint. Similarly, statistical significance within the key secondary endpoints will be considered based on a hierarchical approach, starting with the WI-NRS Week 4 responder rate, then the Day 7 WI-NRS endpoint, and finally the Day 3 WI-NRS endpoint. If an endpoint fails to reach statistical significance at a level of 0.05, the subsequent endpoints will not be considered statistically significant.

6.1.8 Examination of Subgroups

Not applicable to this study.

6.2 Disposition of Subjects

An accounting of all randomized subjects by disposition will be presented. Subjects who discontinue study drug prematurely or withdraw from the study will be summarized and listed, with a description of the reason for early termination/withdrawal.

The number of subjects included in each population will be summarized. Subjects who are excluded from a population will be summarized by the reasons for exclusion.

6.3 Protocol Deviations

Protocol deviations leading to exclusion from an analysis population will be tabulated. Other protocol deviations will be presented in a data listing.

6.4 Data Sets Analyzed

The following analysis populations will be reviewed and approved by the Sponsor prior to unblinding the study.

6.4.1 Full Analysis Set (FAS) Population

Primary efficacy analyses will be based upon an intent-to-treat (ITT) philosophy. The primary efficacy population will be the Full Analysis Set (FAS), which will include all randomized subjects who received at least one dose of study drug. Subjects will be analyzed within the treatment group to which they are randomized.

6.4.2 Safety Population

The primary safety population will be all treated subjects with at least one post-baseline assessment or a reported TEAE. For safety analyses, subjects will be classified based upon treatment received. In the case that a subject received both treatments, subjects will summarized within the serlopitant 5 mg group.

6.4.3 Per-Protocol Population

Additional analyses performed on the Per-Protocol (PP) population will be considered supportive. The PP population will include all subjects in the safety population who complete the Week 8 evaluations without any significant protocol deviations (i.e., any subject or investigator activity that could have possibly interfered with the therapeutic administration of the treatment of the precise evaluation of treatment efficacy). The PP population will include subjects in the safety population who do not meet any of the following criteria:

- Violated the inclusion/exclusion criteria;
- Received a strong CYP3A4 inhibitor (See Appendix B in the Protocol);
- Received an excluded medication which may plausibly impact the primary endpoint at Week 8;
- Have not been compliant with the dosing regimen (i.e. subjects must compy with 80-120% of the expected dosage of study medication during participation in the study);
- Have not completed Week 8 visit within ±7 days window
- Have not completed the eDiary to provide the Week 8 WI-NRS Primary Endpoint

Subjects who discontinue from the study drug due to an adverse event related to study treatment or documented lack of treatment effect, or who met protocol-defined non-responder criteria, will be included in the PP population. Prior to breaking the blind other additional criteria may be added to the lists above to accommodate for unforeseen events that occurred during the conduct of the trial that result in noteworthy study protocol deviations.

Subjects will be analyzed within the treatment group to which they are randomized.

6.5 Demographic and Other Baseline Characteristics

All baseline summaries will be done for the FAS, Safety, and PP populations.

Sex, race, and ethnicity will be summarized by counts and percentages. Age, height (cm), and weight (kg) will be summarized with descriptive statistics.

PGA, and sPGA will be summarized by counts and percentages. BSA (%), WI-NRS (average result measured over the week prior to treatment), Night-time Scratching Events, Sleep Efficiency, Mean Activity During Sleep Period, and PIQ will be summarized with descriptive statistics.

Medical histories will be coded using MedDRA, tabulated by System Organ Class and Preferred Term, and presented in a by-subject listing.

Psoriasis/pruritus histories and prior psoriasis/pruritus therapies will be presented in a by-subject listing.

6.6 Prior and Concomitant Medications

Prior and concomitant medications will be coded by the WHO-DDE to Anatomical Therapeutic Classification (ATC) and preferred drug name. Concomitant medications will be summarized by ATC level 2 term and preferred drug name.

A by-subject listing of all prior and concomitant medications will be presented. The associated by-subject listing will have a prior/concomitant determination that is based on the date of first dose.

6.7 Analysis of Efficacy

The efficacy endpoints will be summarized within the FAS and PP populations using descriptive statistics by time point and treatment. Results including averaged imputed values will be summarized at Baseline, Week 2, 4, 8 and Follow-up and the change from baseline for these measures will be summarized at Week 2, 4, 8 and Follow-up. The WI-NRS measures will also be summarized at Week 6. The WI-NRS and change from baseline will also be presented for each study day in a data listing. The PGIC is a measure of change and so will only be summarized at Week 2, 4, 8 and Follow-up.

For the 4- and 3-point responder rate endpoints, subjects will be considered responders if they have at least a 4- / 3-point reduction between baseline and the corresponding week. Subjects that were discontinued due to lack of efficacy or used an excluded medication to treat their pruritus or psoriasis will be considered non-responders.

6.7.1 Primary Efficacy Analysis

The difference in the primary efficacy outcome measure (WI-NRS 4-point responder rate at Week 8) will be tested using a CMH test controlling for the 'as randomized' stratification factors. Conceptually the hypotheses being tested are:

$$H_0: P_{Placebo} \geq P_{Serlopitant} \qquad H_a: P_{Placebo} < P_{Serlopitant}$$

where $P_{Placebo}$ is the percent of placebo responders and $P_{Serlopitant}$ is the similar percent for serlopitant.

6.7.2 Secondary Efficacy Analysis

The WI-NRS 4-point responder rate at Week 4 will be analyzed using methods consistent with testing the primary endpoint. The remaining key secondary endpoints will be analyzed using an analysis of covariance (ANCOVA) model with treatment group and stratification factor as fixed effects and the respective baseline values as a covariate. Both least squares means and observed means will be presented.

To confirm the assumptions for the ANCOVA model (i.e., that the errors are normally distributed with equal variances), residuals will be examined using the Shapiro-Wilk test. If there is overwhelmingly strong evidence that the assumptions are not satisfied, the data will be rank-transformed prior to submitting to the ANCOVA. Results of the rank-transformed analysis then will be considered the primary analysis; however, results of the non-rank transformed analysis will also be presented.

The preceding analyses are to be conducted for the FAS and PP populations.

6.8 Sensitivity Analysis

6.8.1 First Sensitivity Analysis

As a sensitivity analysis, missing values will be imputed using LOCF. Each primary and key secondary endpoint will be analyzed as it was using the multiply imputed data.

6.8.2 Second Sensitivity Analysis

As a second sensitivity analysis, repeated measures analyses will be used on observed data for the primary and key secondary endpoints.

Responder variables will be analyzed using a repeated measures logistic regression model (generalized estimating equations) with treatment group, stratification, and visit (i.e., Baseline, Days 2-7, and Weeks 2-8) as independent factors.

```
proc genmod data = datain;
  class SUBJECT TRT VISIT STRATA;
  model RESP = TRT STRATA VISIT TRT * VISIT / dist=bin link=logit;
  repeated subject = SUBJECT / type = cs;
  lsmeans TRT | VISIT / diff;
run;
```

Change from baseline variables will be analyzed using a repeated measures ANCOVA, with treatment group, stratification, and visit (i.e., Days 2-7, and Weeks 2-8) as independent factors and the baseline value as a covariate.

```
proc mixed data = datain method = ML;
  class SUBJECT TRT VISIT STRATA;
  model CHG = TRT STRATA VISIT TRT * VISIT BASE / solution;
  repeated VISIT / subject = SUBJECT type = cs;
  lsmeans TRT | VISIT / diff;
run;
```

6.9 Safety Evaluation

6.9.1 Extent of Exposure

The extent of exposure to study drug in each treatment group will be summarized by days with exposure and total number of tablets used.

A subject will be considered compliant with the dosing regimen if the subject takes 80% to 120% of the expected number of doses while enrolled in the study. Total number of days of exposure will be computed as follows:

Total Exposure = Date of Last Dose – Date of First Dose + 1

Total Doses = (Date of Last Dose – Date of First Dose + 1 + 2)

– Missed Doses + Extra Doses

Treatment compliance will be based on the expected number of doses given the treatment period duration. The number of expected doses will be computed from the Baseline/Day 1 visit date and the Week 8 visit date. If a subject does not have a Week 8 visit, the number of expected doses will be calculated based on end of treatment period date given available information (e.g., date of last dose, last completed visit date).

Expected Doses = End of Treatment Period Date – Day 1 Date + 2

If the subject is documented as dosing on the End of Treatment Period Date, a dose will be added to the Expected Doses. To allow for the +7 day window around Week 8 that is used for defining PP population, if the number of expected doses exceeds 66, the number of expected doses will be considered 66 doses.

Percent compliance will be calculated from total number of doses and total number of expected doses as follows:

Percent Compliance = 100*(Total Doses/Expected Doses).

Percent compliance will not be calculated for subjects who are lost to follow-up during the treatment period.

6.9.2 Adverse Events

The incidence of all AEs and TEAEs will be tabulated by treatment received. These AEs will be classified by system organ class and preferred term using MedDRA. For incidence reporting, if a subject reported more than one AE that was coded to the same system organ class or preferred term, the subject will be counted only once for the specific system organ class or preferred term. An overview of AEs, which includes subject incidence of AEs, treatment-related AEs, AEs by severity, SAEs, deaths, and AEs leading to discontinuation, will be presented.

SAEs will be listed and summarized in a similar manner to AEs.

6.9.3 Clinical Laboratory Evaluation

Clinical safety laboratory values will be measured by a central laboratory. Summary statistics for actual values and for changes from baseline will be tabulated for laboratory results by scheduled visit.

Subjects with clinical laboratory values outside of the normal reference range at any post-baseline assessment will be summarized. Shifts from baseline laboratory values will be tabulated, with the exception of those for reproductive endocrinology laboratory values.

By-subject listings of all laboratory data, as well as abnormal laboratory results, will be presented.

6.9.4 Other Observations Related to Safety

6.9.4.1 ECG Measurements

Summary statistics for actual values and for changes from baseline will be tabulated for ECG parameter results by scheduled visit. The overall ECG assessment (abnormal or normal) will be summarized along with a summary of how many subjects developed a post treatment abnormal result. The study relevance of the finding (i.e. clinical significance as determined by the investigator) will be provided in a listing.

6.9.4.2 Vital Signs

The observed data and change from baseline for each measurement day will be summarized with descriptive statistics, as well as provided in a by-subject listing.

6.9.4.3 Physical Exams

Clinically significant physical exam findings will be recorded by the sites within medical history or adverse events and otherwise not summarized.

6.10 Pharmacokinetic Analysis

The plasma concentrations of serlopitant and metabolites will be reported in a PK report that will be a part of the clinical study report.

The plasma concentrations of serlopitant and metabolites will also be combined with the data from other serlopitant clinical studies for population PK analysis with PK endpoint of individual model parameter estimates and covariates identification. A specific population PK data analysis plan will be developed that will outline the detailed approach to data handling, model development and diagnostics, individual model parameter estimation, exploration of covariate effects, and final model evaluation techniques. The population PK analysis report will not be a part of the clinical study report.

By-subject listings of the plasma concentrations of serlopitant and metabolites will be presented.

7. DETERMINATION OF SAMPLE SIZE

The decision rule is based on the Phase 2b screening methodology presented in Fleming and Richardson (Fleming 2004). The two-category decision guideline as applied to this clinical trial compares the observed one-sided p-value for the primary endpoint to two categories: (0.025, 0.05) and (0, 0.025).

- If the one-sided p-value is between 2.5% and 5% then the serlopitant-based regimen is plausibly efficacious and should be evaluated definitively in a subsequent Phase 3 clinical trial.
- If the one-sided p-value is less than 2.5%, then the serlopitant-based regimen will have met the generally accepted level of evidence required to demonstrate efficacy.

The sample size of 100 per group has been selected to achieve 90% power for the primary endpoint with

- 5% one-sided alpha and responder rates of 24% (placebo) and 43.5% (serlopitant)
- 2.5% one-sided alpha and responder rates of 24% (placebo) and 46% (serlopitant)

The sample size calculations have been performed in PASS 13 ("PASS 13 Power Analysis and Sample Size Software" 2014) and use a Chi-Squared test. The primary analysis will control for the stratification factors. It is expected that this unstratified power estimate will under-estimate the true power as it does not take the variance reduction resulting from stratification into account (Matts 1988).

8. CHANGES IN THE PLANNED ANALYSES

No graphs of laboratory values over time will be created.

9. REFERENCES

Fleming TR, Richardson BA. Some design issues in trials of microbicides for the prevention of HIV infection. *J Infect Dis*. 2004;190(4):666-674.

Matts JP LJ. Properties of permuted-block randomization in clinical trials. *Control ClinTrials*. 1988;9(4):327-344.

PASS 13 Power Analysis and Sample Size Software [computer program]. Kaysville, Utah, USA, ncss.com/software/pass.: NCSS, LLC; 2014.

10. INDEX OF PLANNED END-OF-TEXT TABLES

Table 14.0.1: Summary of Subject Completion/Discontinuation
(Randomized Subjects)

	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Completed Treatment		
Yes	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)
Reason for Discontinuation from Treatment		
Adverse Event	xx (xx.x%)	xx (xx.x%)
Lost to Follow-Up	xx (xx.x%)	xx (xx.x%)
Pregnancy	xx (xx.x%)	xx (xx.x%)
Protocol Deviation	xx (xx.x%)	xx (xx.x%)
Use of Excluded Medication for Pruritus or Psoriasis	xx (xx.x%)	xx (xx.x%)
Use of Strong CYP3A4 Inhibitors	xx (xx.x%)	xx (xx.x%)
Other Protocol Deviation	xx (xx.x%)	xx (xx.x%)
Withdrawal by Subject	xx (xx.x%)	xx (xx.x%)
Investigator Decision	xx (xx.x%)	xx (xx.x%)
Other	xx (xx.x%)	xx (xx.x%)
Completed Follow-up/Study		
Yes	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)
Reason for Discontinuation from Follow-up/Study		
Withdrawal by Subject	xx (xx.x%)	xx (xx.x%)
Study Burden	xx (xx.x%)	xx (xx.x%)
Lack of Efficacy	xx (xx.x%)	xx (xx.x%)
Adverse Event	xx (xx.x%)	xx (xx.x%)
Other	xx (xx.x%)	xx (xx.x%)
Lost to Follow-up	xx (xx.x%)	xx (xx.x%)

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.0.2: Summary of Subjects Excluded from Analyses
(Randomized Subjects)

	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Number of Subjects Included in the Full Analysis Set	xx (xx.x%)	xx (xx.x%)
Number of Subjects Excluded from the Full Analysis Set	xx (xx.x%)	xx (xx.x%)
Reason for Exclusion from the Full Analysis Set		
No Evidence of Subject Dosing	xx (xx.x%)	xx (xx.x%)
Number of Subjects Included in the Safety Population	xx (xx.x%)	xx (xx.x%)
Number of Subjects Excluded from the Safety Population	xx (xx.x%)	xx (xx.x%)
Reason for Exclusion from the Safety Population		
No Evidence of Subject Dosing	xx (xx.x%)	xx (xx.x%)
No Post Baseline Assessment	xx (xx.x%)	xx (xx.x%)
Number of Subjects Included in the Per-Protocol Population	xx (xx.x%)	xx (xx.x%)
Number of Subjects Excluded from the Per-Protocol Population	xx (xx.x%)	xx (xx.x%)
Reason for Exclusion from the Per-Protocol Population		
No Evidence of Subject Dosing	xx (xx.x%)	xx (xx.x%)
No Post Baseline Assessment	xx (xx.x%)	xx (xx.x%)
Violated the Inclusion/Exclusion Criteria	xx (xx.x%)	xx (xx.x%)
Received a Strong CYP3A4 Inhibitor	xx (xx.x%)	xx (xx.x%)
Received an Excluded Medication	xx (xx.x%)	xx (xx.x%)
Has not been Compliant with the Dosing Regimen	xx (xx.x%)	xx (xx.x%)
Week 8 WI-NRS Data Not Available	xx (xx.x%)	xx (xx.x%)
Did not Attend the Week 8 Visit	xx (xx.x%)	xx (xx.x%)
Week 8 Visit not within +/- 7 days Window	xx (xx.x%)	xx (xx.x%)

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.1.1.1: Summary of Subject Demographics
(Full Analysis Set)
(Page 1 of 2)

	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)	Total (N=xxx)
Age (years)			
n	xxx	xxx	xxx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Sex			
n	xxx	xxx	xxx
Male	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Female	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Ethnicity			
n	xxx	xxx	xxx
Hispanic or Latino	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Not Hispanic or Latino	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Race			
n	xxx	xxx	xxx
American Indian or Alaska Native	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Asian	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Black or African American	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Native Hawaiian or Other Pacific Islander	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
White	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Multiple/Other	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.1.1.1: Summary of Subject Demographics
(Full Analysis Set)
(Page 2 of 2)

	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)	Total (N=xxx)
Height (cm)			
n	xxx	xxx	xxx
Mean	xxx.x	xxx.x	xxx.x
SD	xxx.xx	xxx.xx	xxx.xx
Median	xxx.x	xxx.x	xxx.x
Min. to Max.	xxx to xxx	xxx to xxx	xxx to xxx
Weight (kg)			
n	xxx	xxx	xxx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.1.1.1 for the following:

Table 14.1.1.2: Summary of Subject Demographics (Per-Protocol Population)
Table 14.1.1.3: Summary of Subject Demographics (Safety Population)

Table 14.1.2.1: Subject Baseline Characteristics
(Full Analysis Set)
(Page 1 of 3)

	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)	Total (N=xxx)
Baseline WI-NRS (1-Week Average Prior to Baseline)			
n	xxx	xxx	xxx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Night-time Scratching Events			
n	xxx	xxx	xxx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Sleep Efficiency			
n	xxx	xxx	xxx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Mean Activity During Sleep Period			
n	xxx	xxx	xxx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.1.2.1: Subject Baseline Characteristics
(Full Analysis Set)
(Page 2 of 3)

	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)	Total (N=xxx)
Patient-Reported Outcomes Measurement Information System Itch Questionnaire (PIQ) – General			
n	xxx	xxx	xxx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
PIQ – Scratching Behavior			
n	xxx	xxx	xxx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
PIQ – Mood and Sleep			
n	xxx	xxx	xxx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
PIQ – Activity and Clothing			
n	xxx	xxx	xxx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.1.2.1: Subject Baseline Characteristics
(Full Analysis Set)
(Page 3 of 3)

	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)	Total (N=xxx)
Static Patient Global Assessment (sPGA) of Itch Severity			
n	xxx	xxx	xxx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Very Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Body Surface Area Involving Plaque Psoriasis (%)			
n	xxx	xxx	xxx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Physician Global Assessment (PGA) of Psoriasis			
n	xxx	xxx	xxx
0 – Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 – Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 – Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 – Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 – Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
5 – Very Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.1.2.1 for the following:
Table 14.1.2.2: Subject Baseline Characteristics (Per-Protocol Population)
Table 14.1.2.3: Subject Baseline Characteristics (Safety Population)

Table 14.1.3: Summary of Medical History by MedDRA System Organ Class and Preferred Term
(Full Analysis Set)
(Page 1 of xx)

System Organ Class[a] Preferred Term	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)	Total (N=xxx)
System Organ Class	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
System Organ Class	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] Counts reflect numbers of subjects reporting one or more medical histories that map to MedDRA. At each level of summarization (System Organ Class or Preferred Term) subjects are counted once.
Note: MedDRA Version 20.1.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.1.4: Summary of Concomitant Medications by ATC Level 2 Term and Preferred Drug Name
(Full Analysis Set)
(Page 1 of xx)

ATC Level 2 Term[a] Preferred Drug Name	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)	Total (N=xxx)
ATC Level 2 Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Drug Name	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Drug Name	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Drug Name	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Drug Name	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Drug Name	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Drug Name	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Drug Name	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Drug Name	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
ATC Level 2 Term			
Preferred Drug Name	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Drug Name	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Drug Name	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Drug Name	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] Counts reflect numbers of subjects reporting one or more concomitant medications that map to the WHO-DDE. At each level of summarization (ATC Level 2 Term or Standard Medication Name) subjects are counted once.
Note: WHO Drug Dictionary Enhanced, Format B3, Version March 1, 2017.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.1.1: Analysis of the Primary Efficacy Endpoint: Worst-Itch Numeric Rating Score (WI-NRS) Responder at Week 8
(Full Analysis Set)

	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)	P-value[a]
At Least 4-Point Reduction in Weekly Average WI-NRS at Week 8			
Success	xx.xx	xx.xx	x.xxx
Failure	xx.xx	xx.xx	

[a] One-sided p-value from a Cochran Mantel Haenszel (CMH) test stratified by Baseline WI-NRS used for randomization stratification. Value has been adjusted for multiple imputation.

Note: Summary statistics represent average values, obtained by averaging the summary statistics generated from each imputed dataset. Multiple imputation (MCMC) used to impute missing values.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.2.1.1 for the following:

Table 14.2.1.2: Primary Efficacy Analysis: Worst-Itch Numeric Rating Score (WI-NRS) Responder at Week 8 (Per-Protocol Population)

Table 14.2.1.3: Sensitivity Analyses of the Primary Efficacy Endpoint: Worst-Itch Numeric Rating Score (WI-NRS) Responder at Week 8
(Full Analysis Set)

	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)	P-value
Missing Values Imputed using Last Observation Carried Forward (LOCF)			
At Least 4-Point Reduction in Weekly Average WI-NRS at Week 8			
Success	xx (xx.x%)	xx (xx.x%)	x.xxx[a]
Failure	xx (xx.x%)	xx (xx.x%)	
Repeated Measures Analysis on Observed Data			
At Least 4-Point Reduction in Weekly Average WI-NRS at Week 8			
Success	xx.xx	xx.xx	x.xxx[b]
Failure	xx.xx	xx.xx	

[a] One-sided p-value from a Cochran Mantel Haenszel (CMH) test stratified by Baseline WI-NRS randomization stratification.
[b] One-sided p-value from a repeated measures logistic regression with factors of treatment group, randomization stratification, visit and treatment group by visit interaction.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.1: Analysis of Key Secondary Efficacy Endpoints
(Full Analysis Set)

	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)	Normality P-Value	Treatment P-Value
At Least 4-Point Reduction in Weekly Average Worst Itch Numeric Rating Scale (WI-NRS) at Week 4				
Success	xx.x%	xx.x%	N/A	x.xxx[a]
Failure	xx.x%	xx.x%		
WI-NRS – Absolute Change from Baseline to Day 7				
LS Mean[b]	x.xx	x.xx	x.xxx[c]	x.xxx[b]
LS SD[b]	x.xxx	x.xxx		x.xxx[e]
Median[d]	x.xx	x.xx		
Min. to Max.[d]	x.x to x.x	x.x to x.x		
WI-NRS – Absolute Change from Baseline to Day 3				
LS Mean[b]	x.xx	x.xx	x.xxx[c]	x.xxx[b]
LS SD[b]	x.xxx	x.xxx		x.xxx[e]
Median[d]	x.xx	x.xx		
Min. to Max.[d]	x.x to x.x	x.x to x.x		

[a] One-sided p-value from a Cochran Mantel Haenszel (CMH) test stratified by Baseline WI-NRS used for randomization stratification. Value has been adjusted for multiple imputation.
[b] One-sided p-values, least squares means and standard deviations from an analysis of covariance (ANCOVA) with treatment group and stratification factor as fixed effects, and baseline value as a covariate. Values have been adjusted for multiple imputation.
[c] P-value from a Shapiro-Wilk test for normality. Average p-value across imputations is presented.
[d] Median, minimum and maximum represent average values, obtained from averaging the summary statistics generated from each imputed dataset.
[e] One-sided p-value from a ranked analysis of covariance (ANCOVA) with treatment group and stratification factor as fixed effects, and baseline value as a covariate. Value has been adjusted for multiple imputation.
Note: Change calculated as follow-up – baseline.
Multiple imputation (MCMC) used to impute missing values.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)
Repeat Table 14.2.2.1 for the following:
Table 14.2.2.2: Analysis of Key Secondary Efficacy Endpoints (Per-Protocol Population)

Table 14.2.2.3: Sensitivity Analyses of Key Secondary Efficacy Endpoints
(Full Analysis Set)
(Page 1 of 2)

Missing Values Imputed using Last Observation Carried Forward (LOCF)	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)	Normality P-Value	Treatment P-Value
At Least 4-Point Reduction in Weekly Average Worst Itch Numeric Rating Scale (WI-NRS) at Week 4				
Success	xx (xx.x%)	xx (xx.x%)	N/A	x.xxx[a]
Failure	xx (xx.x%)	xx (xx.x%)		
WI-NRS – Absolute Change from Baseline to Day 7				
LS Mean[b]	x.xx	x.xx	x.xxx[c]	x.xxx[b]
LS SD[b]	x.xxx	x.xxx		x.xxx[d]
Median	x.xx	x.xx		
Min. to Max.	x.x to x.x	x.x to x.x		
WI-NRS – Absolute Change from Baseline to Day 3				
LS Mean[b]	x.xx	x.xx	x.xxx[c]	x.xxx[b]
LS SD[b]	x.xxx	x.xxx		x.xxx[d]
Median	x.xx	x.xx		
Min. to Max.	x.x to x.x	x.x to x.x		

[a] One-sided p-value from a Cochran Mantel Haenszel (CMH) test stratified by Baseline WI-NRS used for randomization stratification.
[b] One-sided p-values, least squares means and standard deviations from an analysis of covariance (ANCOVA) with treatment group and stratification factor as fixed effects, and baseline value as a covariate.
[c] P-value from a Shapiro-Wilk test for normality.
[d] One-sided p-value from a ranked analysis of covariance (ANCOVA) with treatment group and stratification factor as fixed effects, and baseline value as a covariate.
Note: Change calculated as follow-up – baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.3: Sensitivity Analyses of Key Secondary Efficacy Endpoints
(Full Analysis Set)
(Page 2 of 2)

Repeated Measures Analysis on Observed Data	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)	Normality P-Value	Treatment P-Value
At Least 4-Point Reduction in Weekly Average Worst Itch Numeric Rating Scale (WI-NRS) at Week 4				
Success	xx (xx.x%)	xx (xx.x%)	N/A	x.xxx[a]
Failure	xx (xx.x%)	xx (xx.x%)		
WI-NRS – Absolute Change from Baseline to Day 7				
LS Mean[b]	x.xx	x.xx	x.xxx[c]	x.xxx[b]
LS SD[b]	x.xxx	x.xxx		x.xxx[d]
Median	x.xx	x.xx		
Min. to Max.	x.x to x.x	x.x to x.x		
WI-NRS – Absolute Change from Baseline to Day 3				
LS Mean[b]	x.xx	x.xx	x.xxx[c]	x.xxx[b]
LS SD[b]	x.xxx	x.xxx		x.xxx[d]
Median	x.xx	x.xx		
Min. to Max.	x.x to x.x	x.x to x.x		

[a] One-sided p-value from a repeated measures logistic regression with factors of treatment group, randomization stratification, visit and treatment group by visit interaction..

[b] One-sided p-values, least squares means and standard deviations from a repeated measures analysis of covariance (ANCOVA) with treatment group and stratification factor as fixed effects, and baseline value as a covariate.

[c] P-value from a Shapiro-Wilk test for normality.

[d] One-sided p-value from a ranked repeated measures analysis of covariance (ANCOVA) with treatment group and stratification factor as fixed effects, and baseline value as a covariate.

Note: Change calculated as follow-up – baseline.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.3.1: Summary of Worst Itch Numeric Rating Scale (WI-NRS)
(Full Analysis Set)
(Page 1 of 8)

WI-NRS	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x

Note: Multiple imputation (MCMC) used to impute missing values. Summary statistics represent average values, obtained by averaging the summary statistics generated from each imputed dataset. Change calculated as follow-up – baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.3.1: Summary of Worst Itch Numeric Rating Scale (WI-NRS)
(Full Analysis Set)
(Page 2 of 8)

WI-NRS	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Day 2		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
>= 3 Point Reduction from Baseline	xx.xx%	xx.xx%
>= 4 Point Reduction from Baseline	xx.xx%	xx.xx%
Day 3		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
>= 3 Point Reduction from Baseline	xx.xx%	xx.xx%
>= 4 Point Reduction from Baseline	xx.xx%	xx.xx%

Note: Multiple imputation (MCMC) used to impute missing values. Summary statistics represent average values, obtained by averaging the summary statistics generated from each imputed dataset. Change calculated as follow-up – baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.3.1: Summary of Worst Itch Numeric Rating Scale (WI-NRS)
(Full Analysis Set)
(Page 3 of 8)

WI-NRS	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Day 4		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
>= 3 Point Reduction from Baseline	xx.xx%	xx.xx%
>= 4 Point Reduction from Baseline	xx.xx%	xx.xx%
Day 5		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
>= 3 Point Reduction from Baseline	xx.xx%	xx.xx%
>= 4 Point Reduction from Baseline	xx.xx%	xx.xx%

Note: Multiple imputation (MCMC) used to impute missing values. Summary statistics represent average values, obtained by averaging the summary statistics generated from each imputed dataset. Change calculated as follow-up – baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.3.1: Summary of Worst Itch Numeric Rating Scale (WI-NRS)
(Full Analysis Set)
(Page 4 of 8)

WI-NRS	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Day 6		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
>= 3 Point Reduction from Baseline	xx.xx%	xx.xx%
>= 4 Point Reduction from Baseline	xx.xx%	xx.xx%
Day 7		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
>= 3 Point Reduction from Baseline	xx.xx%	xx.xx%
>= 4 Point Reduction from Baseline	xx.xx%	xx.xx%

Note: Multiple imputation (MCMC) used to impute missing values. Summary statistics represent average values, obtained by averaging the summary statistics generated from each imputed dataset. Change calculated as follow-up – baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.3.1: Summary of Worst Itch Numeric Rating Scale (WI-NRS)
(Full Analysis Set)
(Page 5 of 8)

WI-NRS	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Week 2		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
>= 3 Point Reduction from Baseline	xx.xx%	xx.xx%
>= 4 Point Reduction from Baseline	xx.xx%	xx.xx%
Week 3		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
>= 3 Point Reduction from Baseline	xx.xx%	xx.xx%
>= 4 Point Reduction from Baseline	xx.xx%	xx.xx%

Note: Multiple imputation (MCMC) used to impute missing values. Summary statistics represent average values, obtained by averaging the summary statistics generated from each imputed dataset. Change calculated as follow-up – baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.3.1: Summary of Worst Itch Numeric Rating Scale (WI-NRS)
(Full Analysis Set)
(Page 6 of 8)

WI-NRS	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Week 4		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
>= 3 Point Reduction from Baseline	xx.xx%	xx.xx%
>= 4 Point Reduction from Baseline	xx.xx%	xx.xx%
Week 5		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
>= 3 Point Reduction from Baseline	xx.xx%	xx.xx%
>= 4 Point Reduction from Baseline	xx.xx%	xx.xx%

Note: Multiple imputation (MCMC) used to impute missing values. Summary statistics represent average values, obtained by averaging the summary statistics generated from each imputed dataset. Change calculated as follow-up – baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.3.1: Summary of Worst Itch Numeric Rating Scale (WI-NRS)
(Full Analysis Set)
(Page 7 of 8)

WI-NRS	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Week 6		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
>= 3 Point Reduction from Baseline	xx.xx%	xx.xx%
>= 4 Point Reduction from Baseline	xx.xx%	xx.xx%
Week 7		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
>= 3 Point Reduction from Baseline	xx.xx%	xx.xx%
>= 4 Point Reduction from Baseline	xx.xx%	xx.xx%

Note: Multiple imputation (MCMC) used to impute missing values. Summary statistics represent average values, obtained by averaging the summary statistics generated from each imputed dataset. Change calculated as follow-up – baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.3.1: Summary of Worst Itch Numeric Rating Scale (WI-NRS)
(Full Analysis Set)
(Page 8 of 8)

WI-NRS	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Week 8		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
>= 3 Point Reduction from Baseline	xx.xx%	xx.xx%
>= 4 Point Reduction from Baseline	xx.xx%	xx.xx%
Follow-up (Observed Data)		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
>= 3 Point Reduction from Baseline	xx.xx%	xx.xx%
>= 4 Point Reduction from Baseline	xx.xx%	xx.xx%

Note: Multiple imputation (MCMC) used to impute missing values. Summary statistics represent average values, obtained by averaging the summary statistics generated from each imputed dataset. Change calculated as follow-up – baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.2.3.1 for the following:

Table 14.2.3.2: Summary of Worst Itch Numeric Rating Scale (WI-NRS) (Per-Protocol Population)

Table 14.2.4.1: Summary of Night-Time Scratching Events
(Full Analysis Set)
(Page 1 of 5)

Night-Time Scratching Events	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Week 1		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x

Note: No imputation of missing values. Change calculated as post-baseline – baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.4.1: Summary of Night-Time Scratching Events
(Full Analysis Set)
(Page 2 of 5)

Night-Time Scratching Events	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Week 2		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Week 3		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x

Note: No imputation of missing values. Change calculated as post-baseline – baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.4.1: Summary of Night-Time Scratching Events
(Full Analysis Set)
(Page 3 of 5)

Night-Time Scratching Events	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Week 4		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Week 5		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x

Note: No imputation of missing values. Change calculated as post-baseline – baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.4.1: Summary of Night-Time Scratching Events
(Full Analysis Set)
(Page 4 of 5)

Night-Time Scratching Events	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Week 6		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Week 7		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x

Note: No imputation of missing values. Change calculated as post-baseline – baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.4.1: Summary of Night-Time Scratching Events
(Full Analysis Set)
(Page 5 of 5)

Night-Time Scratching Events	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Week 8		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Follow-up		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x

Note: No imputation of missing values. Change calculated as post-baseline – baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.2.4.1 for the following:

Table 14.2.4.2: Summary of Night-Time Scratching Events (Per-Protocol Population)

Table 14.2.5.1: Summary of Sleep Efficiency
(Full Analysis Set)
(Page 1 of 5)

Sleep Efficiency	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Week 1		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x

Note: No imputation of missing values. Change calculated as post-baseline – baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.5.1: Summary of Sleep Efficiency
(Full Analysis Set)
(Page 2 of 5)

Sleep Efficiency	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Week 2		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Week 3		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x

Note: No imputation of missing values. Change calculated as post-baseline – baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.5.1: Summary of Sleep Efficiency
(Full Analysis Set)
(Page 3 of 5)

Sleep Efficiency	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Week 4		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Week 5		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x

Note: No imputation of missing values. Change calculated as post-baseline – baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.5.1: Summary of Sleep Efficiency
(Full Analysis Set)
(Page 4 of 5)

Sleep Efficiency	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Week 6		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Week 7		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x

Note: No imputation of missing values. Change calculated as post-baseline – baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.5.1: Summary of Sleep Efficiency
(Full Analysis Set)
(Page 5 of 5)

Sleep Efficiency	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Week 8		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Follow-up		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x

Note: No imputation of missing values. Change calculated as post-baseline – baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.2.5.1 for the following:

Table 14.2.5.2: Summary of Sleep Efficiency (Per-Protocol Population)

Table 14.2.6.1: Summary of Mean Activity During the Sleep Period
(Full Analysis Set)
(Page 1 of 5)

Mean Activity During the Sleep Period	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Week 1		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x

Note: No imputation of missing values. Change calculated as post-baseline – baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.6.1: Summary of Mean Activity During the Sleep Period
(Full Analysis Set)
(Page 2 of 5)

Mean Activity During the Sleep Period	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Week 2		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Week 3		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x

Note: No imputation of missing values. Change calculated as post-baseline – baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.6.1: Summary of Mean Activity During the Sleep Period
(Full Analysis Set)
(Page 3 of 5)

Mean Activity During the Sleep Period	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Week 4		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Week 5		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x

Note: No imputation of missing values. Change calculated as post-baseline – baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.6.1: Summary of Mean Activity During the Sleep Period
(Full Analysis Set)
(Page 4 of 5)

Mean Activity During the Sleep Period	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Week 6		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Week 7		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x

Note: No imputation of missing values. Change calculated as post-baseline – baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.6.1: Summary of Mean Activity During the Sleep Period
(Full Analysis Set)
(Page 5 of 5)

Mean Activity During the Sleep Period	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Week 8		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Follow-up		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x

Note: No imputation of missing values. Change calculated as post-baseline – baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.2.6.1 for the following:

Table 14.2.6.2: Summary of Mean Activity During the Sleep Period (Per-Protocol Population)

Table 14.2.7.1: Summary of Static Patient Global Assessment (sPGA) of Itch Severity
(Full Analysis Set)
(Page 1 of 4)

sPGA of Itch Severity	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Baseline		
n	xx	xx
None	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)
Very Severe	xx (xx.x%)	xx (xx.x%)
Week 2		
n	xx	xx
None	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)
Very Severe	xx (xx.x%)	xx (xx.x%)
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x

Note: No imputation of missing values. Change calculated as post-baseline – baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.7.1: Summary of Static Patient Global Assessment (sPGA) of Itch Severity
(Full Analysis Set)
(Page 2 of 4)

sPGA of Itch Severity	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Week 4		
n	xx	xx
None	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)
Very Severe	xx (xx.x%)	xx (xx.x%)
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x

Note: No imputation of missing values. Change calculated as post-baseline – baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.7.1: Summary of Static Patient Global Assessment (sPGA) of Itch Severity
(Full Analysis Set)
(Page 3 of 4)

sPGA of Itch Severity	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Week 8		
n	xx	xx
None	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)
Very Severe	xx (xx.x%)	xx (xx.x%)
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x

Note: No imputation of missing values. Change calculated as post-baseline – baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.7.1: Summary of Static Patient Global Assessment (sPGA) of Itch Severity
(Full Analysis Set)
(Page 4 of 4)

sPGA of Itch Severity	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Follow-up		
n	xx	xx
None	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)
Very Severe	xx (xx.x%)	xx (xx.x%)
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x

Note: No imputation of missing values. Change calculated as post-baseline – baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.2.7.1 for the following:

Table 14.2.7.2: Summary of Static Patient Global Assessment (sPGA) of Itch Severity (Per-Protocol Population)

Table 14.2.8.1: Summary of Patient Global Impression of Change (PGIC) in Itch Severity
(Full Analysis Set)
(Page 1 of 2)

PGIC in Itch Severity	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Week 2		
n	xx	xx
Very much better	xx (xx.x%)	xx (xx.x%)
Moderately better	xx (xx.x%)	xx (xx.x%)
A little better	xx (xx.x%)	xx (xx.x%)
No change	xx (xx.x%)	xx (xx.x%)
A little worse	xx (xx.x%)	xx (xx.x%)
Moderately worse	xx (xx.x%)	xx (xx.x%)
Very much worse	xx (xx.x%)	xx (xx.x%)
Week 4		
n	xx	xx
Very much better	xx (xx.x%)	xx (xx.x%)
Moderately better	xx (xx.x%)	xx (xx.x%)
A little better	xx (xx.x%)	xx (xx.x%)
No change	xx (xx.x%)	xx (xx.x%)
A little worse	xx (xx.x%)	xx (xx.x%)
Moderately worse	xx (xx.x%)	xx (xx.x%)
Very much worse	xx (xx.x%)	xx (xx.x%)

Note: No imputation of missing values.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.8.1: Summary of Patient Global Impression of Change (PGIC) in Itch Severity
(Full Analysis Set)
(Page 2 of 2)

PGIC in Itch Severity	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Week 8		
n	xx	xx
Very much better	xx (xx.x%)	xx (xx.x%)
Moderately better	xx (xx.x%)	xx (xx.x%)
A little better	xx (xx.x%)	xx (xx.x%)
No change	xx (xx.x%)	xx (xx.x%)
A little worse	xx (xx.x%)	xx (xx.x%)
Moderately worse	xx (xx.x%)	xx (xx.x%)
Very much worse	xx (xx.x%)	xx (xx.x%)
Follow-up		
n	xx	xx
Very much better	xx (xx.x%)	xx (xx.x%)
Moderately better	xx (xx.x%)	xx (xx.x%)
A little better	xx (xx.x%)	xx (xx.x%)
No change	xx (xx.x%)	xx (xx.x%)
A little worse	xx (xx.x%)	xx (xx.x%)
Moderately worse	xx (xx.x%)	xx (xx.x%)
Very much worse	xx (xx.x%)	xx (xx.x%)

Note: No imputation of missing values.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.2.8.1 for the following:

Table 14.2.8.2: Summary of Patient Global Impression of Change (PGIC) in Itch Severity (Per-Protocol Population)

Table 14.2.9.1: Summary of Physician Global Assessment (PGA) of Psoriasis
(Full Analysis Set)
(Page 1 of 4)

PGA of Psoriasis	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Baseline		
n	xx	xx
0 – Clear	xx (xx.x%)	xx (xx.x%)
1 – Almost Clear	xx (xx.x%)	xx (xx.x%)
2 – Mild	xx (xx.x%)	xx (xx.x%)
3 – Moderate	xx (xx.x%)	xx (xx.x%)
4 – Severe	xx (xx.x%)	xx (xx.x%)
5 – Very Severe	xx (xx.x%)	xx (xx.x%)
Week 2		
n	xx	xx
0 – Clear	xx (xx.x%)	xx (xx.x%)
1 – Almost Clear	xx (xx.x%)	xx (xx.x%)
2 – Mild	xx (xx.x%)	xx (xx.x%)
3 – Moderate	xx (xx.x%)	xx (xx.x%)
4 – Severe	xx (xx.x%)	xx (xx.x%)
5 – Very Severe	xx (xx.x%)	xx (xx.x%)
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x

Note: No imputation of missing values. Change calculated as post-baseline – baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.9.1: Summary of Physician Global Assessment (PGA) of Psoriasis
(Full Analysis Set)
(Page 2 of 4)

PGA of Psoriasis	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Week 4		
n	xx	xx
0 – Clear	xx (xx.x%)	xx (xx.x%)
1 – Almost Clear	xx (xx.x%)	xx (xx.x%)
2 – Mild	xx (xx.x%)	xx (xx.x%)
3 – Moderate	xx (xx.x%)	xx (xx.x%)
4 – Severe	xx (xx.x%)	xx (xx.x%)
5 – Very Severe	xx (xx.x%)	xx (xx.x%)
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x

Note: No imputation of missing values. Change calculated as post-baseline – baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.9.1: Summary of Physician Global Assessment (PGA) of Psoriasis
(Full Analysis Set)
(Page 3 of 4)

PGA of Psoriasis	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Week 8		
n	xx	xx
0 – Clear	xx (xx.x%)	xx (xx.x%)
1 – Almost Clear	xx (xx.x%)	xx (xx.x%)
2 – Mild	xx (xx.x%)	xx (xx.x%)
3 – Moderate	xx (xx.x%)	xx (xx.x%)
4 – Severe	xx (xx.x%)	xx (xx.x%)
5 – Very Severe	xx (xx.x%)	xx (xx.x%)
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x

Note: No imputation of missing values. Change calculated as post-baseline – baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.9.1: Summary of Physician Global Assessment (PGA) of Psoriasis
(Full Analysis Set)
(Page 4 of 4)

PGA of Psoriasis	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Follow-up		
n	xx	xx
0 – Clear	xx (xx.x%)	xx (xx.x%)
1 – Almost Clear	xx (xx.x%)	xx (xx.x%)
2 – Mild	xx (xx.x%)	xx (xx.x%)
3 – Moderate	xx (xx.x%)	xx (xx.x%)
4 – Severe	xx (xx.x%)	xx (xx.x%)
5 – Very Severe	xx (xx.x%)	xx (xx.x%)
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x

Note: No imputation of missing values. Change calculated as post-baseline – baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.2.9.1 for the following:

Table 14.2.9.2: Summary of Physician Global Assessment (PGA) of Psoriasis (Per-Protocol Population)

Table 14.2.10.1: Summary of Body Surface Area (BSA) Involving Plaque Psoriasis
(Full Analysis Set)
(Page 1 of 3)

BSA Involving Plaque Psoriasis (%)	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Week 2		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x

Note: No imputation of missing values. Change calculated as post-baseline – baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.10.1: Summary of Body Surface Area (BSA) Invoving Plaque Psoriasis
(Full Analysis Set)
(Page 2 of 3)

BSA Involving Plaque Psoriasis (%)	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Week 4		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Week 8		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x

Note: No imputation of missing values. Change calculated as post-baseline – baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.10.1: Summary of Body Surface Area (BSA) Invoving Plaque Psoriasis
(Full Analysis Set)
(Page 3 of 3)

BSA Involving Plaque Psoriasis (%)	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Follow-up		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x

Note: No imputation of missing values. Change calculated as post-baseline – baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.2.10.1 for the following:

Table 14.2.10.2: Summary of Body Surface Area (BSA) Involving Plaque Psoriasis (Per-Protocol Population)

Table 14.2.11.1.1: Summary of Patient-Reported Outcomes Measurement Information System Itch Questionnaire (PIQ) – General
(Full Analysis Set)
(Page 1 of 2)

PIQ – General	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Week 4		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x

Note: No imputation of missing values. Change calculated as post-baseline – baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.11.1.1: Summary of Patient-Reported Outcomes Measurement Information System Itch Questionnaire (PIQ) - General
(Full Analysis Set)
(Page 2 of 2)

PIQ - General	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Week 8		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Follow-up		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x

Note: No imputation of missing values. Change calculated as post-baseline – baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.2.11.1.1 for the following:

Table 14.2.11.1.2: Summary of Patient-Reported Outcomes Measurement Information System Itch Questionnaire (PIQ) - General (Per-Protocol Population)

Table 14.2.11.2.1: Summary of Patient-Reported Outcomes Measurement Information System Itch Questionnaire (PIQ) – Scratching Behavior
(Full Analysis Set)
(Page 1 of 2)

PIQ – Scratching Behavior	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Week 4		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x

Note: No imputation of missing values. Change calculated as post-baseline – baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.11.2.1: Summary of Patient-Reported Outcomes Measurement Information System Itch Questionnaire (PIQ) – Scratching Behavior
(Full Analysis Set)
(Page 2 of 2)

PIQ – Scratching Behavior	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Week 8		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Follow-up		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x

Note: No imputation of missing values. Change calculated as post-baseline – baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.2.11.2.1 for the following:
Table 14.2.11.2.2: Summary of Patient-Reported Outcomes Measurement Information System Itch Questionnaire (PIQ) – Scratching Behavior (Per-Protocol Population)

Table 14.2.11.3.1: Summary of Patient-Reported Outcomes Measurement Information System Itch Questionnaire (PIQ) – Mood and Sleep
(Full Analysis Set)
(Page 1 of 2)

PIQ – Mood and Sleep	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Week 4		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x

Note: No imputation of missing values. Change calculated as post-baseline – baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.11.3.1: Summary of Patient-Reported Outcomes Measurement Information System Itch Questionnaire (PIQ) – Mood and Sleep
(Full Analysis Set)
(Page 2 of 2)

PIQ – Mood and Sleep	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Week 8		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Follow-up		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x

Note: No imputation of missing values. Change calculated as post-baseline – baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.2.11.3.1 for the following:
Table 14.2.11.3.2: Summary of Patient-Reported Outcomes Measurement Information System Itch Questionnaire (PIQ) – Mood and Sleep (Per-Protocol Population)

Table 14.2.11.4.1: Summary of Patient-Reported Outcomes Measurement Information System Itch Questionnaire (PIQ) –Activity and Clothing
(Full Analysis Set)
(Page 1 of 2)

PIQ – Activitiy and Clothing	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Week 4		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x

Note: No imputation of missing values. Change calculated as post-baseline – baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.11.4.1: Summary of Patient-Reported Outcomes Measurement Information System Itch Questionnaire (PIQ) –Activity and Clothing
(Full Analysis Set)
(Page 2 of 2)

PIQ – Activity and Clothing	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Week 8		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Follow-up		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x
Absolute Change from Baseline		
n	xxx	xxx
Mean	x.xx	x.xx
SD	x.xxx	x.xxx
Median	x.xx	x.xx
Min. to Max.	x.x to x.x	x.x to x.x

Note: No imputation of missing values. Change calculated as post-baseline – baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.2.11.4.1 for the following:
Table 14.2.11.4.2: Summary of Patient-Reported Outcomes Measurement Information System Itch Questionnaire (PIQ) – Activity and Clothing (Per-Protocol Population)

Table 14.3.0.1: Summary of Extent of Exposure
(Full Analysis Set)

	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Total Number of Tablets Used		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Total Number of Days of Exposure		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Compliant[a]		
n	xx	xx
Yes	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)

[a] A subject was considered compliant with the dosing regimen if the subject took at least 80% but no more than 120% of expected doses.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Repeat Table 14.3.0.1 for the following:

Table 14.3.0.2: Summary of Extent of Exposure (Per-Protocol Population)
Table 14.3.0.3: Summary of Extent of Exposure (Safety Population)

Table 14.3.1.1.1: Overall Summary of Treatment-Emergent Adverse Event (TEAEs)
(Safety Population)

	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Subjects with any TEAE	xx (xx.x%)	xx (xx.x%)
Number of TEAEs	xx	xx
Subjects with any Related TEAE	xx (xx.x%)	xx (xx.x%)
Number of Related TEAEs	xx	xx
Subjects with any Serious TEAE	xx (xx.x%)	xx (xx.x%)
Number of Serious TEAEs	xx	xx
Subjects with any Related Serious TEAE	xx (xx.x%)	xx (xx.x%)
Number of Related Serious TEAEs	xx	xx
Subjects who Died	xx (xx.x%)	xx (xx.x%)
Subjects who Discontinued Study Drug Due to TEAE	xx (xx.x%)	xx (xx.x%)
Subjects who Discontinued Study Due to TEAE	xx (xx.x%)	xx (xx.x%)
Maximum Severity by Subject		
Grade 5	xx (xx.x%)	xx (xx.x%)
Grade 4	xx (xx.x%)	xx (xx.x%)
Grade 3	xx (xx.x%)	xx (xx.x%)
Grade 2	xx (xx.x%)	xx (xx.x%)
Grade 1	xx (xx.x%)	xx (xx.x%)
Maximum Relationship by Subject		
Likely Related	xx (xx.x%)	xx (xx.x%)
Likely Unrelated	xx (xx.x%)	xx (xx.x%)

Note: TEAEs are AEs with an onset after first dose of study drug.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.1.2: Summary of Subjects Reporting Treatment-Emergent Adverse Events (TEAEs) by MedDRA System Organ Class and Preferred Term
(Safety Population)
(Page 1 of xx)

System Organ Class[a] Preferred Term	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Total	xx (xx.x%)	xx (xx.x%)
System Organ Class	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)

[a] Counts reflect numbers of subjects reporting one or more TEAEs that map to MedDRA. At each level of summarization (System Organ Class or Preferred Term) subjects are counted once.

Note: TEAEs are AEs with an onset date after first dose of study drug.
MedDRA Version 20.1.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.1.3: Summary of Treatment-Emergent Adverse Events (TEAEs) Leading to Discontinuation of Study Drug
(Safety Population)
(Page 1 of xx)

System Organ Class[a] Preferred Term	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Total	xx (xx.x%)	xx (xx.x%)
System Organ Class	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)

[a] Counts reflect numbers of subjects reporting one or more TEAEs that map to MedDRA. At each level of summarization (System Organ Class or Preferred Term) subjects are counted once.

Note: TEAEs are AEs with an onset date after first dose of study drug.
MedDRA Version 20.1.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.1.4: Summary of Subjects Reporting Treatment-Emergent Adverse Events (TEAEs) by Severity
(Safety Population)
(Page 1 of xx)

System Organ Class[a] Preferred Term	Severity[b]	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Total	Grade 5	xx (xx.x%)	xx (xx.x%)
	Grade 4	xx (xx.x%)	xx (xx.x%)
	Grade 3	xx (xx.x%)	xx (xx.x%)
	Grade 2	xx (xx.x%)	xx (xx.x%)
	Grade 1	xx (xx.x%)	xx (xx.x%)
System Organ Class	Grade 5	xx (xx.x%)	xx (xx.x%)
	Grade 4	xx (xx.x%)	xx (xx.x%)
	Grade 3	xx (xx.x%)	xx (xx.x%)
	Grade 2	xx (xx.x%)	xx (xx.x%)
	Grade 1	xx (xx.x%)	xx (xx.x%)
Preferred Term	Grade 5	xx (xx.x%)	xx (xx.x%)
	Grade 4	xx (xx.x%)	xx (xx.x%)
	Grade 3	xx (xx.x%)	xx (xx.x%)
	Grade 2	xx (xx.x%)	xx (xx.x%)
	Grade 1	xx (xx.x%)	xx (xx.x%)

[a] Counts reflect numbers of subjects reporting one or more TEAEs that map to MedDRA. At each level of summarization (System Organ Class or Preferred Term) subjects are counted once under the greatest reported severity.
[b] Grade 1 = Mild; Grade 2 = Moderate; Grade 3 = Severe; Grade 4 = Life Threatening; Grade 5 = Death.
Note: TEAEs are AEs with an onset after first dose of study drug.
MedDRA Version 20.1.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.1.5: Summary of Subjects Reporting Treatment-Emergent Adverse Events (TEAEs) by Relationship to Study Drug
(Safety Population)
(Page 1 of xx)

System Organ Class[a] Preferred Term	Relationship	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Total	Likely Related	xx (xx.x%)	xx (xx.x%)
	Likely Unrelated	xx (xx.x%)	xx (xx.x%)
System Organ Class	Likely Related	xx (xx.x%)	xx (xx.x%)
	Likely Unrelated	xx (xx.x%)	xx (xx.x%)
Preferred Term	Likely Related	xx (xx.x%)	xx (xx.x%)
	Likely Unrelated	xx (xx.x%)	xx (xx.x%)
Preferred Term	Likely Related	xx (xx.x%)	xx (xx.x%)
	Likely Unrelated	xx (xx.x%)	xx (xx.x%)

[a] Counts reflect numbers of subjects reporting one or more TEAEs that map to MedDRA. At each level of summarization (System Organ Class or Preferred Term) subjects are counted once under the greatest reported relationship.

Note: TEAEs are AEs with an onset after first dose of study drug.
MedDRA Version 20.1.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.2.1: Summary of Subjects Reporting Serious Treatment-Emergent Adverse Events (TEAEs) by MedDRA System Organ Class and Preferred Term
(Safety Population)
(Page 1 of xx)

System Organ Class[a] Preferred Term	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Total	xx (xx.x%)	xx (xx.x%)
System Organ Class	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)

[a] Counts reflect numbers of subjects reporting one or more TEAEs that map to MedDRA. At each level of summarization (System Organ Class or Preferred Term) subjects are counted once.

Note: TEAEs are AEs with an onset date after first dose of study drug.
MedDRA Version 20.1.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.2.2: Summary of Subjects Reporting Serious Treatment-Emergent Adverse Events (TEAEs) by Severity
(Safety Population)
(Page 1 of xx)

System Organ Class[a] Preferred Term	Severity	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Total	Grade 5	xx (xx.x%)	xx (xx.x%)
	Grade 4	xx (xx.x%)	xx (xx.x%)
	Grade 3	xx (xx.x%)	xx (xx.x%)
	Grade 2	xx (xx.x%)	xx (xx.x%)
	Grade 1	xx (xx.x%)	xx (xx.x%)
System Organ Class	Grade 5	xx (xx.x%)	xx (xx.x%)
	Grade 4	xx (xx.x%)	xx (xx.x%)
	Grade 3	xx (xx.x%)	xx (xx.x%)
	Grade 2	xx (xx.x%)	xx (xx.x%)
	Grade 1	xx (xx.x%)	xx (xx.x%)
Preferred Term	Grade 5	xx (xx.x%)	xx (xx.x%)
	Grade 4	xx (xx.x%)	xx (xx.x%)
	Grade 3	xx (xx.x%)	xx (xx.x%)
	Grade 2	xx (xx.x%)	xx (xx.x%)
	Grade 1	xx (xx.x%)	xx (xx.x%)

[a] Counts reflect numbers of subjects reporting one or more serious TEAEs that map to MedDRA. At each level of summarization (System Organ Class or Preferred Term) subjects are counted once under the greatest reported severity.
[b] Grade 1 = Mild; Grade 2 = Moderate; Grade 3 = Severe; Grade 4 = Life Threatening; Grade 5 = Death.
Note: TEAEs are AEs with an onset after first dose of study drug.
MedDRA Version 20.1.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.2.3: Summary of Subjects Reporting Serious Treatment-Emergent Adverse Events (TEAEs) by Relationship to Study Drug
(Safety Population)
(Page 1 of xx)

System Organ Class[a] Preferred Term	Relationship	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Total	Likely Related	xx (xx.x%)	xx (xx.x%)
	Likely Unrelated	xx (xx.x%)	xx (xx.x%)
System Organ Class	Likely Related	xx (xx.x%)	xx (xx.x%)
	Likely Unrelated	xx (xx.x%)	xx (xx.x%)
Preferred Term	Likely Related	xx (xx.x%)	xx (xx.x%)
	Likely Unrelated	xx (xx.x%)	xx (xx.x%)
Preferred Term	Likely Related	xx (xx.x%)	xx (xx.x%)
	Likely Unrelated	xx (xx.x%)	xx (xx.x%)

[a] Counts reflect numbers of subjects reporting one or more TEAEs that map to the MedDRA. At each level of summarization (System Organ Class or Preferred Term) subjects are counted once under the greatest reported relationship.

Note: TEAEs are AEs with an onset after first dose of study drug.
MedDRA Version 20.1.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.3.1.1: Summary of Hematology Laboratory Results
(Safety Population)
(Page 1 of xx)

	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
<Test Name> (<units>)		
Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Week 4		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Absolute Change from Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx

Note: No imputation of missing values. Baseline is the latest recorded value prior to first dose of study drug. Change calculated as post-baseline – baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table to include post-baseline visits of "Week 4", "Week 8", "Follow-up".

Table 14.3.1.3.1.2: Shift Summary of Hematology Laboratory Results
(Safety Population)
(Page 1 of xx)

<Test Name> (<units>)		Placebo (N=xxx)			Serlopitant 5 mg (N=xxx)		
		Week 4			Week 4		
	Baseline	BNL	WNL	ANL	BNL	WNL	ANL
	BNL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	WNL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	ANL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		Week 8			Week 8		
	Baseline	BNL	WNL	ANL	BNL	WNL	ANL
	BNL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	WNL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	ANL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		Follow-up			Follow-up		
	Baseline	BNL	WNL	ANL	BNL	WNL	ANL
	BNL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	WNL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	ANL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: BNL=Below Normal Limit, WNL=Within Normal Limits, ANL=Above Normal Limit.
No imputation of missing values. Baseline is the latest recorded value prior to first dose of study drug.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.3.2.1: Summary of Chemistry Laboratory Results
(Safety Population)
(Page 1 of xx)

	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
<Test Name> (<units>)		
Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Week 4		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Absolute Change from Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx

Note: No imputation of missing values. Baseline is the latest recorded value prior to first dose of study drug. Change calculated as post-baseline – baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table to include post-baseline visits of "Week 4", "Week 8", "Follow-up".

Table 14.3.1.3.2.2: Shift Summary of Chemistry Laboratory Results
(Safety Population)
(Page 1 of xx)

<Test Name> (<units>)		Placebo (N=xxx)			Serlopitant 5 mg (N=xxx)		
		Week 4			Week 4		
	Baseline	BNL	WNL	ANL	BNL	WNL	ANL
	BNL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	WNL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	ANL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		Week 8			Week 8		
	Baseline	BNL	WNL	ANL	BNL	WNL	ANL
	BNL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	WNL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	ANL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		Follow-up			Follow-up		
	Baseline	BNL	WNL	ANL	BNL	WNL	ANL
	BNL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	WNL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	ANL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: BNL=Below Normal Limit, WNL=Within Normal Limits, ANL=Above Normal Limit.
No imputation of missing values. Baseline is the latest recorded value prior to first dose of study drug.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.3.3.1: Summary of Quantitative Urinalysis Laboratory Results
(Safety Population)
(Page 1 of xx)

	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
<Test Name> (<units>)		
Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Week 4		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Absolute Change from Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx

Note: No imputation of missing values. Baseline is the latest recorded value prior to first dose of study drug. Change calculated as post-baseline – baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table to include post-baseline visits of "Week 4", "Week 8", "Follow-up".

Table 14.3.1.3.3.2: Shift Summary of Quantitative Urinalysis Laboratory Results
(Safety Population)
(Page 1 of xx)

<Test Name> (<units>)		Placebo (N=xxx)			Serlopitant 5 mg (N=xxx)		
		Week 4			Week 4		
	Baseline	BNL	WNL	ANL	BNL	WNL	ANL
	BNL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	WNL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	ANL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		Week 8			Week 8		
	Baseline	BNL	WNL	ANL	BNL	WNL	ANL
	BNL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	WNL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	ANL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		Follow-up			Follow-up		
	Baseline	BNL	WNL	ANL	BNL	WNL	ANL
	BNL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	WNL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	ANL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: BNL=Below Normal Limit, WNL=Within Normal Limits, ANL=Above Normal Limit.
No imputation of missing values. Baseline is the latest recorded value prior to first dose of study drug.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.3.4.1: Summary of Categorical Urinalysis Laboratory Results
(Safety Population)
(Page 1 of xx)

<Test Name> (<units>)	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Baseline		
n	xx	xx
Category1	xx (xx.x%)	xx (xx.x%)
Category2	xx (xx.x%)	xx (xx.x%)
Category3	xx (xx.x%)	xx (xx.x%)
Category4	xx (xx.x%)	xx (xx.x%)
Week 4		
n	xx	xx
Category1	xx (xx.x%)	xx (xx.x%)
Category2	xx (xx.x%)	xx (xx.x%)
Category3	xx (xx.x%)	xx (xx.x%)
Category4	xx (xx.x%)	xx (xx.x%)

Note: No imputation of missing values. Baseline is the latest recorded value prior to first dose of study drug.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table to include post-baseline visits of "Week 4", "Week 8", "Follow-up".

Table 14.3.1.3.4.2: Shift Summary of Categorical Urinalysis Laboratory Results
(Safety Population)
(Page 1 of xx)

<Test Name> (<units>)		Placebo (N=xxx)		Serlopitant 5 mg (N=xxx)	
		Week 4		Week 4	
Baseline		Normal	Abnormal	Normal	Abnormal
Normal		xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Abnormal		xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		Week 8		Week 8	
Baseline		Normal	Abnormal	Normal	Abnormal
Normal		xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Abnormal		xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		Follow-up		Follow-up	
Baseline		Normal	Abnormal	Normal	Abnormal
Normal		xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Abnormal		xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: No imputation of missing values. Baseline is the latest recorded value prior to first dose of study drug.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.3.5.1: Summary of Endocrine/Reproductive Endocrine Laboratory Results
(Safety Population)
(Page 1 of xx)

	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
<Test Name> (<units>)		
Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Week 8		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Absolute Change from Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx

Note: No imputation of missing values. Baseline is the latest recorded value prior to first dose of study drug. Change calculated as post-baseline – baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table to include post-baseline visits of "Week 8", "Follow-up".

Table to include following lab tests: "TSH ULTRASENSITIVE", "THYROXINE, FREE", "CORTISOL, SERUM RANDOM", "ACTH, PLASMA", "ANTI-MULLERIAN HORMONE", "FSH", "ESTRADIOL", "LUTEINIZING HORMONE", "PROGESTERONE".

Table 14.3.1.3.5.2: Shift Summary of Endocrine/Reproductive Endocrine Laboratory Results
(Safety Population)
(Page 1 of xx)

<Test Name> (<units>)		Placebo (N=xxx)			Serlopitant 5 mg (N=xxx)		
		Week 8			Week 8		
	Baseline	BNL	WNL	ANL	BNL	WNL	ANL
	BNL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	WNL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	ANL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		Follow-up			Follow-up		
	Baseline	BNL	WNL	ANL	BNL	WNL	ANL
	BNL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	WNL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	ANL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: BNL=Below Normal Limit, WNL=Within Normal Limits, ANL=Above Normal Limit.
No imputation of missing values. Baseline is the latest recorded value prior to first dose of study drug.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table to include following lab tests: "TSH ULTRASENSITIVE", "THYROXINE, FREE", "CORTISOL, SERUM RANDOM", "ACTH, PLASMA", "ANTI-MULLERIAN HORMONE".

Table 14.3.1.4.1: Summary of Treatment-Emergent Electrocardiogram (ECG) Parameter Abnormalities
(Safety Population)
(Page 1 of 2)

	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Number of Subjects with Treatment-Emergent ECG Results	xxx	xxx
PR Interval		
> 200 msec	xx (xx.x%)	xx (xx.x%)
> 220 msec	xx (xx.x%)	xx (xx.x%)
Change from Baseline in PR Interval		
>= 25% and > 200 msec	xx (xx.x%)	xx (xx.x%)
QRS Interval		
> 110 msec	xx (xx.x%)	xx (xx.x%)
> 120 msec	xx (xx.x%)	xx (xx.x%)
Change from Baseline in QRS Interval		
>= 25% and > 110 msec	xx (xx.x%)	xx (xx.x%)
>= 25% and > 120 msec	xx (xx.x%)	xx (xx.x%)
QTcF Interval		
> 450 - 470 msec	xx (xx.x%)	xx (xx.x%)
> 470 - 500 msec	xx (xx.x%)	xx (xx.x%)
> 500 msec	xx (xx.x%)	xx (xx.x%)
Change from Baseline in QTcF Interval		
> 30 - 60 msec	xx (xx.x%)	xx (xx.x%)
> 60 msec	xx (xx.x%)	xx (xx.x%)
QTcF Interval > 500 msec and Change from Baseline > 60 msec	xx (xx.x%)	xx (xx.x%)

Note: No imputation of missing values. Baseline is the latest recorded value prior to first dose of study drug. Change calculated as post-baseline – baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.4.1: Summary of Treatment-Emergent Electrocardiogram (ECG) Abnormalities
(Safety Population)
(Page 2 of 2)

	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
Number of Subjects with Treatment-Emergent ECG Results	xxx	xxx
QTcB Interval		
> 450 - 470 msec	xx (xx.x%)	xx (xx.x%)
> 470 - 500 msec	xx (xx.x%)	xx (xx.x%)
> 500 msec	xx (xx.x%)	xx (xx.x%)
Change from Baseline in QTcB Interval		
> 30 - 60 msec	xx (xx.x%)	xx (xx.x%)
> 60 msec	xx (xx.x%)	xx (xx.x%)
QTcB Interval > 500 msec and Change from Baseline > 60 msec	xx (xx.x%)	xx (xx.x%)

Note: No imputation of missing values. Baseline is the latest recorded value prior to first dose of study drug. Change calculated as post-baseline – baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.4.2: Summary of Electrocardiogram Parameters
(Safety Population)
(Page 1 of xx)

	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
<Parameter> (<units>)		
Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Week 4		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Absolute Change from Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx

Note: No imputation of missing values. Baseline is the latest recorded value prior to first dose of study drug. Change calculated as post-baseline – baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table to include parameters "ECG Mean Heart Rate (beats/min)", "PR Interval, Aggregate (msec)", "QRS Duration, Aggregate (msec)", "QT Interval, Aggregate (msec)", "QTcB Interval, Aggregate (msec)", "QTcF Interval, Aggregate (msec)", "RR Interval, Aggregate (msec)".

Table to include post-baseline visits of "Week 4", "Follow-up".

Table 14.3.1.4.3: Shift Summary of Overall Electrocardiogram (ECG) Assessments
(Safety Population)

Overall ECG Assessment (per Investigator)	Placebo (N=xxx)		Serlopitant 5 mg (N=xxx)	
	Week 4		Week 4	
Baseline	Normal	Abnormal	Normal	Abnormal
Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Abnormal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Follow-up		Follow-up	
Baseline	Normal	Abnormal	Normal	Abnormal
Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Abnormal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: No imputation of missing values. Baseline is the latest recorded value prior to first dose of study drug.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.5: Summary of Vital Signs
(Safety Population)
(Page 1 of xx)

	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
<Parameter> (<units>)		
Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Week 2		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Absolute Change from Baseline		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx

Note: Baseline is the latest recorded value prior to first dose of study drug. Change calculated as post-baseline – baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table to include parameters in following order: "Temperature (degrees Celsius)", "Respiration Rate (breaths/min)", "Heart Rate (beats/min)", "Systolic Blood Pressure (mmHg)", "Diastolic Blood Pressure (mmHg)".

Table to include post-baseline visits of "Week 2", "Week 4", Week 8, "Follow-up".

Table 14.3.1.6: Summary of Pharmacokinetic Concentrations
(Safety Population)

	Placebo (N=xxx)	Serlopitant 5 mg (N=xxx)
<Analyte> (<units>)		
Week 4		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx
Week 8		
n	xx	xx
Mean	xx.x	xx.x
SD	xx.xx	xx.xx
Median	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx

Note: No imputation of missing values.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

11. INDEX OF PLANNED LISTINGS

Listing 16.1.7: Randomization Scheme
(Page xx of yy)

Subject	Age/Sex	Evaluable	Randomization Strata	Randomization Date	Assigned Treatment Group	Was the subject previously a Screen Fail?	Previous Screening Subject Number
xxxxxx	xxxx	xxxxxxxxx	xxxx	xxxxxxxxxx	xxxxxxx xxxxxx	xxx	xxxxxx
xxxxxx	xxxx	xxxxxxxxx	xxxx	xxxxxxxxxx	xxxxxxx xxxxxx	xxx	xxxxxx
xxxxxx	xxxx	xxxxxxxxx	xxxx	xxxxxxxxxx	xxxxxxx xxxxxx	xxx	xxxxxx

Note: FAS = Full Analysis Set; S = Safety Population; PP = Per-Protocol Population.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject.

Listing 16.2.1.1: Subject Disposition Information
Treatment Group
(Page xx of yy)

S: Subject A: Age/Sex E: Evaluable	F: Date of First Dose L: Date of Last Dose	R: Reason for Treatment Discontinuation P: Primary AE Number/Specify	E: Study Discontinuation Date (Day)[1] R: Reason for Study Discontinuation	D: Date of Last Contact P: Primary AE Number/Specify
S: xxxxxx A: xxxx E: xxxxxxxxx	F: xxxx-xx-xx L: xxxx-xx-xx	R: xxxxxxxxxx xx xxxxxxxxxxxxxx P: xxxxxxxxxx	E: xxxx-xx-xx (xx) R: xxxxxxxxxx xx xxxxxxxxxx	D: xxxx-xx-xx P: xxxxxxxxxxx
S: xxxxxx A: xxxx E: xxxxxxxxx	F: xxxx-xx-xx L: xxxx-xx-xx	R: xxxxxxxxxx xx xxxxxxxxxxxxxx P: xxxxxxxxxx	E: xxxx-xx-xx (xx) R: xxxxxxxxxx xx xxxxxxxxxx	D: xxxx-xx-xx P: xxxxxxxxxxx
S: xxxxxx A: xxxx E: xxxxxxxxx	F: xxxx-xx-xx L: xxxx-xx-xx	R: xxxxxxxxx xxxx xxxxxxxx xxxxx P: xxxxxxxxxx	E: xxxx-xx-xx (xx) R: xxxx xx xxxxxxxxx	D: P: xxxxxxxxxxx

[1] Day is calculated as date – date of first dose for dates prior to first dose. Otherwise, day is calculated as date – date of first dose + 1 for dates on or after first dose.
Note: FAS = Full Analysis Set; S = Safety Population; PP = Per-Protocol Population.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject.

Listing 16.2.1.2: Discontinued Subjects
Treatment Group
(Page xx of yy)

S: Subject A: Age/Sex E: Evaluable	F: Date of First Dose L: Date of Last Dose	R: Reason for Treatment Discontinuation P: Primary AE Number/Specify	E: Study Discontinuation Date (Day)[1] R: Reason for Study Discontinuation	D: Date of Last Contact P: Primary AE Number/Specify
S: xxxxxx A: xxxx E: xxxxxxxxx	F: xxxx-xx-xx L: xxxx-xx-xx	R: xxxxxxxxxx xx xxxxxxxxxxxxxx P: xxxxxxxxxx	E: xxxx-xx-xx (xx) R: xxxxxxxxxx xx xxxxxxxxxx	D: xxxx-xx-xx P: xxxxxxxxxxx
S: xxxxxx A: xxxx E: xxxxxxxxx	F: xxxx-xx-xx L: xxxx-xx-xx	R: xxxxxxxxxx xx xxxxxxxxxxxxxx P: xxxxxxxxxx	E: xxxx-xx-xx (xx) R: xxxxxxxxxx xx xxxxxxxxxx	D: xxxx-xx-xx P: xxxxxxxxxxx
S: xxxxxx A: xxxx E: xxxxxxxxx	F: xxxxxxxxxx L: xxxxxxxxxx	R: xxxxxxxxx xxxx xxxxxxxx xxxxx P: xxxxxxxxxx	E: xxxx-xx-xx (xx) R: xxxx xx xxxxxxxxx	D: P: xxxxxxxxxxx

[1] Day is calculated as date – date of first dose for dates prior to first dose. Otherwise, day is calculated as date – date of first dose + 1 for dates on or after first dose.
Note: FAS = Full Analysis Set; S = Safety Population; PP = Per-Protocol Population.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject.

Listing 16.2.1.3: Screen Failures
(Page x of xx)

Subject	Age/Sex	Screen Failure Date	Screen Failure Reason	Inclusion/Exclusion Criterion Failed	Inclusion/Exclusion Description
xxxxxx	xxxx	xxxx-xx-xx	xxx xxxxx xx xxxx	xxxxx	xxxxx xxxx xxx xxx xxx xxxxx xxxx xxx xxx xxx xxxxx xxxx xxx xxx xxx
xxxxxx	xxxx	xxxx-xx-xx	xxx xxxxx xx xxxx	xxxxx	xxxxx xxxx xxx xxx xxx xxxxx xxxx xxx xxx xxx xxxxx xxxx xxx xxx xxx

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject, Screen Failure Date, Screen Failure Reason, and Criterion Failed.

Listing 16.2.2: Inclusion/Exclusion Criteria Not Met
Treatment Group
(Page xx of yy)

Subject	Age/Sex	Evaluable	Criterion Failed	Description
xxxxxx	xxxx	xxxxxxxxx	xxxxxx	xxxxx xxx xx xxxxxxxx xxxx xxxxxxxxxxxxxxxxxx xxxxxxxx
xxxxxx	xxxx	xxxxxxxxx	xxxxx	xxxxx xxx xx xxxxxxxx xxxx xxxxxxxxxxxxxxxxxx xxxxxxxx
xxxxxx	xxxx	xxxxxxxxx	xxxxx	xxxxx xxx xx xxxxxxxx xxxx xxxxxxxxxxxxxxxxxx xxxxxxxx
			xxxxx	xxxxx xxx xx xxxxxxxx xxxx xxxxxxxxxxxxxxxxxx xxxxxxxx
			xxxxx	xxxxx xxx xx xxxxxxxx xxxx xxxxxxxxxxxxxxxxxx xxxxxxxx xxxxxxxxxxxxx xxxxxxxxx x xxxxxxxxxxxxxxxx xxx

Note: FAS = Full Analysis Set; S = Safety Population; PP = Per-Protocol Population.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject and Criterion Failed.

Listing 16.2.3: Analysis Populations
Treatment Group
(Page xx of yy)

Subject	Age/Sex	Population	Included	Reason(s) Excluded	Exception(s)
xxxxxx	xxxx	Full Analysis Set	xxx		
		Safety	xxx		
		Per-Protocol	xx	xxxxxxxxxxx xxxxxxx xxxxxxxxx xxxxxxxxxxx xxxxxxx xxxxxxxxx	
xxxxxx	xxxx	Full Analysis Set	xxx		
		Safety	xxx		
		Per-Protocol	xx	xxxxxxxxxxx xxxxxxx xxxxxxxxx xxxxxxxxxxx xxxxxxx xxxxxxxxx	xxxxxxxxxxx xxxxxxx xxxxxxxxx
xxxxxx	xxxx	Full Analysis Set	xxx		
		Safety	xx	xxxxxxxxxxx xxxxxxx xxxxxxxxx	
		Per-Protocol	xx	xxxxxxxxxxx xxxxxxx xxxxxxxxx xxxxxxxxxxx xxxxxxx xxxxxxxxx	

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject and Population (as ordered above).

Listing 16.2.4.1: Subject Demographic Information
Treatment Group
(Page xx of yy)

Subject	Evaluable	B: Date of Birth A: Age S: Sex	R: Race E: Ethnicity	C: Childbearing Potential M: Method of Contraception	P: Protocol Version I: Informed Consent Date	Did Subject Require Washout?
xxxxxx	xxxxxxxxx	B: xxxx-xx-xx A: xx S: xxxxxx	R: xxxxxx xxxxxxxx xx xxxxx xxxxxxx xxxxxxxx xxxxxxxxxx E: xxx xxxxxxxx xx xxxxxx	C: xxx M: xxxxxxxxx xxxxxxxxxx xxxxxxxxxxxx xxxxxxxxxxx xxxx x xxxxxxxxxx xx xxxxxxxxx xxxxxxxxxx xxxx xxxxxxx	P: xxxxxxxxxx I: xxxx-xx-xx	xxx
xxxxxx	xxxxxxxxx	B: xxxx-xx-xx A: xx S: xxxx	R: xxxxx E: xxxxxxxx xx xxxxxx	C: xx M:	P: xxxxxxxxxx I: xxxx-xx-xx	xxx
xxxxxx	xxxxxxxxx	B: xxxx-xx-xx A: xx S: xxxxxx	R: xxxxx E: xxxxxxxx xx xxxxxx	C: xxx M: xxxxxxxx xxxxxxxxxxxxx	P: xxxxxxxxxx I: xxxx-xx-xx	xxx

Note: FAS = Full Analysis Set; S = Safety Population; PP = Per-Protocol Population.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject.

Listing 16.2.4.2.1: Unique Medical History Coded to MedDRA System Organ Classes and Preferred Terms
(Page xx of yy)

MedDRA System Organ Class	MedDRA Preferred Term	Medical History Verbatim Term
xxxx xxx xxxxx	xxxx xxx xxxxx	xxxx
		xxxxxx xxxxxxxxxx xx xxxxxx
		xxxxxx xxxxxxxxxx xx xxxxx
xxxx xxx xxxxx	xxxx xxx xxxxx	xxxx
		xxxxxx xxxxxxxxxx xx xxxxxx
		xxxxxx xxxxxxxxxx xx xxxxx

Note: System Organ Class and Preferred Term map to the MedDRA dictionary (Version 20.1).
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by MedDRA System Organ Class, MedDRA Preferred Term, and Medical History Verbatim Term.

Listing 16.2.4.2.2: Medical History
Treatment Group
(Page xx of yy)

Subject	Age/Sex	Evaluable	Condition/Surgery Verbatim Term	P: MedDRA Preferred Term S: MedDRA System Organ Class	S: Onset Date E: End Date
xxxxxx	xxxx	xxxxxxxx	xxxxxx xxxxxxx (xxxxxxxx xxxxx)	P: xxxxxx xxxxxxxxxx S: xxxxxxxxxxx xxxxxxx	S: xxxx-xx-xx E:
			xxxxxxxx xxxxxxxxxx	P: xxxxxxx xxxxxxxx S: xxxxxx xxxxxxxxxxxxx	S: xxxx-xx E: xxxx-xx-xx

Note: FAS = Full Analysis Set; S = Safety Population; PP = Per-Protocol Population.
System Organ Class and Preferred Term map to MedDRA (Version 20.1).
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject, Medical Condition/Surgery Verbatim Term, Onset Date, and End Date.

Listing 16.2.4.3.1: Psoriasis/Pruritus History
Treatment Group
(Page xx of yy)

Subject	Age/Sex	Evaluable	Date of Plaque Psoriasis Diagnosis	Severity of Plaque Psoriasis at Screening Visit	Body Locations of Plaque Psoriasis	Body Locations of Pruritus
xxxxxx	xxxx	xxxxxxxx	xxxx-xx-xx	xxxxx xxxx xxxx x xxxxxx	xxxxxxxxx xxxxx; xxxxxx; xxxx xxx xxxx; xxxxxxxxx	xxxxxxxxx xxxxx; xxxxxxx; xxxx xxx xxxx; xxxxxxxxx
xxxxxx	xxxx	xxxxxxxx	xxxx-xx-xx	xxxx xx xxxx x xxxxxx	xxxxxxxxx xxxxx; xxxxx xxxxx; xxxxx; xxxxxxxxx	xxxxxxxxx xxxxx; xxxxx xxxxx; xxxxx; xxxxxxxxx

Note: FAS = Full Analysis Set; S = Safety Population; PP = Per-Protocol Population.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject.

Listing 16.2.4.3.2: Prior Psoriasis/Pruritus Therapies
Treatment Group
(Page xx of yy)

Subject	Age/Sex	Evaluable	Category of Therapy	Type of Therapy	Indication	S: Start Date E: End Date	Reason for Discontinuing Therapy
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxxxxxx	xxxxxxxxxxx xxxx	xxxx xxxxxxxxx xxx xxxx	S: xxxx-xx-xx E: xxxx-xx-xx	xxxx xx xxxxxxxx
			xxxxx	xxxxxx xxxxxxx	xxxx	S: xxxx-xx-xx E: xxxx-xx-xx	xxxxxxxxxxx
			xxxxxxxx xxxxx xxxxxxxx	xxxx xx xxxxxx	xxxxxxxxx	S: xxxx-xx-xx E: xxxx-xx-xx	xxxxxx

Note: FAS = Full Analysis Set; S = Safety Population; PP = Per-Protocol Population.
System Organ Class and Preferred Term map to MedDRA (Version 20.1).
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject, Category of Therapy, Type of Therapy, Start Date, and End Date.

Note to Programmer: Category of Therapy is one of 'INVESTIGATIONAL', 'PHOTO', 'SYSTEMIC SMALL MOLECULE', 'SYSTEMIC BIOLOGIC' or 'TOPICAL'. If Type of Therapy is 'Other', 'Bland Emollients' or 'Shampoos' then 'OTHER: <specification of other>, 'BLAND EMOLLIENTS: <specification of bland emollients>, or 'SHAMPOOS: <specification of shampoos> should be used.

Listing 16.2.4.4.1: Unique Medication Names Coded to WHO DDE ATC Level 2 Terms and Preferred Names
(Page xx of yy)

ATC Level 2 Term	Standardized Medication Name	Medication Name	I: Indication R: Route
xxxxxxxxxxxxxx	xxxxxxxxxxxxxx	xxxxxxxx	I: xxxxxxxxxxx R: xxxxxxxxxxx
		xxxxxxxxx	I: xxxxxxxxxxx R: xxxxxxxxxxx
xxxxxxxxxxxxxx	xxxxxxxxxxxxxx	xxxxxxxx	I: xxxxxxxxxxx R: xxxxxxxxxxx
		xxxxxxxxx	I: xxxxxxxxxxx R: xxxxxxxxxxx

Note: Standardized Medication Name and ATC Level 2 Term map to the WHO DDE (Version March 1, 2017).
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by ATC Level 2 Term, Standardized Medication Name, Medication Name, Indication, and Route.

Note to Programmer: If Indication or Route is 'Other' then the applicable variable is 'OTHER: <specification of other>'.

Listing 16.2.4.4.2: Prior and Concomitant Medications/Emollients
Treatment Group
(Page xx of yy)

Subject	Age/Sex	Evaluable	M: Medication Name P: Standardized Medication Name A: ATC Level 2 Term I: Indication	T: Prior/Concomitant F: Date of First Dose S: Start Date (Day)[1] E: End Date (Day)[1]	D: Dose U: Units F: Frequency R: Route
xxxxxx	xxxx	xxxxxxxxxx	M: xxxxxxxxxxxxx P: xxxxxxxxxxxxx A: xxxxxxxxxxxxx I: xxxxxxxx	T: xxxxxxxxxx F: xxxx-xx-xx S: xxxx-xx-xx (xx) E: xxxx-xx-xx (xx)	D: xx U: xx F: xxxx R: xxxxxx
			M: xxxxxxxxxxxxx P: xxxxxxxxxxxxx A: xxxxxxxxxxxxx I: xxxxxxxx	T: xxxxxxxxxx F: xxxx-xx-xx S: xxxx-xx E:	D: xxxxx U: xx F: xx R: xxxx
xxxxxx	xxxx	xxxxxxxxxx	M: xxxxxxxxxxxxx P: xxxxxxxxxxxxx A: xxxxxxxxxxxxx I: xxxxxxxx	T: xxxxxxxxxx F: xxxx-xx-xx S: xxxx-xx-xx (x) E: xxxx-xx-xx (xx)	D: xxx U: xx F: xx R: xxxx

[1] Day is calculated as date – date of first dose for dates prior to first dose. Otherwise, day is calculated as date – date of first dose + 1 for dates on or after first dose.
Note: FAS = Full Analysis Set; S = Safety Population; PP = Per-Protocol Population.
Standardized Medication Name and ATC Level 2 Term map to the WHO DDE (Version March 1, 2017).
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject, Start Date, End Date, Medication Name, Indication, and Route. If ongoing, include 'Ongoing' in place of End Date.

Note to Programmer: If Units, Frequency, Indication, or Route is 'Other' then the applicable variable is 'OTHER: <specification of other>'.

Listing 16.2.4.5: Prior and Concomitant Procedures/Therapies
Treatment Group
(Page xx of yy)

Subject	Age/Sex	Evaluable	Procedure/Therapy	F: Date of First Dose S: Start Date (Day)[1] E: End Date (Day)[1]	Reason for Procedure or Therapies
xxxxxx	xxxx	xxxxxxxxxx	xxxxxxxxxxxx	F: xxxx-xx-xx S: xxxx-xx-xx (xx) E: xxxx-xx-xx (xx)	x xxxxxx xxxx xxxxxx xxxxxxxxx
xxxxxx	xxxx	xxxxxxxxxx	xxxxxxxxxxxx	F: xxxx-xx-xx S: xxxx-xx E: xxxx-xx-xx (xx)	x xxxxxx xxxx xxxxxx xxxxxxxxx
xxxxxx	xxxx	xxxxxxxxxx	xxxxxxxxxxxx	F: xxxx-xx-xx S: xxxx-xx-xx (xx) E: xxxx-xx-xx (xx)	x xxxxxx xxxx xxxxxx xxxxxxxxx
				F: xxxx-xx-xx S: xxxx-xx-xx (xx) E: xxxx-xx-xx (xx)	x xxxxxx xxxx xxxxxx xxxxxxxxx

[1] Day is calculated as date – date of first dose for dates prior to first dose. Otherwise, day is calculated as date – date of first dose + 1 for dates on or after first dose.
Note: FAS = Full Analysis Set; S = Safety Population; PP = Per-Protocol Population.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject, Start Date, End Date, and Procedure/Therapy. If ongoing, include 'Ongoing' in place of End Date.

Listing 16.2.4.6: Physical Examination
Treatment Group
(Page x of xx)

Subject	Age/Sex	Evaluable	Visit	Date of Assessment (Day)[1]	Physical Exam Completed	Reason Not Done
xxxxxxxxxx	xxxx	xxxxxxxxx	xxxxxxxxxx	xxxx-xx-xx (xx)	xxxxxxxx	
xxxxxxxxxx	xxxx	xxxxxxxxx	xxxxxxxxxx	xxxx-xx-xx (xx)	xxxxxxxx	
xxxxxxxxxx	xxxx	xxxxxxxxx	xxxxxxxxxx	xxxx-xx-xx (xx)	xxxxxxxx	
xxxxxxxxxx	xxxx	xxxxxxxxx	xxxxxxxxxx	xxxx-xx-xx (x)	xxxxxxxx	
xxxxxxxxxx	xxxx	xxxxxxxxx	xxxxxxxxxx	xxxx-xx-xx (xx)	xxxxxxx	xxxxx xx xxx xxxx xxx xxxx
xxxxxxxxxx	xxxx	xxxxxxxxx	xxxxxxxxxx	xxxx-xx-xx (xx)	xxxxxxxx	

[1] Day is calculated as date – date of first dose for dates prior to first dose. Otherwise, day is calculated as date – date of first dose + 1 for dates on or after first dose.
Note: FAS = Full Analysis Set; S = Safety Population; PP = Per-Protocol Population.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject, Visit, and Date of Assessment.

Listing 16.2.5.1: Study Visit/Phone Call Compliance
Treatment Group
(Page xx of yy)

Subject	Age/Sex	Evaluable	Visit	Visit Date	Study Day[1]	Within Visit Window	Visit Not Done/ Reason for Unscheduled Visit
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxx	xxxx-xx-xx	xx	xxx	
			xxxxxxxx	xxxx-xx-xx	xx	xxx	
			xxxxxx	xxxx-xx-xx	xx	xxx	
			xxxxxx	xxxx-xx-xx	xx	xxx	x xxxx xxxxxxx x xxxxxx xxxxxxx xxxxx xxxxxx xx xxxx xxx xxxx xx xxx xxxx
			xxxxxx	xxxx-xx-xx	xx	xxx	
			xxxxxxxxxxxxxxx	xxxx-xx-xx	xx	xxx	
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxx	xxxx-xx-xx	xx	xxx	
			xxxxxx	xxxx-xx-xx	xx	xxx	
			xxxxxxxxxxxxxxx	xxxx-xx-xx	xx	xxx	

[1] Day is calculated as date – baseline date for dates prior to baseline date. Otherwise, day is calculated as date – baseline date + 1 for dates on or after baseline date.
Note: FAS = Full Analysis Set; S = Safety Population; PP = Per-Protocol Population.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject, Visit, and Visit Date.

Note to Programmer: If a visit is ranged present the 'Visit Date' column as '<Start Date> to <End Date>' same with the Study Day column.

Listing 16.2.5.2: Study Drug Dispensing and Return
Treatment Group
(Page xx of yy)

Subject	Age/Sex	Evaluable	Bottle Number	Date Bottle Dispensed	Date Bottle Returned	Number of Tablets Dispensed	Number of Tablets Returned	Tablets Used
xxxxxx	xxxx	xxxxxxxxx	xxxxxx	xxxx-xx-xx	xxxx-xx-xx	xx	xx	xx
			xxxxxx	xxxx-xx-xx	xxxx-xx-xx	xx	xx	xx
xxxxxx	xxxx	xxxxxxxxx	xxxxxx	xxxx-xx-xx	xxxx-xx-xx	xx	xx	xx
			xxxxxx	xxxx-xx-xx	xxxx-xx-xx	xx	xx	xx

Note: FAS = Full Analysis Set; S = Safety Population; PP = Per-Protocol Population.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject, Date Bottle Dispensed, and Date Bottle Returned.

Listing 16.2.5.3: Dosing and Meal Deviations
Treatment Group
(Page xx of yy)

Subject	Age/Sex	Evaluable	Date of Deviation	Type of Deviation	Number of Tablets Taken
xxxxxx	xxxx	xxxxxxxxx	xxxx-xx-xx	xxxxxx	xxxxxxxxxxxxxxxxxxxxx
xxxxxx	xxxx	xxxxxxxxx	xxxx-xx-xx	xxxxxx	x
			xxxx-xx-xx	xxxxxx	xxxxxxxxxxxxxxxxxxxxx
			xxxx-xx-xx	xxxxxx	xxxxxxxxxxxxxxxxxxxxx
			xxxx-xx-xx	xxxxxx	xxxxxxxxxxxxxxxxxxxxx
xxxxxx	xxxx	xxxxxxxxx	xxxx-xx-xx	xxxx	
			xxxx-xx-xx	xxxxxx	x

Note: FAS = Full Analysis Set; S = Safety Population; PP = Per-Protocol Population.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject, Date of Deviation, Type of Deviation, and Number of Tablets Taken.

Listing 16.2.6.1.1: Worst Itch Numeric Rating Scale (WI-NRS) at Screening
Treatment Group
(Page xx of yy)

Subject	Age/Sex	Evaluable	Date of Assessment (Day)[1]	WI-NRS[2] in the past 24 hours
xxxxxxxx	xxx	xxxxxxxxx	xxxx-xx-xx (xx)	xx
xxxxxxxx	xxx	xxxxxxxxx	xxxx-xx-xx (xx)	xx
xxxxxxxx	xxx	xxxxxxxxx	xxxx-xx-xx (xx)	xx
xxxxxxxx	xxx	xxxxxxxxx	xxxx-xx-xx (xx)	xx

[1] Day is calculated as date – date of first dose for dates prior to first dose. Otherwise, day is calculated as date – date of first dose + 1 for dates on or after first dose.
[2] Scaled from 0 - No Itch to 10 - Worst Itch Imaginable.
Note: FAS = Full Analysis Set; S = Safety Population; PP = Per-Protocol Population.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject and Date of Assessment.

Listing 16.2.6.1.2: Worst Itch Numeric Rating Scale (WI-NRS)
Treatment Group
(Page xx of yy)

Subject	Age/Sex	Evaluable	Timepoint	Date of Assessment (Day)[1]	WI-NRS in past 24 hrs[2]	Change from Baseline[3]
xxxxxx	xxx	xxxxxxxx		xxxx-xx-xxTxx:xx:xx (xxx)	x	
				xxxx-xx-xxTxx:xx:xx (xxx)	x	
				xxxx-xx-xxTxx:xx:xx (xxx)	x	
				xxxx-xx-xxTxx:xx:xx (xxx)	x	
				xxxx-xx-xxTxx:xx:xx (xxx)	x	
				xxxx-xx-xxTxx:xx:xx (xxx)	x	
			xxxxxxxx	xxxx-xx-xxTxx:xx:xx (xxx)	x	
			xxxxxxxx	xxxx-xx-xxTxx:xx:xx (xxx)	x	
			xxxxxxxx	xxxx-xx-xxTxx:xx:xx (xxx)	x	
			xxxxxxxx	xxxx-xx-xxTxx:xx:xx (xxx)	x	
			xxxxxxxx	Average	xxxxx	
			xxxxxxxx	xxxx-xx-xxTxx:xx:xx (xxx)	x	xxxx
			xxxxxxxx	xxxx-xx-xxTxx:xx:xx (xxx)	x	xxxx
			xxxxxxxx	xxxx-xx-xxTxx:xx:xx (xxx)	x	xxxx
			xxxxxxxx	xxxx-xx-xxTxx:xx:xx (xxx)	x	xxxx
			xxxxxxxx	Average	xxxxx	xxxx

[1] Day is calculated as date – date of first dose for dates prior to first dose. Otherwise, day is calculated as date – date of first dose + 1 for dates on or after first dose.
[2] Scaled from 0 – No Itch to 10 – Worst Itch Imaginable
[3] The WI-NRS Baseline is the average of the results for the week prior to starting the study drug (Timepoint = BASELINE).
Note: FAS = Full Analysis Set; S = Safety Population; PP = Per-Protocol Population.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject, Date of Assessment, Timepoint (where the Average over a given Timepoint is presented in the order above), and WI-NRS in past 24 hours.

Listing 16.2.6.2: Actigraphy Results
Treatment Group
(Page xx of yy)

		Sleep		Scratching	
S: Subject A: Age/Sex E: Evaluable	S: Start Date/Time E: End Date/Time	D: Duration (h) M: Mean (cts/min)	T: TST[1] (min) W: WASO[2] (min) E: Efficiency	F: Time of First Event L: Time of Last Event	N: Number of Events D: Duration of Events H: Events per Hour
S: xxxxxx A: xxxx E: xxxxxxxx	S: xxxx-xx-xxTxx:xx:xx E: xxxx-xx-xxTxx:xx:xx	D: xx.xx M: xxx.xx	T: xxx W: xxx E: xx.xx	F: xxxxxxxx L: xxxxxxxx	N: xxx D: xxxx.xx H: xx.xx
	S: xxxx-xx-xxTxx:xx:xx E: xxxx-xx-xxTxx:xx:xx	D: xx.xx M: xxx.xx	T: xxx W: xxx E: xx.xx	F: xxxxxxxx L: xxxxxxxx	N: xxx D: xxxx.xx H: xx.xx
		D: xx.xx M: xxx.xx	T: xxx W: xxx E: xx.xx	F: xxxxxxxx L: xxxxxxxx	N: xxx D: xxxx.xx H: xx.xx
	S: xxxx-xx-xxTxx:xx:xx E: xxxx-xx-xxTxx:xx:xx	D: xx.xx M: xxx.xx	T: xxx W: xxx E: xx.xx	F: xxxxxxxx L: xxxxxxxx	N: xxx D: xxxx.xx H: xx.xx
		D: xx.xx M: xxx.xx	T: xxx W: xxx E: xx.xx	F: xxxxxxxx L: xxxxxxxx	N: xxx D: xxxx.xx H: xx.xx
S: xxxxxx A: xxxx E: xxxxxxxx	S: xxxx-xx-xxTxx:xx:xx E: xxxx-xx-xxTxx:xx:xx	D: xx.xx M: xxx.xx	T: xxx W: xxx E: xx.xx	F: xxxxxxxx L: xxxxxxxx	N: xxx D: xxxx.xx H: xx.xx

[1] Total Sleep Time
[2] Wake After Sleep Onset
Note: FAS = Full Analysis Set; S = Safety Population; PP = Per-Protocol Population.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject, Start Date/Time, and End Date/Time.

Listing 16.2.6.3: BSA, PGA, sPGA, and PGIC Results
Treatment Group
(Page xx of yy)

					Psoriasis		Pruritus	
Subject	Age/Sex	Evaluable	Visit	Date of Assessment (Day)[1]	BSA (%)	PGA	sPGA	PGIC
xxxxxxxx	xxx	xxxxxxxxx	xxxxxxx	xxxx-xx-xx (xx)	xxx.x		xxxx xxxxxx	
				xxxx-xx-xx (xx)	xxx.x	x - xxxx xxxxxx	xxxx xxxxxx	
				xxxx-xx-xx (xx)	xxx.x	x - xxxx xxxxxx	xxxx xxxxxx	xxxx xxxx xxxxx
				xxxx-xx-xx (xx)	xxx.x	x - xxxx xxxxxx	xxxx xxxxxx	xxxx xxxx xxxxx
				xxxx-xx-xx (xx)	xxx.x	x - xxxx xxxxxx	xxxx xxxxxx	xxxx xxxx xxxxx
				xxxx-xx-xx (xx)	xxx.x	x - xxxx xxxxxx	xxxx xxxxxx	xxxx xxxx xxxxx
xxxxxxxx	xxx	xxxxxxxxx	xxxxxxx	xxxx-xx-xx (xx)	xxx.x		xxxx xxxxxx	
				xxxx-xx-xx (xx)	xxx.x	x - xxxx xxxxxx	xxxx xxxxxx	
				xxxx-xx-xx (xx)	xxx.x	x - xxxx xxxxxx	xxxx xxxxxx	xxxx xxxx xxxxx
				xxxx-xx-xx (xx)	xxx.x	x - xxxx xxxxxx	xxxx xxxxxx	xxxx xxxx xxxxx
				xxxx-xx-xx (xx)	xxx.x	x - xxxx xxxxxx	xxxx xxxxxx	xxxx xxxx xxxxx
				xxxx-xx-xx (xx)	xxx.x	x - xxxx xxxxxx	xxxx xxxxxx	xxxx xxxx xxxxx

[1] Day is calculated as date - date of first dose for dates prior to first dose. Otherwise, day is calculated as date - date of first dose + 1 for dates on or after first dose.
Note: FAS = Full Analysis Set; S = Safety Population; PP = Per-Protocol Population.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject, Visit, and Date of Assessment.

Listing 16.2.6.4.1: Patient Reported Outcomes Measurement Information System Itch Questionnaire Details
Treatment Group
(Page xx of yy)

S: Subject A: Age/Sex E: Evaluable	V: Visit D: Date of Assessment (Day)[1]	Section	Question: In the last 7 days...	Result
S: xxxxxx A: xxxx E: xxxxxxxx	V: xxxxxxxx D: xxxx-xx-xx (xx)	General	Because of itch, I was absent from work.	x - xxxxxxxx
			Because of itch, it was hard to work.	x - xxxxxxxx
			Because of itch, it was hard to do even simple tasks.	x - xxxxxxxx
			Because of itch, I made more mistakes than normal.	x - xxxxxxxx
			Because of itch, it was hard to watch television.	x - xxxxxxxx
			Because of itch, it was hard to shower or take a bath.	x - xxxxxxxx
			Because of itch, I avoided being around people.	x - xxxxxxxx
			Because of itch, it was hard to interact with my family.	x - xxxxxxxx
		Scratching Behavior	I scratched myself until I bled.	x - xxxxxxxx
			It was hard to stop scratching or rubbing.	x - xxxxxxxx
			I worried about having open wounds from scratching.	x - xxxxxxxx
			I worried about flaking skin from scratching.	x - xxxxxxxx
			I worried about getting scars from scratching.	x - xxxxxxxx
		Mood and Sleep	Because of itch, I felt miserable.	x - xxxxxxxx
			Because of itch, I felt embarrassed.	x - xxxxxxxx
			Because of itch, I felt sad.	x - xxxxxxxx
			Because of itch, I was nervous.	x - xxxxxxxx
			Because of itch, I was restless.	x - xxxxxxxx
			Because of itch, I had difficulty falling asleep.	x - xxxxxxxx
			Because of itch, I had trouble staying asleep.	x - xxxxxxxx
			Because of itch, my sleep was restless.	x - xxxxxxxx
		Activity and Clothing	Because of itch, my physical activities were limited.	x - xxxxxxxx
			Because of itch, it was hard to do activities that made me sweat.	x - xxxxxxxx
			Because of itch, it was hard to do light physical activity.	x - xxxxxxxx
			Because of itch, it was hard to do moderate physical activity, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf.	x - xxxxxxxx

[1] Day is calculated as date - date of first dose for dates prior to first dose. Otherwise, day is calculated as date - date of first dose + 1 for dates on or after first dose.
Note: FAS = Full Analysis Set; S = Safety Population; PP = Per-Protocol Population.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject, Visit, Date of Assessment, Section (as ordered above), and Question (as ordered above).

Listing 16.2.6.4.2: Patient Reported Outcomes Measurement Information System Itch Questionnaire Summary
Treatment Group
(Page xx of yy)

Subject	Age/Sex	Evaluable	Visit	Date of Assessment (Day)[1]	Section	Score
xxxxxx	xxxx	xxxxxxxx	xxxxxxxx	xxxx-xx-xx (xx)	General Score	xx
					Scratching Behavior Score	xx
					Mood and Sleep Score	xx
					Activity and Clothing Score	xx
			xxxxxxxx	xxxx-xx-xx (xx)	General Score	xx
					Scratching Behavior Score	xx
					Mood and Sleep Score	xx
					Activity and Clothing Score	xx
			xxxxxxxx	xxxx-xx-xx (xx)	General Score	xx
					Scratching Behavior Score	xx
					Mood and Sleep Score	xx
					Activity and Clothing Score	xx

[1] Day is calculated as date – date of first dose for dates prior to first dose. Otherwise, day is calculated as date – date of first dose + 1 for dates on or after first dose.
Note: FAS = Full Analysis Set; S = Safety Population; PP = Per-Protocol Population.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject, Visit, Date of Assessment, and Section (as ordered above).

Listing 16.2.7.1.1: Unique Adverse Events Coded to MedDRA System Organ Classes and Preferred Terms
(Page xx of yy)

MedDRA System Organ Class	MedDRA Preferred Term	Adverse Event
xxxxx xxxxx xxxxx	xxxxx xxxxx xxxxx	xxxxxxxxxx
		xxxxxxxx xxxxxxxx xxxxxxxxxx
		xxxxxxxx xxxxxxxxx xxxxxxxxxxxxxxx
	xxxxx xxxxx xxxxx	xxxxxxxxxx
		xxxxxxxx xxxxxxxx xxxxxxxxxx
		xxxxxxxx xxxxxxxxx xxxxxxxxxxxxxxx
	xxxxxxxxxx	xxxxx xxxxx xxxxx
		xxxxxxxx xxxxxxxx xxxxxxxxxx
		xxxxxxxx xxxxxxxxx xxxxxxxxxxxxxxx

Note: System Organ Class and Preferred Term map to MedDRA (Version 20.1).
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by MedDRA System Organ Class, Preferred Term, and Adverse Event.

Listing 16.2.7.1.2: Treatment-Emergent Adverse Events
Treatment Group
(Page xx of yy)

S: Subject A: Age/Sex E: Evaluable	A: Event C: System Organ Class P: Preferred Term	F: Date of First Dose S: Start Date (Day)[1] E: End Date (Day)[1]	S: Grade[2] R: Relationship to Study Treatment O: Outcome	S: Is AE Serious? R: Reason(s) for Serious T: Action Taken with Study Treatment A: Any Other Action(s)
S: xxxxxx A: xxx xx E: xxxxxxxxx	A: xxxxxxxxxxxxxxx C: xxxxxxxxxxxxxxx P: xxxxxxxxxxxxxxx	F: xxxx-xx-xx S: xxxx-xx-xx (xx) E: xxxx-xx-xx (xx)	S: xxxx R: xxxxxxxxxx O: xxxxxxxxxx	S: xx R: xxxx xxx xxxxxxx T: xxx A: xxxxxxx
	A: xxxxxxxxxxxxxxx C: xxxxxxxxxxxxxxx P: xxxxxxxxxxxxxxx	F: xxxx-xx-xx S: xxxx-xx-xx (x) E: xxxx-xx-xx (xx)	S: xxxx R: xxxxxxxxxx O: xxxxxxxxxx	S: xx R: xxxx xxx xxxxxxx T: xxx A: xxxxxxx
S: xxxxxx A: xxx xx E: xxxxxxxxx	A: xxxxxxxxxxxxxxx C: xxxxxxxxxxxxxxx P: xxxxxxxxxxxxxxx	F: xxxx-xx-xx S: xxxx-xx-xx (xx) E: xxxx-xx-xx (xx)	S: xxxx R: xxxxxxxxxx O: xxxxxxxxxx	S: xx R: xxxx xxx xxxxxxx T: xxx A: xxxxxxx
S: xxxxxx A: xxx xx E: xxxxxxxxx	A: xxxxxxxxxxxxxxx C: xxxxxxxxxxxxxxx P: xxxxxxxxxxxxxxx	F: xxxx-xx-xx S: xxxx-xx-xx (xx) E: xxxx-xx-xx (xx)	S: xxxx R: xxxxxxxxxx O: xxxxxxxxxx	S: xx R: xxxx xxx xxxxxxx T: xxx A: xxxxxxx

[1] Day is calculated as date – date of first dose for dates prior to first dose. Otherwise, day is calculated as date – date of first dose + 1 for dates on or after first dose.
[2] Grade 1 = Mild; Grade 2 = Moderate; Grade 3 = Severe; Grade 4 = Life Threatening; Grade 5 = Death.
Note: FAS = Full Analysis Set; S = Safety Population; PP = Per-Protocol Population.
System Organ Class and Preferred Term map to MedDRA (Version 20.1).
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject, Start Date, End Date, and Adverse Event.

Listing 16.2.7.1.3: Serious Adverse Events
Treatment Group
(Page xx of yy)

S: Subject A: Age/Sex E: Evaluable	A: Event C: System Organ Class P: Preferred Term	F: Date of First Dose S: Start Date (Day)[1] E: End Date (Day)[1]	S: Grade[2] R: Relationship to Study Treatment O: Outcome	S: Is AE Serious? R: Reason(s) for Serious T: Action Taken with Study Treatment A: Any Other Action(s)
S: xxxxxx A: xxx xx E: xxxxxxxxx	A: xxxxxxxxxxxxxx C: xxxxxxxxxxxxxx P: xxxxxxxxxxxxxx	F: xxxx-xx-xx S: xxxx-xx-xx (xx) E: xxxx-xx-xx (xx)	S: xxxx R: xxxxxxxxxx O: xxxxxxxxxx	S: xx R: xxxx xxx xxxxxxx T: xxx A: xxxxxxx
	A: xxxxxxxxxxxxxx C: xxxxxxxxxxxxxx P: xxxxxxxxxxxxxx	F: xxxx-xx-xx S: xxxx-xx-xx (x) E: xxxx-xx-xx (xx)	S: xxxx R: xxxxxxxxxx O: xxxxxxxxxx	S: xx R: xxxx xxx xxxxxxx T: xxx A: xxxxxxx
S: xxxxxx A: xxx xx E: xxxxxxxxx	A: xxxxxxxxxxxxxx C: xxxxxxxxxxxxxx P: xxxxxxxxxxxxxx	F: xxxx-xx-xx S: xxxx-xx-xx (xx) E: xxxx-xx-xx (xx)	S: xxxx R: xxxxxxxxxx O: xxxxxxxxxx	S: xx R: xxxx xxx xxxxxxx T: xxx A: xxxxxxx
S: xxxxxx A: xxx xx E: xxxxxxxxx	A: xxxxxxxxxxxxxx C: xxxxxxxxxxxxxx P: xxxxxxxxxxxxxx	F: xxxx-xx-xx S: xxxx-xx-xx (xx) E: xxxx-xx-xx (xx)	S: xxxx R: xxxxxxxxxx O: xxxxxxxxxx	S: xx R: xxxx xxx xxxxxxx T: xxx A: xxxxxxx

[1] Day is calculated as date – date of first dose for dates prior to first dose. Otherwise, day is calculated as date – date of first dose + 1 for dates on or after first dose.
[2] Grade 1 = Mild; Grade 2 = Moderate; Grade 3 = Severe; Grade 4 = Life Threatening; Grade 5 = Death.
Note: FAS = Full Analysis Set; S = Safety Population; PP = Per-Protocol Population.
System Organ Class and Preferred Term map to MedDRA (Version 20.1).
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject, Start Date, End Date, and Adverse Event.

Listing 16.2.7.1.4: Subjects Who Permanently Discontinued Study Drug Due to Adverse Events
Treatment Group
(Page xx of yy)

		Completion/Discontinuation		
		D: Date of Study Discontinuation (Day)[1]	Adverse Events	
	F: Date of First	T: Primary Reason for Treatment	A: Event	S: Start Date (Day)[1]
S: Subject	Dose	Discontinuation	S: Grade[2]	E: End Date (Day)[1]
A: Age/Sex	L: Date of Last	S: Primary Reason for Study	R: Relationship to	A: Action Taken with Study
E: Evaluable	Dose	Discontinuation	Study Treatment	Treatment
S: xxxxxx	F: xxxx-xx-xx	D: xxxx-xx-xx (xx)	A: xxxxxxxxxx	S: xxxx-xx-xx (xx)
A: xxsx	L: xxxx-xx-xx	T: xxxxxx	S: xxxxxxx	E: xxxx-xx-xx (xx)
E: xxxsxxsx		S: xxxxxxxxxxxxx	R: xxxxxxxxxxxxxxx	A: xxxxxxxxxxx

[1] Day is calculated as date – date of first dose for dates prior to first dose. Otherwise, day is calculated as date – date of first dose + 1 for dates on or after first dose.
[2] Grade 1 = Mild; Grade 2 = Moderate; Grade 3 = Severe; Grade 4 = Life Threatening; Grade 5 = Death.
Note: FAS = Full Analysis Set; S = Safety Population; PP = Per-Protocol Population.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject, Start Date, End Date, and Adverse Event.

Listing 16.2.8.1: Pregnancy Test Results
Treatment Group
(Page xx of yy)

S: Subject A: Age/Sex E: Evaluable	V: Visit D: Date (Day)[1]	S: Specimen[2] R: Result	S: Was a Serum Pregnancy Test Ordered? E: If Positive/Equivocal, Why Not Ordered	Comments
S: xxxxxx A: xxxx E: xxxxxxxx	V: xxxxxxxxx D: xxxx-xx-xx (xxx)	S: xxxxx R: xxxxxxxx	S: xxx E:	xxxxxxxxxxxxx
	V: xxxxxxxxx D: xxxx-xx-xx (xxx)	S: xxxxx R: xxxxxxxx	S: xx E:	
	V: xxxxxxxxx D: xxxx-xx-xx (xxx)	S: xxxxx R: xxxxxxxx	S: xx E:	
	V: xxxxxxxxx D: xxxx-xx-xx (xxx)	S: xxxxx R: xxxxxxxx	S: xx E:	
S: xxxxxx A: xxxx E: xxxxxxxx	V: xxxxxxxxx D: xxxx-xx-xx (xxx)	S: xxxxx R: xxxxxxxx	S: xx E: xxxxxxxxxxxxxxxxxxxxxxxxx	

[1] Day is calculated as date – date of first dose for dates prior to first dose. Otherwise, day is calculated as date – date of first dose + 1 for dates on or after first dose.
[2] For Serum pregnancy results: HCG levels less than 10 mIU/mL are considered negative for pregnancy. Levels between 10 - 24.9 mIU/mL are equivocal and a redraw of the patient after 48 hours is suggested. Levels greater than or equal to 25 mUI/mL are considered positive for pregnancy.
Note: FAS = Full Analysis Set; S = Safety Population; PP = Per-Protocol Population.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject, Visit, Date, and Specimen. NOTE: Serum Pregnancy Questions (S: E:) are only applicable to Urine Pregnancy test records.

Listing 16.2.8.2.1: Laboratory Test Results
Treatment Group
(Page xx of yy)

S: Subject A: Age/Sex E: Evaluable	V: Visit D: Date (Day)[1] C: Category	Laboratory Test	Results (Units)	Reference Range Low	Reference Range High	Reference Range Indicator(CS[2])	Comments
S: xxxxxx A: xxxx E: xxxxxxxx	V: xxxxxxxxx D: xxxx-xx-xxTxx:xx:xx (xxx) C: xxxxxxxxxxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxxx	xxxx (xxxxxx)				xxxxxxxxxxxxxxxxxxx xxxxxxxxxxxxxxxxx xxxxxxxxxxxxxx
	V: xxxxxxxxx D: xxxx-xx-xxTxx:xx:xx (xxx) C: xxxxxxxxxxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxxx	xxxx (xxxxxx)	x	xx	xxxxxxxxxxx (xxx)	xxxxxxxxxxxxxxx xxxxxxxxxxxxxxxxx xxxxxxxxxxxxxx
	V: xxxxxxxxx D: xxxx-xx-xxTxx:xx:xx (xxx) C: xxxxxxxxxxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxxx	xxxx (xxxxxx)	x	xx	xxxxxxxxxxx (xxx)	

[1] Day is calculated as date – date of first dose for dates prior to first dose. Otherwise, day is calculated as date – date of first dose + 1 for dates on or after first dose.
[2] Clinical significance based on Investigator interpretation. CS = Clinically Significant; NCS = Not Clinically Significant.
Note: FAS = Full Analysis Set; S = Safety Population; PP = Per-Protocol Population.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject, Visit, Date, Category, and Lab Test.

Listing 16.2.8.2.2: Out of Range Laboratory Results
Treatment Group
(Page xx of yy)

S: Subject A: Age/Sex E: Evaluable	V: Visit D: Date (Day)[1] C: Category	Laboratory Test	Results (Units)	Reference Range Low	Reference Range High	Reference Range Indicator(CS[2])	Comments
S: xxxxxx A: xxxx E: xxxxxxxx	V: xxxxxxxxx D: xxxx-xx-xxTxx:xx:xx (xxx) C: xxxxxxxxxxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxxx	xxxx (xxxxxx)				xxxxxxxxxxxxxxxxxxx xxxxxxxxxxxxxxxxx xxxxxxxxxxxxxx
	V: xxxxxxxxx D: xxxx-xx-xxTxx:xx:xx (xxx) C: xxxxxxxxxxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxxx	xxxx (xxxxxx)	x	xx	xxxxxxxxxxx (xxx)	xxxxxxxxxxxxxxx xxxxxxxxxxxxxxxxx xxxxxxxxxxxxxx
	V: xxxxxxxxx D: xxxx-xx-xxTxx:xx:xx (xxx) C: xxxxxxxxxxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxxx	xxxx (xxxxxx)	x	xx	xxxxxxxxxxx (xxx)	

[1] Day is calculated as date – date of first dose for dates prior to first dose. Otherwise, day is calculated as date – date of first dose + 1 for dates on or after first dose.
[2] Clinical significance based on Investigator interpretation. CS = Clinically Significant; NCS = Not Clinically Significant.
Note: FAS = Full Analysis Set; S = Safety Population; PP = Per-Protocol Population.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject, Visit, Date, Category, and Lab Test.

Listing 16.2.8.2.3: Common Laboratory Comments Including Reference Ranges for Specific Laboratory Tests
(Page 1 of 1)

Category	Laboratory Test	Comments
xxxxxxxxxxxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
	xxxxxxxxxxxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
xxxxxxxxxxxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
xxxxxxxxxxxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Category and Lab Test.

Listing 16.2.8.3: Electrocardiogram Test Results
Treatment Group
(Page x of xx)

S: Subject A: Age/Sex E: Evaluable	Category	ECG Parameter	V: Visit D: Date/Time of ECG (Day)[1]	Result (unit)	Clinical Significance[2]	Comments
S: xxxxxxxxx A: xxxx E: xxx/xx/xxx	xxxxxxxxxx	xxxxxxxxxx	V: xxxxxxxxx D: xxxx-xx-xxTxx:xx:xx (xx)	xxxx xxxxx xx (xxx)	xxx	

[1] Day is calculated as date – date of first dose for dates prior to first dose. Otherwise, day is calculated as date – date of first dose + 1 for dates on or after first dose.
[2] Clinical significance based on Investigator interpretation. CS = Clinically Significant; NCS = Not Clinically Significant.
Note: FAS = Full Analysis Set; S = Safety Population; PP = Per-Protocol Population.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject, Category, Parameter, Visit, and Date. **Note: for interpretation records, EGEVAL should be concatenated into ECG Parameter as EGTEST (EGEVAL).**

Listing 16.2.8.4: Vital Signs
Treatment Group
(Page x of xx)

Subject	Age/Sex	Evaluable	Visit	Date of Measurements (Day)[1]	Vital Sign	Result	Units
xxxxxxxxx	xxxx	xxxxx	xxxxxxxxxx	xxxx-xx-xx (xxx)	xxxxx xxx	xx	xxxx
					xxxxx xxx	xx	xxxx
					xxxxx xxx	xx	xxxx
					xxxxx xxx	xx	xxxx
					xxxxx xxx	xx	xxxx
			xxxxxxxxxx	xxxx-xx-xx (xxx)	xxxxx xxx	xx	xxxx
					xxxxx xxx	xx	xxxx
					xxxxx xxx	xx	xxxx
					xxxxx xxx	xx	xxxx
					xxxxx xxx	xx	xxxx
xxxxxxxxx	xxxx	xxxxx	xxxxxxxxxx	xxxx-xx-xx (xxx)	xxxxx xxx	xx	xxxx
					xxxxx xxx	xx	xxxx
					xxxxx xxx	xx	xxxx
					xxxxx xxx	xx	xxxx
					xxxxx xxx	xx	xxxx
			xxxxxxxxxx	xxxx-xx-xx (xxx)	xxxxx xxx	xx	xxxx
					xxxxx xxx	xx	xxxx
					xxxxx xxx	xx	xxxx
					xxxxx xxx	xx	xxxx
					xxxxx xxx	xx	xxxx

[1] Day is calculated as date – date of first dose for dates prior to first dose. Otherwise, day is calculated as date – date of first dose + 1 for dates on or after first dose.
Note: FAS = Full Analysis Set; S = Safety Population; PP = Per-Protocol Population.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject, Visit, Date, and Vital Sign (ordered as: Height, Weight, Temperature, Respiration Rate, Heart Rate, Systolic Blood Pressure, Diastolic Blood Pressure).

Listing 16.2.8.5: Pharmacokinetics Blood Sample Collection and Plasma Concentrations
Treatment Group
(Page x of xx)

S: Subject A: Age/Sex E: Evaluable	Analyte	Visit	Date/Time of Pre-PK Study Drug Dose	Date/Time PK Sample Obtained	Concentration (ng/mL)	Reason Not Done
S: xxxxxx A: xxx E: xxxxx	xxxxxxxxxxx	xxxxxxxxxx	xxxx-xx-xxTxx:xx	xxxx-xx-xxTxx:xx	xxxxxxxxxx	xxxxxxxxx
		xxxxxxxxxx	xxxx-xx-xxTxx:xx	xxxx-xx-xxTxx:xx	xxxxxxxxxx	xxxxxxxxx
		xxxxxxxxxx	xxxx-xx-xxTxx:xx	xxxx-xx-xxTxx:xx	xxxxxxxxxx	xxxxxxxxx
		xxxxxxxxxx	xxxx-xx-xxTxx:xx	xxxx-xx-xxTxx:xx	xxxxxxxxxx	xxxxxxxxx
	xxxxxxxxxxx	xxxxxxxxxx	xxxx-xx-xxTxx:xx	xxxx-xx-xxTxx:xx	xxxxxxxxxx	xxxxxxxxx
		xxxxxxxxxx	xxxx-xx-xxTxx:xx	xxxx-xx-xxTxx:xx	xxxxxxxxxx	xxxxxxxxx
S: xxxxxx A: xxx E: xxxxx	xxxxxxxxxxx	xxxxxxxxxx	xxxx-xx-xxTxx:xx	xxxx-xx-xxTxx:xx	xxxxxxxxxx	xxxxxxxxx
		xxxxxxxxxx	xxxx-xx-xxTxx:xx	xxxx-xx-xxTxx:xx	xxxxxxxxxx	xxxxxxxxx
		xxxxxxxxxx	xxxx-xx-xxTxx:xx	xxxx-xx-xxTxx:xx	xxxxxxxxxx	xxxxxxxxx

Note: FAS = Full Analysis Set; S = Safety Population; PP = Per-Protocol Population.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject, Analyte, Visit, Date.