- **Protocol number:** MTI-107
- **Document title:** An open-label long-term safety study of serlopitant for the treatment of pruritus.
- **Version numbers:** SAP Version 4.0
- **Date of the documents:** 12 May 2020
- **NCT number:** NCT03540160

STATISTICAL ANALYSIS PLAN

Protocol Number:	MTI-107
Study Title:	AN OPEN-LABEL LONG-TERM SAFETY STUDY OF SERLOPITANT FOR THE TREATMENT OF PRURITUS
Development Phase of Study:	Phase 3
Sponsor:	Menlo Therapeutics Inc. 200 Cardinal Way, 2nd Floor Redwood City, CA 94063 USA
Sponsor Contact:	PPD
Statistical Analysis Plan based on Protocol Version:	Version 3.0, 21 March 2019
Statistical Analysis Plan Date:	12 May 2020
Statistical Analysis Plan Version:	Version 4

Authored by:

PPD

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Revision History:

Version	Date	Summary of Changes	Author
Version 1	13 November 2018	Original document	PPD
Version 2	03 April 2019	Updated title page to reflect current version of protocol. Updated SAP version and date. Updated Section 7 to include expected number of subjects to be enrolled.	PPD
Version 3	11 February 2020	Updated SAP version and date. Editorial and grammatical updates including abbreviations and references. Added table, figure and listing shells.	PPD
Version 4	12 May 2020	Updated SAP version and date. Updated SAP throughout, including text, table shells and listing shells to facilitate abbreviated study report.	PPD

1. LIST OF ABBREVIATIONS AND DEFINITIONS OF TERMS

AD	Atopic Dermatitis
AE(s)	Adverse event(s)
DLQI	Dermatology Life Quality Index
ECG	Electrocardiogram
EOS	End of Study
EOT	End of Treatment
ESS	Epworth Sleepiness Scale
HADS	Hospital Anxiety and Depression Scale
IGA PN-S	Investigator's Global Assessment of Prurigo Nodularis Stage
MedDRA	Medical Dictionary for Regulatory Activities
PN	Prurigo Nodularis
SAE(s)	Serious adverse event(s)
SAS®	Statistical Analysis System (SAS® Institute Inc., Cary, NC)
TEAE(s)	Treatment-emergent adverse event(s)
WHO-DD	World Health Organization Drug Dictionary
WI-NRS	Worst-Itch Numeric Rating Scale

2. INTRODUCTION

The MTI-107 study described herein is an open-label study to assess the long-term safety of serlopitant in adults with pruritus associated with prurigo nodularis (PN), atopic dermatitis (AD), or psoriasis.

Subjects enrolled in MTI-107 may have or may not have participated in previous Menlo Therapeutics Inc. studies. Previous study participation includes studies in PN (MTI-105, MTI-106, TCP-102), in AD (MTI-103) and in psoriasis (MTI-109).

The MTI-107 study has been terminated early by Sponsor. The Statistical Analysis Plan has been updated to facilitate an abbreviated clinical study report.

3. STUDY OBJECTIVES

The primary objective of this study is to assess the long-term safety of serlopitant in adults with pruritus associated with PN, AD, or psoriasis.

The secondary objectives of this study are to assess the change in severity of pruritus in subjects with PN, AD, or psoriasis using the worst-itch numeric rating scale (WI-NRS); to assess the change in severity and extent of PN using the Investigator's Global Assessment of PN Stage

(IGA PN-S), for those subjects with PN; and to assess whether serlopitant produces physical dependence.

4. STUDY DESIGN

4.1 Overall Study Design

This is a multicenter, open-label study to assess the long-term safety of serlopitant in adults with pruritus associated with PN, AD, or psoriasis. Eligible subjects who have completed selected studies of serlopitant may be given the opportunity, at the Investigator's discretion, to consent to and participate in this open-label study, regardless of their treatment allocation in prior studies. If deemed necessary by Menlo Therapeutics to meet enrollment objectives, eligible subjects who have not participated in a prior serlopitant study may also be enrolled in study MTI-107. Approximately 120 study sites may enroll subjects in this long-term safety study.

This study will consist of two periods, for a total study period of 57 weeks:

- Treatment period: 52 weeks
- Post-drug observation period: 5 weeks

4.1.1 Schedule of Visits and Assessments

The schedule of assessments can be found in Section 6.4 and Appendix A of the Protocol.

4.1.2 Method of Assigning Subjects to Treatment Groups

This is an open-label single-arm study. Eligible subjects will receive serlopitant 5 mg tablets.

4.1.3 Blinding

This is an open-label study.

5. EFFICACY AND SAFETY ENDPOINTS

5.1 Efficacy Endpoints

Efficacy endpoints are as follows:

- Change from baseline in WI-NRS to Weeks 4, 8, 20, 28, 36, 44, and 52
- Change from baseline in Dermatology Life Quality Index (DLQI) to Weeks 20, 36, and 52
- Change from baseline in Investigator's Global Assessment of PN Stage (IGA PN-S) to Weeks 4, 8, 20, 28, 36, 44, and 52

5.2 Safety Endpoints

Safety endpoints include the following:

- Incidence of treatment-emergent adverse events (TEAEs) and serious adverse events (SAEs)
- Changes from baseline in clinical laboratory parameters
- Changes from baseline in vital sign and electrocardiogram (ECG) parameters
- Change from baseline in the Hospital Anxiety and Depression Scale (HADS)
- Change from baseline in the Epworth Sleepiness Scale (ESS)
- Assessment of physical dependence following chronic study drug exposure, in the monitored 5-week post-drug discontinuation period

6. STATISTICAL AND ANALYTICAL PLANS

6.1 General Methodology

All statistical processing will be performed using SAS® Version 9.3 or later, unless otherwise stated. No interim analyses are planned. Endpoints will be summarized with descriptive statistics by visit. For continuous variables, the following information will be presented: n (number of subjects), mean, standard deviation (SD), median, minimum and maximum. For categorical variables, counts and percentages will be presented.

Reported adverse events (AEs), medical history, 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-DD) 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

No change from baseline summaries will be created.

6.1.3 Visit Windowing

Data will be provided in by-subject listings based on nominal visit indications.

6.1.4 Adjustments for Covariates

No inferential statistical analyses are planned.

6.1.5 Handling of Dropouts or Missing Data

Summary statistics will generally be reported based upon observed 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.

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 summaries. Every effort will be made to promote consistency in study execution at each study site.

6.1.7 Multiple Comparisons/Multiplicity

No inferential statistical analyses are planned.

6.1.8 Examination of Subgroups

No subgroup summaries will be created.

6.2 Disposition of Subjects

An accounting of all enrolled 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 the safety population will be summarized. Subjects who are excluded from the safety population will be summarized by the reasons for exclusion.

6.3 Protocol Deviations

Protocol deviations will be presented in a data listing.

6.4 Data Sets Analyzed

6.4.1 Safety Population

All subjects who receive at least 1 confirmed dose of study drug and have at least 1 post-baseline safety assessment or a reported TEAE will be included in the safety population. All analyses will be performed using the safety population.

6.5 Demographic and Other Baseline Characteristics

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

Medical histories will be coded using MedDRA and presented in a by-subject listing.

Disease history (PN, AD, psoriasis) will be presented in a by-subject listing.

6.6 Prior and Concomitant Medications

Prior and concomitant medications will be coded by the WHO-DD to Anatomical Therapeutic Classification (ATC) 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

Efficacy data will be provided in by-subject listings.

6.8 Safety Evaluation

6.8.1 Extent of Exposure

The extent of exposure to study drug will be summarized by days with exposure and total number of tablets used. Subjects will be considered having 6-Month exposure if the date of first dose – date of last dose + 1 is greater than or equal to 182 days. Subjects will be considered having 1-Year exposure if date of first dose – date of last dose + 1 is greater than or equal to 358 days, considering the allowable -7 day window for the Week 52 visit.

6.8.2 Adverse Events

All AEs will be classified by system organ class and preferred term using the MedDRA. TEAEs will be tabulated in a manner which provides information about the incidence of TEAEs for the entire study. For incidence reporting, if a subject reported more than one TEAE that was coded to the same system organ class or preferred term, the subject will be counted only once for that

specific system organ class or preferred term. An overview of AEs, which includes subject incidence of AEs, TEAEs, treatment-related TEAEs, TEAEs by severity, SAEs, deaths, and AEs leading to discontinuation of study drug, will be presented.

All information pertaining to AEs noted during the study will be listed by subject and will include a verbatim description of the event as reported by the investigator, as well as the preferred term, system organ class, start date, end date (if ended), seriousness, severity, action taken regarding the study drug, outcome, and relationship to the study drug. In addition, a listing of subjects who prematurely discontinued study drug due to AEs will be provided.

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

6.8.3 Clinical Laboratory Evaluation

By-subject listings of all laboratory data, as well as abnormal laboratory results, will be presented. Clinically significant laboratory results will be recorded as an AE.

6.8.4 Other Observations Related to Safety

6.8.4.1 Electrocardiogram Measurements

Data will be provided in a by-subject listing.

6.8.4.2 Vital Signs

Data will be provided in a by-subject listing.

6.8.4.3 Physical Exams

Clinically significant physical exam findings will be recorded by the sites within medical history or adverse events and otherwise not summarized. Data will be provided in a by-subject listing.

6.8.4.4 Menstrual Diaries

Data will be provided in a by-subject listing.

6.8.4.5 Hospital Anxiety and Depression Scale (HADS)

Data will be provided in a by-subject listing.

6.8.4.6 Epworth Sleepiness Scale (ESS)

Data will be provided in a by-subject listing.

7. DETERMINATION OF SAMPLE SIZE

No formal sample size calculations were performed. Up to 700 adult subjects with pruritus associated with PN, AD, or psoriasis will be enrolled in this study.

8. CHANGES IN THE PLANNED ANALYSES

No graphs of laboratory values over time will be created.

Planned analyses have been updated to facilitate an abbreviated clinical study report.

9. INDEX OF PLANNED END-OF-TEXT TABLES AND FIGURES

Table 14.0.1.1: Summary of Subject Completion/Discontinuation
(Enrolled Subjects)

	Serlopitant 5 mg (N=xxx)
Completed Treatment	
Yes	xx (xx.x%)
No	xx (xx.x%)
Reason for Discontinuation from Treatment	
Adverse Event	xx (xx.x%)
Lack of Efficacy	xx (xx.x%)
Pregnancy	xx (xx.x%)
Investigator Decision	xx (xx.x%)
Withdrawal by Subject from Treatment	xx (xx.x%)
Protocol Deviation	xx (xx.x%)
Sponsor Decision	xx (xx.x%)
Other	xx (xx.x%)
Completed Follow-up	
Yes	xx (xx.x%)
No	xx (xx.x%)
Reason for Discontinuation from Follow-up	
Withdrawal by Subject from Study	xx (xx.x%)
Lost to Follow-up	xx (xx.x%)
Other	xx (xx.x%)

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

Table 14.0.2.1: Summary of Subjects Excluded from Analyses
(Enrolled Subjects)

	Serlopitant 5 mg (N=xxx)
Safety Population	
Number of Subjects Included	xx (xx.x%)
Number of Subjects Excluded	xx (xx.x%)
Reason for Exclusion	
No Evidence of Subject Dosing	xx (xx.x%)
No Post-Baseline Assessment/TEAE	xx (xx.x%)

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

Table 14.1.1.1: Summary of Subject Demographics
(Safety Population)
(Page 1 of 2)

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

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

Table 14.1.1.1: Summary of Subject Demographics
(Safety Population)
(Page 2 of 2)

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

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

Table 14.3.0.1: Summary of Extent of Exposure
(Safety Population)

	Serlopitant 5 mg (N=xxx)
Total Number of Tablets Used	xxx
n	xxx
Mean	xx.x
SD	xx.xx
Median	xx.x
Min. to Max.	xx to xx
Total Number of Days of Exposure	xxx
n	xxx
Mean	xx.x
SD	xx.xx
Median	xx.x
Min. to Max.	xx to xx
Subjects with 6-Month Exposure[a]	xx (xx.x%)
Subjects with 1-Year Exposure[a]	xx (xx.x%)

[a] Subjects considered having 6-Month exposure if date of first dose – date of last dose + 1 is greater than or equal to 182 days.
Subjects considered having 1-Year exposure if date of first dose – date of last dose + 1 is greater than or equal to 358 days, considering the allowable -7 day window for the Week 52 visit.

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

Table 14.3.1.1.1.1: Overall Summary of Treatment-Emergent Adverse Events (TEAEs)
(Safety Population)

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

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

Table 14.3.1.1.2.1: 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	Serlopitant 5 mg (N=xxx)
Total	xx (xx.x%)
System Organ Class	xx (xx.x%)
Preferred Term	xx (xx.x%)
Preferred Term	xx (xx.x%)
Preferred Term	xx (xx.x%)
Preferred Term	xx (xx.x%)
System Organ Class	xx (xx.x%)
Preferred Term	xx (xx.x%)
Preferred Term	xx (xx.x%)
Preferred Term	xx (xx.x%)
Preferred Term	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 21.1.

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

Table 14.3.1.1.3.1: 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	Serlopitant 5 mg (N=xxx)
Total	xx (xx.x%)
System Organ Class	xx (xx.x%)
Preferred Term	xx (xx.x%)
Preferred Term	xx (xx.x%)
Preferred Term	xx (xx.x%)
Preferred Term	xx (xx.x%)
System Organ Class	xx (xx.x%)
Preferred Term	xx (xx.x%)
Preferred Term	xx (xx.x%)
Preferred Term	xx (xx.x%)
Preferred Term	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 21.1.

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

Table 14.3.1.1.4.1: Summary of Subjects Reporting Treatment-Emergent Adverse Events (TEAEs) by Severity
(Safety Population)

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

Note: TEAEs are AEs with an onset date after first dose of study drug.
MedDRA Version 21.1.
Grade 1=Mild; Grade 2=Moderate; Grade 3=Severe; Grade 4=Life Threatening; Grade 5=Death.

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

Table 14.3.1.1.5.1: 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	Serlopitant 5 mg (N=xxx)
Total	
Likely Related	xx (xx.x%)
Likely Unrelated	xx (xx.x%)
System Organ Class	
Likely Related	xx (xx.x%)
Likely Unrelated	xx (xx.x%)
Preferred Term	
Likely Related	xx (xx.x%)
Likely Unrelated	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 date after first dose of study drug.
MedDRA Version 21.1.

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

Table 14.3.1.3.1.1: Summary of Subjects Reporting Serious Treatment-Emergent Adverse Events (TEAEs) by MedDRA System Organ Class and Preferred Term
(Safety Population)

System Organ Class[a] Preferred Term	Serlopitant 5 mg (N=xxx)
Total	xx (xx.x%)
System Organ Class	xx (xx.x%)
Preferred Term	xx (xx.x%)
Preferred Term	xx (xx.x%)
Preferred Term	xx (xx.x%)
Preferred Term	xx (xx.x%)
System Organ Class	xx (xx.x%)
Preferred Term	xx (xx.x%)
Preferred Term	xx (xx.x%)
Preferred Term	xx (xx.x%)
Preferred Term	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 21.1.

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

Table 14.3.1.3.2.1: Summary of Subjects Reporting Serious Treatment-Emergent Adverse Events (TEAEs) by Severity
(Safety Population)

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

Note: TEAEs are AEs with an onset date after first dose of study drug.
MedDRA Version 21.1.
Grade 1=Mild; Grade 2=Moderate; Grade 3=Severe; Grade 4=Life Threatening; Grade 5=Death.

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

Table 14.3.1.3.3.1: 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	Serlopitant 5 mg (N=xxx)
Total	
Likely Related	xx (xx.x%)
Likely Unrelated	xx (xx.x%)
System Organ Class	
Likely Related	xx (xx.x%)
Likely Unrelated	xx (xx.x%)
Preferred Term	
Likely Related	xx (xx.x%)
Likely Unrelated	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 date after first dose of study drug.
MedDRA Version 21.1.

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

10. INDEX OF PLANNED LISTINGS

Listing 16.2.1.1: Subject Disposition Information
(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: Follow-up Discontinuation Date (Day)[1] R: Reason for Follow-up 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: S = Safety Population.

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

Listing sorted by Subject.

Listing 16.2.1.2: Discontinued Subjects
(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: Follow-up Discontinuation Date (Day)[1] R: Reason for Follow-up 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: S = Safety Population.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject.

Listing 16.2.2.1: Inclusion/Exclusion Criteria Not Met
(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 xxxxxxxxxxxxxx xxxxxxxxx x xxxxxxxxxxxxxxxx xxx

Note: S = Safety Population.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject and Criterion Failed.

Listing 16.2.3: Analysis Populations
(Page xx of yy)

Subject	Age/Sex	Parent Study	Population	Included	Reason(s) Excluded
xxxxxx	xxxx	xxxx	Safety	xxx	
xxxxxx	xxxx	xxxx	Safety	xxx	
xxxxxx	xxxx	xxxx	Safety	xxx	
xxxxxx	xxxx	xxxx	Safety	xx	xxxxxxxxxxxxxx

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

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

Listing 16.2.4.1: Subject Demographic Information
(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	I: Informed Consent Date/Protocol Version P: Did subject consent to photography?
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 xxxxxxxxx xxxx x xxxxxxxxxx xx xxxxxxxxx xxxxxxxxxx xxxx xxxxxxx	I: V2.1/xxxx-xx-xx V3/xxxx-xx-xx P: xxx
xxxxxx	xxxxxxxxx	B: xxxx-xx-xx A: xx S: xxxx	R: xxxxx E: xxxxxxxx xx xxxxxx	C: xx M:	I: V2/xxxx-xx-xx P: xxx
xxxxxx	xxxxxxxxx	B: xxxx-xx-xx A: xx S: xxxxxx	R: xxxxx E: xxxxxxxx xx xxxxxx	C: xxx M: xxxxxxxx xxxxxxxxxxxx	I: V3/xxxx-xx-xx P: xxx

Note: S = Safety Population.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject. Include all instances of informed consents and associated protocol versions.

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 21.1).
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
(Page xx of yy)

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

Note: S = Safety Population.
System Organ Class and Preferred Term map to MedDRA (Version 21.1).
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: Pruritic Disease History
(Page xx of yy)

Subject	Age/Sex	Evaluable	Indication	Date of Diagnosis	Body Locations Affected
xxxxxx	xxxx	xxxxxxxx	Prurigo Nodularis	xxxx-xx-xx	xxxxxxxxx xxxxx; xxxxxx; xxxx xxx xxxx; xxxxxxxxx
xxxxxx	xxxx	xxxxxxxx	Atopic Dermatitis	xxxx-xx-xx	xxxxxxxxx xxxxx; xxxxx xxxxx; xxxxx; xxxxxxxxx

Note: S = Safety Population.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject.

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 September 1, 2018).
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: Concomitant Medications
(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: S = Safety Population.
Standardized Medication Name and ATC Level 2 Term map to the WHO DDE (Version September 1, 2018).
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: Concomitant Procedures/Therapies
(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	xxxxxxxxxxxxx	F: xxxx-xx-xx S: xxxx-xx-xx (xx) E: xxxx-xx-xx (xx)	x xxxxxx xxxx xxxxxx xxxxxxxxx
xxxxxx	xxxx	xxxxxxxxxx	xxxxxxxxxxxxx	F: xxxx-xx-xx S: xxxx-xx E: xxxx-xx-xx (xx)	x xxxxxx xxxx xxxxxx xxxxxxxxx
xxxxxx	xxxx	xxxxxxxxxx	xxxxxxxxxxxxx	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: S = Safety 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
(Page x of xx)

Subject	Age/Sex	Evaluable	Visit	Date of Assessment (Day)[1]	Physical Exam Completed
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
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: S = Safety Population.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

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

Listing 16.2.5.1: Study Visit Compliance
(Page xx of yy)

Subject	Age/Sex	Evaluable	Visit	Visit Date	Visit Not Done/ Reason for Unscheduled Visit
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxx	xxxx-xx-xx	
			xxxxxxxx	xxxx-xx-xx	
			xxxxxx	xxxx-xx-xx	
			xxxxxx	xxxx-xx-xx	x xxxx xxxxxxx x xxxxxx xxxxxxx xxxxx xxxxxx xx xxxx xxx xxxx xx xxx xxxx
			xxxxxx	xxxx-xx-xx	
			xxxxxxxxxxxxxxx	xxxx-xx-xx	
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxx	xxxx-xx-xx	
			xxxxxx	xxxx-xx-xx	
			xxxxxxxxxxxxxxx	xxxx-xx-xx	

[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: S = Safety 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
(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: S = Safety Population.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

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

Listing 16.2.6.1: Worst Itch Numeric Rating Scale (WI-NRS)
(Page xx of yy)

Subject	Age/Sex	Evaluable	Visit	Date of Assessment (Day)[1]	WI-NRS[2] in the past 24 hours
xxxxxxxx	xxxx	xxxxxxxxx	xxxxxxxxxxxxxxxxxxxx	xxxx-xx-xx (xx)	xx
xxxxxxxx	xxxx	xxxxxxxxx	xxxxxxxxxxxxxxxxxxxx	xxxx-xx-xx (xx)	xx
xxxxxxxx	xxxx	xxxxxxxxx	xxxxxxxxxxxxxxxxxxxx	xxxx-xx-xx (xx)	xx
xxxxxxxx	xxxx	xxxxxxxxx	xxxxxxxxxxxxxxxxxxxx	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: S = Safety Population.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject and Date of Assessment.

Listing 16.2.6.2: IGA PN-S Results
(Page xx of yy)

Subject	Age/Sex	Evaluable	Visit	Date of Assessment (Day)[1]	Investigator's Global Assessement of Prurigo Nodularis Stage
xxxxxxxx	xxxx	xxxxxxxxx	xxxxxxxxxxxx	xxxx-xx-xx (xx)	xxxxx x
			xxxxxxxxxxxx	xxxx-xx-xx (xx)	xxxxx x
			xxxxxxxxxxxx	xxxx-xx-xx (xx)	xxxxx x
			xxxxxxxxxxxx	xxxx-xx-xx (xx)	xxxxx x
			xxxxxxxxxxxx	xxxx-xx-xx (xx)	xxxxx x
			xxxxxxxxxxxx	xxxx-xx-xx (xx)	xxxxx x
xxxxxxxx	xxxx	xxxxxxxxx	xxxxxxxxxxxx	xxxx-xx-xx (xx)	xxxxx x
			xxxxxxxxxxxx	xxxx-xx-xx (xx)	xxxxx x
			xxxxxxxxxxxx	xxxx-xx-xx (xx)	xxxxx x
			xxxxxxxxxxxx	xxxx-xx-xx (xx)	xxxxx x
			xxxxxxxxxxxx	xxxx-xx-xx (xx)	xxxxx x
			xxxxxxxxxxxx	xxxx-xx-xx (xx)	xxxxx x

[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: S = Safety Population.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

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

Listing 16.2.6.3: Dermatology Life Quality Index (DLQI)
(Page xx of yy)

Subject	Age/Sex	Evaluable	V: Visit D: Date of Assessment (Day)[1]	Question Number	Question	Result
xxxxxxxx	xxxx	xxxxxxx	V: xxxxxxxxxx D: xxxx-xx-xx (xx)	1	Over the last week, how itchy, sore, painful or stinging has your skin been?	xxxxxx
				2	Over the last week, how embarrassed or self conscious have you been because of your skin?	xxxxxx
				3	Over the last week, how much has your skin interfered with you going shopping or looking after your home or garden?	xxxxxx
				4	Over the last week, how much has your skin influenced the clothes you wear?	xxxxxx
				5	Over the last week, how much has your skin affected any social or leisure activities?	xxxxxx
				6	Over the last week, how much has your skin made it difficult for you to do any sport?	xxxxxx
				7	Over the last week, has your skin prevented you from working or studying?	xxxxxx
				7A	If "No", over the last week how much has your skin been a problem at work or studying?	xxxxxx
				8	Over the last week, how much has your skin created problems with your partner or any of your close friends or relatives?	xxxxxx
				9	Over the last week, how much has your skin caused any sexual difficulties?	xxxxxx
				10	Over the last week, how much of a problem has the treatment for your skin been, for example by making your home messy, or by taking up time?	xxxxxx
					Questionnaire 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: S = Safety Population.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

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

Listing 16.2.6.4: Photography
(Page xx of yy)

Subject	Age/Sex	Evaluable	V: Visit D: Date of Assessment (Day)[1]	Body Areas Photographed
xxxxxxxx	xxxx	xxxxxxx	V: xxxxxxxxxx D: xxxx-xx-xx (xx)	xxxxxxxx; xxxxxxxxxxx; xxxxxxxx
			V: xxxxxxxxxx D: xxxx-xx-xx (xx)	xxxxxxxx; xxxxxxxxxxx; xxxxxxxx
			V: xxxxxxxxxx D: xxxx-xx-xx (xx)	xxxxxxxx; xxxxxxxxxxx; xxxxxxxx
			V: xxxxxxxxxx D: xxxx-xx-xx (xx)	xxxxxxxx; xxxxxxxxxxx; 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: S = Safety Population.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

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

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 xxxxxxxxxxx
		xxxxxxxx xxxxxxxxx xxxxxxxxxxxxxxx
	xxxxx xxxxx xxxxx	xxxxxxxxxx
		xxxxxxxx xxxxxxxx xxxxxxxxxxx
		xxxxxxxx xxxxxxxxx xxxxxxxxxxxxxxx
	xxxxxxxxxx	xxxxx xxxxx xxxxx
		xxxxxxxx xxxxxxxx xxxxxxxxxxx
		xxxxxxxx xxxxxxxxx xxxxxxxxxxxxxxx

Note: System Organ Class and Preferred Term map to MedDRA (Version 21.1).
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
(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: xxxx 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: xxxx 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: xxxx 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: S = Safety Population.
System Organ Class and Preferred Term map to MedDRA (Version 21.1).
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
(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: xxxx 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: xxxx 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: xxxx 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: S = Safety Population.
System Organ Class and Preferred Term map to MedDRA (Version 21.1).
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
(Page xx of yy)

		Completion/Discontinuation	Adverse Events	
S: Subject A: Age/Sex E: Evaluable	F: Date of First Dose L: Date of Last Dose	D: Date of Study Discontinuation (Day)[1] T: Primary Reason for Treatment Discontinuation S: Primary Reason for Study Discontinuation	A: Event S: Grade[2] R: Relationship to Study Treatment	S: Start Date (Day)[1] E: End Date (Day)[1] A: Action Taken with Study Treatment
S: xxxxxx A: xxxx E: xxxxxxx	F: xxxx-xx-xx L: xxxx-xx-xx	D: xxxx-xx-xx (xx) T: xxxxxx S: xxxxxxxxxxxxx	A: xxxxxxxxxx S: xxxxxxx R: xxxxxxxxxxxxxxx	S: xxxx-xx-xx (xx) E: xxxx-xx-xx (xx) 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: S = Safety Population.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

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

Listing 16.2.7.2.1: Hospital Anxiety and Depression Scale
(Page xx of yy)

Subject	Age/Sex	Evaluable	V: Visit D: Date of Assessment (Day)[1]	Question	Result
xxxxxxxx	xxxx	xxxxxxx	V: xxxxxxxxxx D: xxxx-xx-xx (xx)	I feel tense or 'wound up'	xxxxxxxxxxxxxxxxxxx
				I still enjoy the things I used to enjoy	xxxxxxxxxxxxxxxxxxx
				I get a sort of frightened feeling as if something awful is about to happen	xxxxxxxxxxxxxxxxxxx
				I can laugh and see the funny side of things	xxxxxxxxxxxxxxxxxxx
				Worrying thoughts go through my mind	xxxxxxxxxxxxxxxxxxx
				I feel cheerful	xxxxxxxxxxxxxxxxxxx
				I can sit at ease and feel relaxed	xxxxxxxxxxxxxxxxxxx
				Depression Subscale	xx
				Anxiety Subscale	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: S = Safety Population.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing 16.2.7.2.2: Epworth Sleepiness Scale
(Page xx of yy)

Subject	Age/Sex	Evaluable	V: Visit D: Date of Assessment (Day)[1]	Situation	Result
xxxxxxxx	xxxx	xxxxxxx	V: xxxxxxxxxx D: xxxx-xx-xx (xx)	Sitting and reading	xxxxxxxxxxxxxxxxxxx
				Watching TV	xxxxxxxxxxxxxxxxxxx
				Sitting, inactive in a public place (e.g. a theatre or a meeting)	xxxxxxxxxxxxxxxxxxx
				As a passenger in a car for an hour without a break	xxxxxxxxxxxxxxxxxxx
				Lying down to rest in the afternoon when circumstances permit	xxxxxxxxxxxxxxxxxxx
				Sitting and talking to someone	xxxxxxxxxxxxxxxxxxx
				Sitting quietly after a lunch without alcohol	xxxxxxxxxxxxxxxxxxx
				In a car, while stopped for a few minutes in the traffic	xxxxxxxxxxxxxxxxxxx

[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: S = Safety Population.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing 16.2.7.3: Menstrual Diary
(Page xx of yy)

Subject	Age/Sex	Evaluable	Childbearing Potential	Start Date of Period (Day)[1]	End Date of Period (Day)[1]
xxxxxxxx	xxxx	xxxxxxx	xxxxxxxxxxxxx	xxxx-xx-xx (xx)	xxxx-xx-xx (xx)
				xxxx-xx-xx (xx)	xxxx-xx-xx (xx)
				xxxx-xx-xx (xx)	xxxx-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.
Note: S = Safety Population.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing 16.2.8.1: Pregnancy Test Results
(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 no, but was required, explain	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: S = Safety 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
(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	High	Indicator	Comments
S: xxxxxx A: xxxx E: xxxxxxxx	V: xxxxxxxxx D: xxxx-xx-xxTxx:xx:xx (xxx) C: xxxxxxxxxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxxx	xxxx (xxxxxx)				xxxxxxxxxxxxxxxxxxx xxxxxxxxxxxxxxxxx xxxxxxxxxxxxx
	V: xxxxxxxxx D: xxxx-xx-xxTxx:xx:xx (xxx) C: xxxxxxxxxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxxx	xxxx (xxxxxx)	x	xx	xxxxxxxxxxx (xxx)	xxxxxxxxxxxxxxx xxxxxxxxxxxxxxxxx xxxxxxxxxxxxx
	V: xxxxxxxxx D: xxxx-xx-xxTxx:xx:xx (xxx) C: xxxxxxxxxxxxxxxxxxxx	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.

Note: S = Safety 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
(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: S = Safety Population.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

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

Listing 16.2.8.2.3: Laboratory Information Captured within Case Report Forms
(Page xx of yy)

S: Subject A: Age/Sex E: Evaluable	V: Visit C: Category	Y: Was sample collected? D: Date of Sample Collection	Were there any abnormal results?
S: xxxxxx A: xxxx E: xxxxxxxx	V: xxxxxxxxx C: xxxxxxxxxxxxxxxxxxxxx	Y: xxx D: xxxx-xx-xx	xxxxxxxxxxxxx
S: xxxxxx A: xxxx E: xxxxxxxx	V: xxxxxxxxx C: xxxxxxxxxxxxxxxxxxxxx	Y: xxx D: xxxx-xx-xx	xxxxxxxxxxxxx

[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: S = Safety Population.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

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

Listing 16.2.8.2.4: Common Laboratory Comments Including Reference Ranges for Specific Laboratory Tests
(Page 1 of 1)

Category	Laboratory Test	Comments
xxxxxxxxxxxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
	xxxxxxxxxxxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
xxxxxxxxxxxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
xxxxxxxxxxxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

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

Listing sorted by Category and Lab Test.

Listing 16.2.8.3: Electrocardiogram Test Results
(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: S = Safety 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).**

Include information captured within CRF as a separate parameter within listing.

Listing 16.2.8.4: Vital Signs
(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: S = Safety 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).