DATA ANALYSIS PLAN

Protocol Title:	A Phase 2 Randomized, Double-Blind, Placebo-Controlled Study of ATR-101 for the Treatment of Cushing's Syndrome
Protocol Number:	ATR-101-301
Current Protocol:	Global Amendment 2 / 14-MAR-2019
NCT Number:	NCT03053271
Product:	Nevanimibe HCl (ATR-101)
Phase of Study:	2
Sponsor:	Millendo Therapeutics US, Inc.
Data Analysis Plan	V1.0 / 18-SEP-2019

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Protocol Number: ATR-101-301

Current Protocol: Global Amendment 2 / 14-MAR-2019

DAP: V1.0 / 18-SEP-2019

This Data Analysis Plan has been reviewed and approved by:

Miriam Zangmeister, MS — DD-MMM-YYYY

Project Statistician

Medpace

Phillippa Miranda, MD — DD-MMM-YYYY

Medical Director

Medpace

Vivian Lin, MD — DD-MMM-YYYY

Vice President, Clinical Development

Millendo Therapeutics US, Inc.

REVISION HISTORY

Version	Date	Description of Changes
1.0	18-SEP-2019	Original signed version

TABLE OF CONTENTS

1 Introduction

This purpose of this document is to provide specifications for the tables and listings to be provided for Millendo Therapeutics Protocol ATR-101-301. Information regarding the study objectives and procedures can be found in the Protocol.

On August 12, 2019, Millendo Therapeutics elected to discontinue the ATR-101-301 study based on an analysis of the feasibility of patient recruitment and a reprioritization of resources. A total of 4 subjects entered the open-label dose-escalation period of the study, but no subjects entered the double-blind randomized withdrawal period prior to study discontinuation. The available data from subjects who participated in the study will be used for safety summaries, but no formal statistical analysis of safety data will be conducted. The efficacy parameter of 24-hour urinary free cortisol (24-hr UFC) will be summarized but formal statistical analysis will not be performed due to the limited data available.

All available data will be listed. All summaries will be based on observed values only.

1.1 Subject Disposition

Counts of subjects who screened, entered the open-label dose-escalation period (i.e. dosed), and entered the double-blind randomized withdrawal period (i.e. randomized), as well as counts and percentages of subjects who completed the study and who withdrew early from the study, with the reason for early withdrawal, will be presented in total.

1.2 Demographic and Baseline Characteristics

Descriptive summaries of demographic and baseline characteristics will be presented for all dosed subjects. Baseline measurements refer to the last measurement prior to the first dose of study drug.

Demographic and baseline characteristics include, but are not limited to: age at informed consent, sex, race, ethnicity, height at screening, baseline body weight, and baseline body mass index (BMI). Continuous variables (age, height, weight, BMI) will be summarized by subject count, mean, standard deviation, median, minimum, and maximum. Categorical variables (race, sex, ethnicity) will be summarized by the number and percentage of subjects in the corresponding categories.

1.3 24 Hour Urinary Free Cortisol

Descriptive summaries of 24-hr UFC will be presented for all dosed subjects by scheduled visit.

1.4 Pharmacokinetics

Plasma PK samples will be collected to determine the concentrations of nevanimibe HCl (ATR-101; hereafter, “nevanimibe”). Planned sampling time points are listed in the table below. No subjects entered the double-blind randomized withdrawal period, therefore PK samples are not available for R1 and R2.

Visit	Sampling Time Points (Morning Dose Only)
T1 (Day 1, 250 mg BID),	0 (within 30 min predose), 1 (± 5 min), 2 (± 10 min), 3 (±

Visit	Sampling Time Points (Morning Dose Only)
T2 (Day 15, 500 mg) BID, and T3 (Day 29, 1000 mg BID)	10 min) and 4 hr (± 10 min)
Early Termination	0 hr

The exact time of each sample collection will be recorded. If the exact time (measured from dosing) is outside of the collection window for nominal time points, the corresponding concentration will be excluded from concentration versus time descriptive statistical summaries and plots, but will still be used in the calculations of PK parameter estimates.

1.4.1 Handling Missing Data or Concentration Below the Lower Limit of Quantification

Concentrations below the limit of quantitation (BLQ) before the first measurable concentration in a profile will be assigned a value of zero. A single BLQ value between measurable concentrations in a profile will be set to missing in the derivation of PK parameters, statistical analyses, and the individual subject plots. BLQ values that occur after the last measurable concentration will also be set to missing in the derivation of PK parameters and in the individual subject plots.

In cases of missing pre-dose at T1 visit, the missing concentrations will be assumed as zero. In cases of missing pre-dose on T2 or T3 visits, the minimum observed concentration during the dosing interval may be used as pre-dose concentration values. For other cases, the missing data will not be imputed.

1.4.2 Pharmacokinetic Parameters

The following PK parameters will be estimated at T1, T2, and T3 visits for nevanimibe as data permit and as appropriate.

PK Parameter	Definition
C_{max}	The maximum drug concentration determined directly from individual concentration-time data
T_{max}	The observed time to reach maximum concentration
AUC_{0-t}	The area under the concentration-time curve from time zero to the time of the last quantified concentration
AUC_{0-4}	The area under the concentration-time curve from time zero to 4 h after dosing
λz	The terminal phase rate constant, estimated by linear regression through the terminal phase of the log concentration-time profile

PK Parameter	Definition
$t_{½}$	The terminal phase half-life, calculated as: $t½ = \ln(2) \div \lambda z$
$AUC_{0-\infty}$	The area under the concentration versus time curve from time 0 to infinity (first dose only), calculated as $AUC_{0-t} + C_{last}/\lambda z$
AUC%extrap	Percentage of $AUC_{0-\infty}$ extrapolated, represented as $(1 - AUC_{0-t}/AUC_{0-\infty})\times 100$

Plasma PK parameters will be calculated by standard non-compartmental analysis (NCA) for all dosed subjects with available data. The actual dosing and sampling time points will be used for evaluation of PK data. The linear up/log down method will be used in the computation of AUCs.

The λz will not be presented for subjects who do not exhibit a terminal elimination phase in their concentration-time profiles. In order to estimate terminal elimination rate constant, λz, linear regression of concentration in logarithm scale versus time will be performed using at least 3 data points. Uniform weighting will be selected to perform the regression analysis to estimate λz.

Generally, the constant λz will not be assigned if one of the following happens:

1. T_{max} is one of the 3 last data points,
2. The regression coefficient (R-squared) is less than 0.80,
3. The estimated elimination rate indicates a positive slope, or
4. The terminal elimination phase is not linear (as appears in a semi-logarithmic scale) based on visual inspection.

If the λz is not assigned, the values of associated PK parameters will not be calculated. In the cases where AUC%extrap exceeds 20%, the λz will be assigned but the λz and the corresponding λz-related PK parameters will be flagged and listed with an explanatory footnote.

1.4.3 Pharmacokinetic Summaries

Plasma concentrations of nevanimibe will be summarized by nevanimibe dose (250 mg, 500 mg, 1000 mg) by time point, including plots in linear and semi-log scales. If the exact time (measured from dosing) is outside the collection window for the scheduled time point, the corresponding concentration is excluded from the summary of that time point.

Individual concentrations at each nevanimibe dose level will be plotted in linear and semi-log scales.

PK parameters at at each nevanimibe dose level will be summarized.

1.5 Adverse Events

Adverse events (AEs) will be coded and classified by system organ class and preferred term using the Medical Dictionary for Regulatory Activities (MedDRA) version 18.0. All AEs,

regardless of relationship to study drug, should be collected beginning from the time the subject signs the study consent until the last study visit or 30 days after the last dose of study drug, whichever is later. (Any SAE judged by the Investigator to be related to the study treatment should be reported to the Sponsor regardless of the length of time that has passed since study completion.) AEs in study subjects include any change in the subject's condition. This includes symptoms, physical findings, or clinical syndromes.

Treatment-emergent adverse events (TEAEs) will be defined as any adverse event beginning on or after the first dose date of study drug. AE subject counts will be provided for all dosed subjects in total and by treatment at AE onset (nevanimibe 250 mg, 500 mg, or 1000 mg).

An overview with counts of events and subjects will be provided for the incidence of AEs in the following categories.

- Any AE
- Any TEAE
- Maximum severity of TEAE
- Any study drug related TEAE
- Maximum severity of study drug related TEAE
- Any serious AE (SAE)
- AE leading to discontinuation from study drug

The incidence of TEAEs will be summarized by treatment at onset and in total by system organ class and preferred term. The same summaries will be done for study drug related TEAEs.

1.6 Clinical Safety Laboratory Evaluations

Shift tables from baseline to the worst post-dose value will be presented for ALT and AST (>1xULN to 3xULN, >3xULN to 5xULN, >5xULN) and alkaline phosphatase and total bilirubin (>1xULN to 1.5xULN, >1.5xULN to 2xULN, >2xULN).

2 Tables

Table 14.1.1.1
Subject Disposition
All Subjects

Category	Total n (%)
Screened	##
Entered Open-Label Dose-Escalation Period (i.e. Dosed)	4
Nevanimibe 250 mg BID	4 (###.#)
Nevanimibe 500 mg BID	4 (###.#)
Nevanimibe 1000 mg BID	3 (###.#)
Entered Double-Blind Randomized Withdrawal Period	## (###.#)
Completed the Study	## (###.#)
Early termination	## (###.#)
Primary reason for early termination:	
XXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	## (###.#)
XXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	## (###.#)
XXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	## (###.#)
XXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	## (###.#)

Percentages are calculated with the number of subjects that entered the open-label dose escalation period as the denominator.
Note: Subject 103-001 received nevanimibe 250 mg BID, 250 mg BID, and 500 mg BID at T1, T2, and T3 visits, respectively, instead of the planned 250 mg BID, 500 mg BID, and 1000 mg BID doses.

<< Programming Note: Only reasons for withdrawal with total>0 will be displayed. Reasons will be sorted by descending total, then alphabetically. If reason of "other" occurs in the data, it will always appear last. >>

Table 14.1.2.1
Summary of Demographic and Baseline Characteristics
All Dosed Subjects

Characteristic Category/Statistic	Total (N=#)
Age at Informed Consent	
n	##
Mean	##.#
Standard Deviation	##.##
Median	##.#
Minimum	##
Maximum	##
Sex, n (%)	
Female	## (###.#)
Male	## (###.#)
Ethnicity, n (%)	
Hispanic or Latino	## (###.#)
Not Hispanic or Latino	## (###.#)
Race, n (%)	
White	## (###.#)
Black or African American	## (###.#)
Asian	## (###.#)
American Indian or Alaskan Native	## (###.#)
Native Hawaiian or Other Pacific Islander	## (###.#)
Multiple	## (###.#)

Baseline is defined as the last measurement prior to the first dose of study drug.
%=100*n/N where n is the number of subjects in the specified category and N is the number of dosed subjects.

Table 14.1.2.1
Summary of Demographic and Baseline Characteristics
All Dosed Subjects

Characteristic Category/Statistic	Total (N=#)
Height at Screening (cm)	
n	##
Mean	##.##
Standard Deviation	##.###
Median	##.##
Minimum	##.#
Maximum	##.#
Baseline Weight (kg)	
n	##
Mean	##.##
Standard Deviation	##.###
Median	##.##
Minimum	##.#
Maximum	##.#
Baseline Body Mass index (kg/m^2)	
n	##
Mean	##.##
Standard Deviation	##.###
Median	##.##
Minimum	##.#
Maximum	##.#

Baseline is defined as the last measurement prior to the first dose of study drug.
%=100*n/N where n is the number of subjects in the specified category and N is the number of dosed subjects.

Table 14.2.1.1
Summary of 24 hour Urinary Free Cortisol
All Dosed Subjects

Parameter (Unit) Statistic	Screening	T1	T2	T3	ET^
XXXXXXXXXX (XXXXX)					
n	4	4	4	4	2
Mean	##.##	##.##	##.##	##.##	##.##
Standard Deviation	##.###	##.###	##.###	##.###	##.###
Median	##.##	##.##	##.##	##.##	##.##
Minimum	##.#	##.#	##.#	##.#	##.#
Maximum	##.#	##.#	##.#	##.#	##.#

For Screening values, the screening collections 1 and 2 are averaged for each subject prior to summarization. The 24-hr UFC values shown are those collected after each of the indicated visits, and prior to the next visit, as follows:
T1 = Open Label Dose Escalation Visit 1
T2 = Open Label Dose Escalation Visit 2
T3 = Open Label Dose Escalation Visit 3
^ET = End of Treatment/Early Termination Visit. Subjects 103-001 and 201-003 (both enrolled under Global Protocol Amendment 1) had 24-hr UFC summarized as occurring at ET. These collections began at Day 51 and Day 48, respectively. For 103-001, this was 8 days after last dose. For 201-003, it was the same day as last dose.
For subject 112-001, who was enrolled under Global Protocol Amendment 2, collections 1 and 2 for each timepoint are averaged prior to summarization.

<< Programming Note: Source: LB.LBCAT = "24 HOUR URINE" and LBTEST = "Cortisol Excretion Rate, Free". >>

Table 14.2.2.1
Summary of Pharmacokinetic Plasma Concentrations
All Dosed Subjects

Analyte (Unit) / Dose Level	Scheduled Time Point	N	Mean	Standard Deviation	CV%	Standard Error	Median	Minimum	Maximum	Geometric Mean	Geometric CV%
Nevanimibe (XXXX)											
Nevanimibe 250 mg	Pre-dose	##	#.###	#.####	##.#	#.####	#.###	#.##	#.##	#.###	##.#
	1 hour	##	#.###	#.####	##.#	#.####	#.###	#.##	#.##	#.###	##.#
	2 hours	##	#.###	#.####	##.#	#.####	#.###	#.##	#.##	#.###	##.#
	3 hours	##	#.###	#.####	##.#	#.####	#.###	#.##	#.##	#.###	##.#
	4 hours	##	#.###	#.####	##.#	#.####	#.###	#.##	#.##	#.###	##.#
Nevanimibe 500 mg	Pre-dose	##	#.###	#.####	##.#	#.####	#.###	#.##	#.##	#.###	##.#
	1 hour	##	#.###	#.####	##.#	#.####	#.###	#.##	#.##	#.###	##.#
	2 hours	##	#.###	#.####	##.#	#.####	#.###	#.##	#.##	#.###	##.#
	3 hours	##	#.###	#.####	##.#	#.####	#.###	#.##	#.##	#.###	##.#
	4 hours	##	#.###	#.####	##.#	#.####	#.###	#.##	#.##	#.###	##.#
Nevanimibe 1000 mg	Pre-dose	##	#.###	#.####	##.#	#.####	#.###	#.##	#.##	#.###	##.#
	1 hour	##	#.###	#.####	##.#	#.####	#.###	#.##	#.##	#.###	##.#
	2 hours	##	#.###	#.####	##.#	#.####	#.###	#.##	#.##	#.###	##.#
	3 hours	##	#.###	#.####	##.#	#.####	#.###	#.##	#.##	#.###	##.#
	4 hours	##	#.###	#.####	##.#	#.####	#.###	#.##	#.##	#.###	##.#

Subjects with missing samples, below the limit of quantitation (BLQ) results that are set to missing, or samples collected out of window are not included. Geometric CV% = 100*(exp(SD^2)-1)^0.5, where SD is the standard deviation of the log-transformed data.

Table 14.2.2.2
Pharmacokinetic Plasma Parameter Listing and Summary
All Dosed Subjects

Analyte	Dose Level Subject/Statistic	Cmax (ng/mL)	Tmax (h)	Lambda Z (/h)	T1/2 (h)	AUC (0-last) (h*ng/mL)	AUC (0-4) (h*ng/mL)	AUC (0-inf) (h*ng/mL)	AUC%extrap (%)
Nevanimibe	Nevanimibe 250 mg								
	###-###	###	##.##	#.###	##.##	###	###	###	###.#
	###-### [1]	###	##.##	#.###	##.##	###	###	###	###.#
	###-###	###	##.##	#.###	##.##	###	###	###	###.#
	###-###	###	##.##	#.###	##.##				
	n	###	##	#	##	###	###	###	###
	Mean	###.#	##.###	#.####	##.###	###.#	###.#	###.#	###.##
	Standard Deviation	###.##	##.####	#.#####	##.####	###.##	###.##	###.##	###.###
	CV%	###.#	##.#	#.#	##.#	###.#	###.#	###.#	###.#
	Standard Error	###.##	##.####	#.#####	##.####	###.##	###.##	###.##	###.###
	Median	###.#	##.###	#.####	##.###	###.#	###.#	###.#	###.##
	Minimum	###	##.##	#.###	##.##	###	###	###	###.#
	Maximum	###	##.##	#.###	##.##	###	###	###	###.#
	Geometric Mean	###.#	N/A	N/A	N/A	###.#	###.#	###.#	N/A
	Geometric CV%	###.#	N/A	N/A	N/A	###.#	###.#	###.#	N/A

Geometric CV%=100*(exp(SD^2)-1)^0.5, where SD is the standard deviation of the log-transformed data. N/A=Not Applicable.
[1] AUCextr > 20%, implying greater uncertainty in pharmacokinetic parameters dependent on the definition of the terminal phase and/or this extrapolation.

<<Programming Note: Repeat for each dose level. >>

Table 14.3.1.1
Overview of Adverse Events
All Dosed Subjects

Category	Nevanimibe Dose at Onset: 250 mg BID (N=#) n (%)	e	500 mg BID (N=#) n (%)	e	1000 mg BID (N=#) n (%)	e	Total (N=#) n (%)	e
Subjects with any adverse event (AE)							# (###.#)	#
Subjects with any treatment-emergent AE (TEAE)	# (###.#)	#	# (###.#)	#	# (###.#)	#	# (###.#)	#
Maximum severity of TEAE								
Mild	# (###.#)	N/A	# (###.#)	N/A	# (###.#)	N/A	# (###.#)	N/A
Moderate	# (###.#)	N/A	# (###.#)	N/A	# (###.#)	N/A	# (###.#)	N/A
Severe	# (###.#)	N/A	# (###.#)	N/A	# (###.#)	N/A	# (###.#)	N/A
Subjects with any study drug related TEAE	# (###.#)	#	# (###.#)	#	# (###.#)	#	# (###.#)	#
Maximum severity of study drug related TEAE								
Mild	# (###.#)	N/A	# (###.#)	N/A	# (###.#)	N/A	# (###.#)	N/A
Moderate	# (###.#)	N/A	# (###.#)	N/A	# (###.#)	N/A	# (###.#)	N/A
Severe	# (###.#)	N/A	# (###.#)	N/A	# (###.#)	N/A	# (###.#)	N/A
Subjects with any serious AE (SAE)	# (###.#)	#	# (###.#)	#	# (###.#)	#	# (###.#)	#
Subjects with any AE leading to discontinuation of study drug	# (###.#)	#	# (###.#)	#	# (###.#)	#	# (###.#)	#

%=100*n/N, where n is the number of subjects in the specified category and N is the number of dosed subjects per column. e = number of AEs in the specified category. AEs are summarized by the dose level at the onset of the event. TEAEs are defined as any AE beginning on or after the first dose date of study drug. Study drug related AEs include those that are possibly, probably, or definitely related.

Table 14.3.1.2
Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
All Dosed Subjects

System Organ Class Preferred Term	Nevanimibe Dose at Onset 250 mg BID (N=#) n (%) e	 500 mg BID (N=#) n (%) e	 1000 mg BID (N=#) n (%) e	 Total (N=#) n (%) e
Subjects with any TEAE	# (###.#) #	# (###.#) #	# (###.#) #	# (###.#) #
XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	# (###.#) #	# (###.#) #	# (###.#) #	# (###.#) #
XXXXXXXXXXXXXXXXXXXXXXXXXXXXX	# (###.#) #	# (###.#) #	# (###.#) #	# (###.#) #
XXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	# (###.#) #	# (###.#) #	# (###.#) #	# (###.#) #
XXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	# (###.#) #	# (###.#) #	# (###.#) #	# (###.#) #
XXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	# (###.#) #	# (###.#) #	# (###.#) #	# (###.#) #
XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	# (###.#) #	# (###.#) #	# (###.#) #	# (###.#) #
XXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	# (###.#) #	# (###.#) #	# (###.#) #	# (###.#) #
XXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	# (###.#) #	# (###.#) #	# (###.#) #	# (###.#) #

%=100*n/N, where n is the number of subjects in the specified category and N is the number of dosed subjects per column. e = number of adverse events in the specified category. Treatment-emergent adverse events (TEAEs) are defined as any AE beginning on or after the first dose date of study drug. AEs are summarized by the dose level at the onset of the event. At each level of summation (overall, system organ class, preferred term), subjects reporting more than one AE are counted only once. A subject may contribute to more than one preferred term. AEs are coded using MedDRA dictionary version 18.0.

Program Name: XXXXXXXX.sas Run Date: DDMMMYYYY HH:MM Clinical database last extracted: DDMMYYYY HH:MM

<< Programming Note: Table will be sorted by descending frequency (n then e) in the total column for system organ class and preferred term within system organ class. >>

<< Programming Note: The following tables will have the same layout as Table 14.3.1.2: >>

Table 14.3.1.3
Summary of Study Drug Related Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
All Dosed Subjects

<< Programming Note: Replace

Subjects with any TEAE

With

Subjects with any study drug related TEAE

<< Programming Note: Include the additional footnote: >>

Study drug related AEs include those that are possibly, probably, or definitely related.

Table 14.3.3.1
Shift Table of ALT, AST, Alkaline Phosphatase, and Total Bilirubin
All Dosed Subjects

		Highest Post-Baseline Value					
Parameter	Baseline	Normal or Low n (%)	>1 to 3xULN n (%)	>3 to 5xULN n (%)	>5xULN n (%)	Missing n (%)	Total n (%)
ALT	Normal or Low	# (##.#)	# (##.#)	# (##.#)	# (##.#)	# (##.#)	# (##.#)
	>1 – 3xULN	# (##.#)	# (##.#)	# (##.#)	# (##.#)	# (##.#)	# (##.#)
	>3 – 5xULN	# (##.#)	# (##.#)	# (##.#)	# (##.#)	# (##.#)	# (##.#)
	>5xULN	# (##.#)	# (##.#)	# (##.#)	# (##.#)	# (##.#)	# (##.#)
	Missing	# (##.#)	# (##.#)	# (##.#)	# (##.#)	# (##.#)	# (##.#)
	Total	# (##.#)	# (##.#)	# (##.#)	# (##.#)	# (##.#)	# (100.0)
AST	Normal or Low	# (##.#)	# (##.#)	# (##.#)	# (##.#)	# (##.#)	# (##.#)
	>1 – 3xULN	# (##.#)	# (##.#)	# (##.#)	# (##.#)	# (##.#)	# (##.#)
	>3 – 5xULN	# (##.#)	# (##.#)	# (##.#)	# (##.#)	# (##.#)	# (##.#)
	>5xULN	# (##.#)	# (##.#)	# (##.#)	# (##.#)	# (##.#)	# (##.#)
	Missing	# (##.#)	# (##.#)	# (##.#)	# (##.#)	# (##.#)	# (##.#)
	Total	# (##.#)	# (##.#)	# (##.#)	# (##.#)	# (##.#)	# (100.0)

ALT = Alanine Aminotransferase. AST = Aspartate Aminotransferase. ULN = upper limit of normal.
Baseline is defined as the last measurement prior to the first dose of study drug.
%=100*n/N, where n is the number of subjects in the specified category and N is the number of dosed subjects (N=4).

Table 14.3.3.1
Shift Table of ALT, AST, Alkaline Phosphatase, and Total Bilirubin
All Dosed Subjects

		Highest Post-Baseline Value					
Parameter	Baseline	Normal or Low n (%)	>1 to 1.5xULN n (%)	>1.5 to 2xULN n (%)	>2xULN n (%)	Missing n (%)	Total n (%)
Alkaline Phosphatase	Normal or Low	# (##.#)	# (##.#)	# (##.#)	# (##.#)	# (##.#)	# (##.#)
	>1 - 1.5xULN	# (##.#)	# (##.#)	# (##.#)	# (##.#)	# (##.#)	# (##.#)
	>1.5 - 2xULN	# (##.#)	# (##.#)	# (##.#)	# (##.#)	# (##.#)	# (##.#)
	>2xULN	# (##.#)	# (##.#)	# (##.#)	# (##.#)	# (##.#)	# (##.#)
	Missing	# (##.#)	# (##.#)	# (##.#)	# (##.#)	# (##.#)	# (##.#)
	Total	# (##.#)	# (##.#)	# (##.#)	# (##.#)	# (##.#)	# (100.0)
Bilirubin	Normal or Low	# (##.#)	# (##.#)	# (##.#)	# (##.#)	# (##.#)	# (##.#)
	>1 - 1.5xULN	# (##.#)	# (##.#)	# (##.#)	# (##.#)	# (##.#)	# (##.#)
	>1.5 - 2xULN	# (##.#)	# (##.#)	# (##.#)	# (##.#)	# (##.#)	# (##.#)
	>2xULN	# (##.#)	# (##.#)	# (##.#)	# (##.#)	# (##.#)	# (##.#)
	Missing	# (##.#)	# (##.#)	# (##.#)	# (##.#)	# (##.#)	# (##.#)
	Total	# (##.#)	# (##.#)	# (##.#)	# (##.#)	# (##.#)	# (100.0)

ALT = Alanine Aminotransferase. AST = Aspartate Aminotransferase. ULN = upper limit of normal.
Baseline is defined as the last measurement prior to the first dose of study drug.
%=100*n/N, where n is the number of subjects in the specified category and N is the number of dosed subjects (N=4).

3 Figures

Figure 14.2.1.1
Mean Nevanimibe Plasma Concentrations
All Dosed Subjects

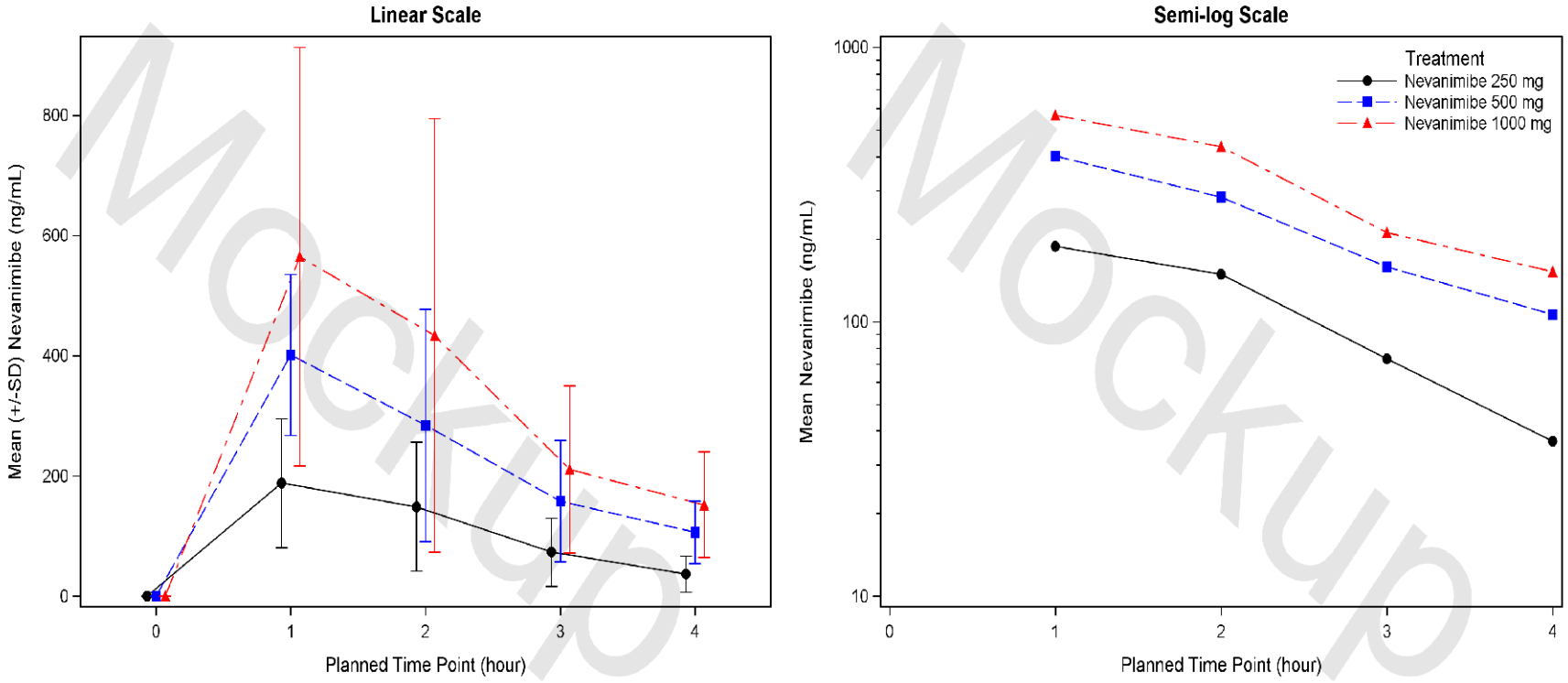
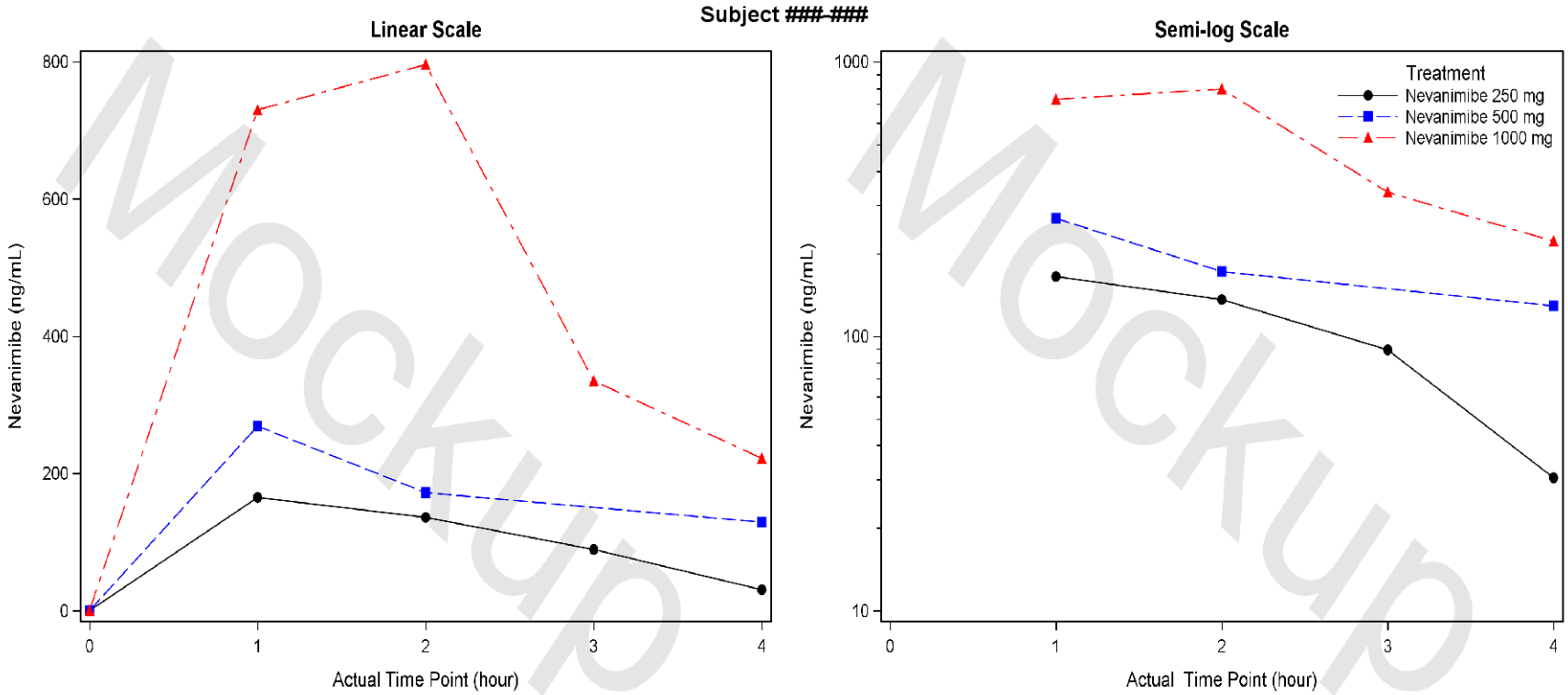


Figure 14.2.1.2
Individual ATR-101 Plasma Concentrations
All Dosed Subjects



4 Listings

Listing 16.2.1.1
Subject Disposition: Informed Consent and Enrollment
All Subjects

Subject	Date of Informed Consent	Did Subject Enroll In the Open-Label Dose Escalation Period?	Date Enrolled	Date of Screen Failure	Reason for Screen Failure	Did Subject Continue to the Double-Blind Randomized Withdrawal Period or the Additional Open-Label Dosing?
###-###	DDMMMYYYY	YES	DDMMMYYYY			NO
###-###	DDMMMYYYY	NO		DDMMMYYYY	XXXXXXXXXXXXXXXXXXXXXXXX	
###-###	DDMMMYYYY	YES	DDMMMYYYY			NO
###-###	DDMMMYYYY	YES	DDMMMYYYY			NO
###-###	DDMMMYYYY	YES	DDMMMYYYY			NO
###-###	DDMMMYYYY	NO		DDMMMYYYY	XXXXXXXXXXXXXXXXXXXXXXXX	
###-###	DDMMMYYYY	NO		DDMMMYYYY	XXXXXXXXXXXXXXXXXXXXXXXX	
###-###	DDMMMYYYY	NO		DDMMMYYYY	XXXXXXXXXXXXXXXXXXXXXXXX	
###-###	DDMMMYYYY	NO		DDMMMYYYY	XXXXXXXXXXXXXXXXXXXXXXXX	

<< Programming Note: Refer to records where DS.DSDECOD = "INFORMED CONSENT OBTAINED", DS.DSSCAT = "ENROLLMENT", DS.DSSCAT = "SCREEN FAILURE", and DS.DSCAT = "PROTOCOL MILESTONE". >>

Listing 16.2.1.2
Inclusion/Exclusion Criteria Not Met
All Subjects

Subject	Category	Criterion	Description
###-### (SF)	XXXXXXXXX	##	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
###-###	XXXXXXXXX	##	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
	XXXXXXXXX	##	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
###-###	XXXXXXXXX	##	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
###-###	XXXXXXXXX	##	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
###-###	XXXXXXXXX	##	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
###-### (SF)	XXXXXXXXX	##	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
###-### (SF)	XXXXXXXXX	##	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
###-### (SF)	XXXXXXXXX	##	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
###-### (SF)	XXXXXXXXX	##	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX

SF = Screen failure subject

Program Name: XXXXXXXX.sas Run Date: DDMMMYYYY HH:MM Clinical database last extracted: DDMMYYYY HH:MM

<< Programming Note: Only use the last 2 digits of IE.IETESTCD for the criterion number. >>

Listing 16.2.1.3
Subject Disposition: End of Study
All Dosed Subjects

Subject	Date of First Dose	Date (Day) of Last Dose	Completed Study?	Date (Day) of Completion/ Early Termination	Primary Reason for Early Termination
###-###	DDMMMYYYY	DDMMMYYYY (##)	XXX	DDMMMYYYY (##)	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
###-###	DDMMMYYYY	DDMMMYYYY (##)	XXX	DDMMMYYYY (##)	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
###-###	DDMMMYYYY	DDMMMYYYY (##)	XXX	DDMMMYYYY (##)	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
###-###	DDMMMYYYY	DDMMMYYYY (##)	XXX	DDMMMYYYY (##)	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX

Day = Date – first dose date +1.

Program Name: XXXXXXXX.sas Run Date: DDMMMYYYY HH:MM Clinical database last extracted: DDMMYYYY HH:MM

Listing 16.2.1.4
Follow-Up Telephone Visit
All Dosed Subjects

Subject	Was the Subject Reached for Follow-Up?	Date (Day) of Contact	Any Adverse Events Since Last Study Visit?	Started or Stopped Any Medications Since Last Study Visit?
###-###	XXX	DDMMMYYYY (##)	XXX	XXX
###-###	XXX	DDMMMYYYY (##)	XXX	XXX
###-###	XXX	DDMMMYYYY (##)	XXX	XXX
###-###	XXX	DDMMMYYYY (##)	XXX	XXX

Day = Date - first dose date +1.

Listing 16.2.2.1
Protocol Deviations
All Subjects

Subject	Date of Verification	Date of Occurrence	Pre-Approved?	Category	Description	CSR Reportable?	Action Type	Confirmed?
###-###	DDMMMYYYY	DDMMMYYYY	XXX	XXXXXXXXXXX	XXXXXXXXXXXXXXXXX	XXX	XXXXXXXXXXXXXXXXXXXXXX	XXX
	DDMMMYYYY	DDMMMYYYY	XXX	XXXXXXXXXXX	XXXXXXXXXXXXXXXXX	XXX	XXXXXXXXXXXXXXXXXXXXXX	XXX
	DDMMMYYYY	DDMMMYYYY	XXX	XXXXXXXXXXX	XXXXXXXXXXXXXXXXX	XXX	XXXXXXXXXXXXXXXXXXXXXX	XXX
	DDMMMYYYY	DDMMMYYYY	XXX	XXXXXXXXXXX	XXXXXXXXXXXXXXXXX	XXX	XXXXXXXXXXXXXXXXXXXXXX	XXX
###-### (SF)	DDMMMYYYY	DDMMMYYYY	XXX	XXXXXXXXXXX	XXXXXXXXXXXXXXXXX	XXX	XXXXXXXXXXXXXXXXXXXXXX	XXX
	DDMMMYYYY	DDMMMYYYY	XXX	XXXXXXXXXXX	XXXXXXXXXXXXXXXXX	XXX	XXXXXXXXXXXXXXXXXXXXXX	XXX
	DDMMMYYYY	DDMMMYYYY	XXX	XXXXXXXXXXX	XXXXXXXXXXXXXXXXX	XXX	XXXXXXXXXXXXXXXXXXXXXX	XXX
	DDMMMYYYY	DDMMMYYYY	XXX	XXXXXXXXXXX	XXXXXXXXXXXXXXXXX	XXX	XXXXXXXXXXXXXXXXXXXXXX	XXX
###-###	DDMMMYYYY	DDMMMYYYY	XXX	XXXXXXXXXXX	XXXXXXXXXXXXXXXXX	XXX	XXXXXXXXXXXXXXXXXXXXXX	XXX
	DDMMMYYYY	DDMMMYYYY	XXX	XXXXXXXXXXX	XXXXXXXXXXXXXXXXX	XXX	XXXXXXXXXXXXXXXXXXXXXX	XXX
	DDMMMYYYY	DDMMMYYYY	XXX	XXXXXXXXXXX	XXXXXXXXXXXXXXXXX	XXX	XXXXXXXXXXXXXXXXXXXXXX	XXX
	DDMMMYYYY	DDMMMYYYY	XXX	XXXXXXXXXXX	XXXXXXXXXXXXXXXXX	XXX	XXXXXXXXXXXXXXXXXXXXXX	XXX
###-###	DDMMMYYYY	DDMMMYYYY	XXX	XXXXXXXXXXX	XXXXXXXXXXXXXXXXX	XXX	XXXXXXXXXXXXXXXXXXXXXX	XXX
	DDMMMYYYY	DDMMMYYYY	XXX	XXXXXXXXXXX	XXXXXXXXXXXXXXXXX	XXX	XXXXXXXXXXXXXXXXXXXXXX	XXX
	DDMMMYYYY	DDMMMYYYY	XXX	XXXXXXXXXXX	XXXXXXXXXXXXXXXXX	XXX	XXXXXXXXXXXXXXXXXXXXXX	XXX
	DDMMMYYYY	DDMMMYYYY	XXX	XXXXXXXXXXX	XXXXXXXXXXXXXXXXX	XXX	XXXXXXXXXXXXXXXXXXXXXX	XXX

SF = Screen failure subject. CSR = Clinical Study Report.

Program Name: XXXXXXXX.sas Run Date: DDMMMYYYY HH:MM Clinical database last extracted: DDMMYYYY HH:MM

Listing 16.2.4.1
Demographics
All Subjects

Subject	Protocol Version	Date of Birth	Age (Years)	Sex	Ethnicity	Race	Race, Specify
###-## (SF)	XXXXXXXXXX	DDMMMYYYY	##	XXXX	XXXXXXXXXXXXX	XXXXXXXXXXXX	XXXXXXXXXXXXXXXXXXXXXXXX
###-##	XXXXXXXXXX	DDMMMYYYY	##	XXXX	XXXXXXXXXXXXX	XXXXXXXXXXXX	XXXXXXXXXXXXXXXXXXXXXXXX
###-##	XXXXXXXXXX	DDMMMYYYY	##	XXXX	XXXXXXXXXXXXX	XXXXXXXXXXXX	XXXXXXXXXXXXXXXXXXXXXXXX
###-##	XXXXXXXXXX	DDMMMYYYY	##	XXXX	XXXXXXXXXXXXX	XXXXXXXXXXXX	XXXXXXXXXXXXXXXXXXXXXXXX
###-## (SF)	XXXXXXXXXX	DDMMMYYYY	##	XXXX	XXXXXXXXXXXXX	XXXXXXXXXXXX	XXXXXXXXXXXXXXXXXXXXXXXX
###-## (SF)	XXXXXXXXXX	DDMMMYYYY	##	XXXX	XXXXXXXXXXXXX	XXXXXXXXXXXX	XXXXXXXXXXXXXXXXXXXXXXXX
###-## (SF)	XXXXXXXXXX	DDMMMYYYY	##	XXXX	XXXXXXXXXXXXX	XXXXXXXXXXXX	XXXXXXXXXXXXXXXXXXXXXXXX
###-##	XXXXXXXXXX	DDMMMYYYY	##	XXXX	XXXXXXXXXXXXX	XXXXXXXXXXXX	XXXXXXXXXXXXXXXXXXXXXXXX
###-##	XXXXXXXXXX	DDMMMYYYY	##	XXXX	XXXXXXXXXXXXX	XXXXXXXXXXXX	XXXXXXXXXXXXXXXXXXXXXXXX

SF = Screen failure subject

Program Name: XXXXXXXX.sas Run Date: DDMMMYYYY HH:MM Clinical database last extracted: DDMMYYYY HH:MM

Listing 16.2.4.2
Cushing's Syndrome Medical History
All Subjects

Subject	Diagnosis Date	Etiology	How was the etiology confirmed?	History of Prior Pituitary Surgery?	Previous Pituitary Radiotherapy?
###-### (SF)	DDMMMYYYY	XXXXXXXXX	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	XXX	XXX
###-###	DDMMMYYYY	XXXXXXXXX	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	XXX	XXX
###-### (SF)	DDMMMYYYY	XXXXXXXXX	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	XXX	XXX
###-###	DDMMMYYYY	XXXXXXXXX	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	XXX	XXX
###-###	DDMMMYYYY	XXXXXXXXX	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	XXX	XXX

SF = Screen failure subject

Listing 16.2.4.3
Tobacco Use
All Subjects

Subject	Cigarette Use	Frequency	Other Tobacco Product use
###-### (SF)	NEVER SMOKED		NEVER USED
###-###	FORMERLY SMOKED	XXXXXXXXXXXXXXX	NEVER USED
###-###	XXXXXXXXXXXXXXX	XXXXXXXXXXXXXXX	XXXXXXXXXX
###-###	XXXXXXXXXXXXXXX	XXXXXXXXXXXXXXX	XXXXXXXXXX

SF = Screen failure subject

<< Programming Note: If other data is reported, e.g. number of cigarettes, other tobacco product information, or start/stop dates, then add columns for the additional data. >>

Listing 16.2.4.4
General Medical History
All Subjects

Subject	System Organ Class/ Preferred Term/ Event/Diagnosis	Start Date	Stop Date
###-### (SF)	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	DDMMMYYYY	DDMMMYYYY
	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	DDMMMYYYY	ONGOING
###-###	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	DDMMMYYYY	DDMMMYYYY

SF = Screen failure subject. Medical history is coded using MedDRA dictionary version 18.0.

<< Programming Note: Only include records where MHPRESP=null. Sort by USUBJID, MHSTDTC, MHENDTC, MHTERM. >>

Listing 16.2.4.5
Pituitary Radiotherapy
All Subjects

Subject	Date of First Dose	Date of Last Dose	Comments
###-###	DDMMMYYYY	DDMMMYYYY	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX

Listing 16.2.4.6
Prior and Concomitant Medications
All Subjects

Subject	Medication Name/ Preferred Term/ Chemical Substance	Start Date/ End Date	Indication	Dose	Units	Frequency	Route
###-###	XXXXXXXXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXXXXXXX	DDMMMYYYY/ DDMMMYYYY	XXXXXXXXXXXXXXXX	XXXXXXX	XXXXX	OTHER: XXXXXXX	XXXXXXXXXXX
	XXXXXXXXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXXXXXXX	DDMMMYYYY/ ONGOING	XXXXXXXXXXXXXXXX	XXXXXXX	OTHER: XXXXXXXXXX	XXXXXXXXXX	XXXXXXXXXXX
	XXXXXXXXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXXXXXXX	DDMMMYYYY/ ONGOING	XXXXXXXXXXXXXXXX	XXXXXXX	XXXXX	XXXXXXXXXX	OTHER: XXXXXXXXXX
###-###	XXXXXXXXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXXXXXXX	DDMMMYYYY/ DDMMMYYYY	XXXXXXXXXXXXXXXX	XXXXXXX	XXXXX	XXXXXXXXXX	XXXXXXXXXXX
###-###	XXXXXXXXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXXXXXXX	DDMMMYYYY/ DDMMMYYYY	XXXXXXXXXXXXXXXX	XXXXXXX	XXXXX	XXXXXXXXXX	XXXXXXXXXXX

Medications are coded with the WHO Drug March 2016E B2 dictionary version.

Program Name: XXXXXXXX.sas Run Date: DDMMMYYYY HH:MM Clinical database last extracted: DDMMYYYY HH:MM

<< Programming Note: Sort by USUBJID, CMSTDTC, CMENDTC, CMTRT. >>

Listing 16.2.4.7
Concomitant Procedures
All Subjects

Subject	Procedure	Indication	Start Date	Stop Date
###-###	XXXXXXXXXXXXXXXXXXXXXXXXXXX	XXXXXXXXXXXXXXXX	DDMMMYYYY	DDMMMYYYY
	XXXXXXXXXXXXXXXXXXXXXXXXXXX	XXXXXXXXXXXXXXXX	DDMMMYYYY	ONGOING
###-###	XXXXXXXXXXXXXXXXXXXXXXXXXXX	XXXXXXXXXXXXXXXX	DDMMMYYYY	DDMMMYYYY
###-###	XXXXXXXXXXXXXXXXXXXXXXXXXXX	XXXXXXXXXXXXXXXX	DDMMMYYYY	DDMMMYYYY
###-###	XXXXXXXXXXXXXXXXXXXXXXXXXXX	XXXXXXXXXXXXXXXX	DDMMMYYYY	DDMMMYYYY

<< Programming Note: Sort by USUBJID, PRSTDTC, PRENDTC, PRTRT. >>

Listing 16.2.5.1
Study Drug Administration
All Dosed Subjects

Subject	Visit	Treatment Name	Date/Time of Administration	Did Subject Consume Food Prior to Administration?	Was the Planned Dose Administered On Site?
###-###	XXXXXXXXXXXX	Nevanimibe 250 mg BID	DDMMMYYYY/HH:MM	XXX	XXX
	XXXXXXXXXXXX	Nevanimibe 500 mg BID	DDMMMYYYY/HH:MM	XXX	XXX
	XXXXXXXXXXXX	Nevanimibe 1000 mg BID	DDMMMYYYY/HH:MM	XXX	XXX
###-###	XXXXXXXXXXXX	XXXXXXXXXXXXXX	DDMMMYYYY/HH:MM	XXX	XXX
	XXXXXXXXXXXX	XXXXXXXXXXXXXX	DDMMMYYYY/HH:MM	XXX	XXX
	XXXXXXXXXXXX	XXXXXXXXXXXXXX	DDMMMYYYY/HH:MM	XXX	XXX
###-###	XXXXXXXXXXXX	XXXXXXXXXXXXXX	DDMMMYYYY/HH:MM	XXX	XXX
	XXXXXXXXXXXX	XXXXXXXXXXXXXX	DDMMMYYYY/HH:MM	XXX	XXX
	XXXXXXXXXXXX	XXXXXXXXXXXXXX	DDMMMYYYY/HH:MM	XXX	XXX
###-###	XXXXXXXXXXXX	XXXXXXXXXXXXXX	DDMMMYYYY/HH:MM	XXX	XXX
	XXXXXXXXXXXX	XXXXXXXXXXXXXX	DDMMMYYYY/HH:MM	XXX	XXX
	XXXXXXXXXXXX	XXXXXXXXXXXXXX	DDMMMYYYY/HH:MM	XXX	XXX

Program Name: XXXXXXXX.sas Run Date: DDMMMYYYY HH:MM Clinical database last extracted: DDMMYYYY HH:MM

<< <u>Programming Note</u>: Only include records where ECOCCUR = "Y". >>

Listing 16.2.5.2
Study Drug Accountability
All Dosed Subjects

Subject	Bottle Number	Treatment	Dispense Date	Dispense Number of Tablets	Return Date	Return Number of Tablets	80-120% Compliant?
###-###	#####	Nevanimibe 250 mg BID	DDMMMYYYY	##	DDMMMYYYY	##	XXX
	#####	Nevanimibe 500 mg BID	DDMMMYYYY	##	DDMMMYYYY	##	XXX
	#####	Nevanimibe 1000 mg BID	DDMMMYYYY	##	DDMMMYYYY	##	XXX
	#####	Nevanimibe 1000 mg BID	DDMMMYYYY	##	DDMMMYYYY	##	XXX
###-###	#####	XXXXXXXXXXXXXXXXXXX	DDMMMYYYY	##	DDMMMYYYY	##	XXX
	#####	XXXXXXXXXXXXXXXXXXX	DDMMMYYYY	##	DDMMMYYYY	##	XXX
	#####	XXXXXXXXXXXXXXXXXXX	DDMMMYYYY	##	DDMMMYYYY	##	XXX

<< Programming Note: Sort by Subject, Dispense Date, Return Date. The compliance question is sourced from SUPPDA where QNAM = "COMP". >>

Listing 16.2.5.3
Study Drug Exposure and Compliance
All Dosed Subjects

	Nevanimibe 250 mg BID			Nevanimibe 500 mg BID			Nevanimibe 1000 mg BID		
Subject	Number of Tablets	Days of Exposure	Compliance (%)	Number of Tablets	Days of Exposure	Compliance (%)	Number of Tablets	Days of Exposure	Compliance (%)
###-###	##	##	###.#	##	##	###.#	##	##	###.#
###-###	##	##	###.#	##	##	###.#			
###-###	##	##	###.#	##	##	###.#	##	##	###.#
###-###	##	##	###.#	##	##	###.#	##	##	###.#

Number of tablets = number of tablets dispensed – number of tablets returned.
Days of exposure = last dose date of the specified dose level – first dose date of the specified dose level +1.
Compliance = 100*number of tablets/(days of exposure*2) for the 250 mg BID and 500 mg BID groups.
Compliance = 100*number of tablets/(days of exposure*4) for the 1000 mg BID group.

Program Name: XXXXXXXX.sas Run Date: DDMMMYYYY HH:MM Clinical database last extracted: DDMMYYYY HH:MM

<< Programming Note: For the last dose level (i.e. 500 mg for subject 103-001 and 1000 mg for others), exposure = TRTEDT – TR03SDT + 1. For other dose levels, assume that the "last dose date of the specified dose level" is the day before the first dose date of the next dose level. For example for 250 mg (except 103-001), exposure = TR02SDT – TR01SDT. >>

Listing 16.2.6.1
24 Hour Urine Laboratory Results
All Subjects

Subject	Parameter (Unit)	Visit	Collection Start Date/Time	Collection End Date/Time	Result	Normal Range	Flag
###-### (SF)	XXXXXXXXXXX (XXXXX)	XXXXXXXXXXXX	DDMMMYYYY/HH:MM	DDMMMYYYY/HH:MM	XXXXX	XX - XX	
		XXXXXXXXXXXX	DDMMMYYYY/HH:MM	DDMMMYYYY/HH:MM	XXXXX	XX - XX	HIGH
		XXXXXXXXXXXX	DDMMMYYYY/HH:MM	DDMMMYYYY/HH:MM	XXXXX	XX - XX	
		XXXXXXXXXXXX	DDMMMYYYY/HH:MM	DDMMMYYYY/HH:MM	XXXXX	XX - XX	
		XXXXXXXXXXXX	DDMMMYYYY/HH:MM	DDMMMYYYY/HH:MM	XXXXX	XX - XX	LOW
		XXXXXXXXXXXX	DDMMMYYYY/HH:MM	DDMMMYYYY/HH:MM	XXXXX	XX - XX	
	XXXXXXXXXXX (XXXXX)	XXXXXXXXXXXX	DDMMMYYYY/HH:MM	DDMMMYYYY/HH:MM	XXXXX	XX - XX	
		XXXXXXXXXXXX	DDMMMYYYY/HH:MM	DDMMMYYYY/HH:MM	XXXXX	XX - XX	
		XXXXXXXXXXXX	DDMMMYYYY/HH:MM	DDMMMYYYY/HH:MM	XXXXX	XX - XX	
		XXXXXXXXXXXX	DDMMMYYYY/HH:MM	DDMMMYYYY/HH:MM	XXXXX	XX - XX	
		XXXXXXXXXXXX	DDMMMYYYY/HH:MM	DDMMMYYYY/HH:MM	XXXXX	XX - XX	
		XXXXXXXXXXXX	DDMMMYYYY/HH:MM	DDMMMYYYY/HH:MM	XXXXX	XX - XX	
###-###	XXXXXXXXXXX (XXXXX)	XXXXXXXXXXXX	DDMMMYYYY/HH:MM	DDMMMYYYY/HH:MM	XXXXX	XX - XX	
		XXXXXXXXXXXX	DDMMMYYYY/HH:MM	DDMMMYYYY/HH:MM	XXXXX	XX - XX	
		XXXXXXXXXXXX	DDMMMYYYY/HH:MM	DDMMMYYYY/HH:MM	XXXXX	XX - XX	
		XXXXXXXXXXXX	DDMMMYYYY/HH:MM	DDMMMYYYY/HH:MM	XXXXX	XX - XX	
		XXXXXXXXXXXX	DDMMMYYYY/HH:MM	DDMMMYYYY/HH:MM	XXXXX	XX - XX	
		XXXXXXXXXXXX	DDMMMYYYY/HH:MM	DDMMMYYYY/HH:MM	XXXXX	XX - XX	
###-###	XXXXXXXXXXX (XXXXX)	XXXXXXXXXXXX	DDMMMYYYY/HH:MM	DDMMMYYYY/HH:MM	XXXXX	XX - XX	
		XXXXXXXXXXXX	DDMMMYYYY/HH:MM	DDMMMYYYY/HH:MM	XXXXX	XX - XX	
		XXXXXXXXXXXX	DDMMMYYYY/HH:MM	DDMMMYYYY/HH:MM	XXXXX	XX - XX	
		XXXXXXXXXXXX	DDMMMYYYY/HH:MM	DDMMMYYYY/HH:MM	XXXXX	XX - XX	
		XXXXXXXXXXXX	DDMMMYYYY/HH:MM	DDMMMYYYY/HH:MM	XXXXX	XX - XX	

SF = Screen failure subject.

Program Name: XXXXXXXX.sas   Run Date: DDMMMYYYY HH:MM   Clinical database last extracted: DDMMYYYY HH:MM

<< Programming Note: Include all results where LBCAT = "24 HOUR URINE".

In all lab listings, report results in US conventional units (LBORRES variables). >>

Listing 16.2.6.2
ARUP Laboratories: Plasma and Serum Samples
All Subjects

Subject	Parameter (Unit)	Visit	Date/Time of Collection	Result	Normal Range	Flag
###-### (SF)	XXXXXXXXXXX (XXXXX)	XXXXXXXXXXXX	DDMMMYYYY/HH:MM	XXXXX	XX - XX	
		XXXXXXXXXXXX	DDMMMYYYY/HH:MM	XXXXX	XX - XX	HIGH
		XXXXXXXXXXXX	DDMMMYYYY/HH:MM	XXXXX	XX - XX	
		XXXXXXXXXXXX	DDMMMYYYY/HH:MM	XXXXX	XX - XX	
		XXXXXXXXXXXX	DDMMMYYYY/HH:MM	XXXXX	XX - XX	LOW
		XXXXXXXXXXXX	DDMMMYYYY/HH:MM	XXXXX	XX - XX	
	XXXXXXXXXXX (XXXXX)	XXXXXXXXXXXX	DDMMMYYYY/HH:MM	XXXXX	XX - XX	
		XXXXXXXXXXXX	DDMMMYYYY/HH:MM	XXXXX	XX - XX	
		XXXXXXXXXXXX	DDMMMYYYY/HH:MM	XXXXX	XX - XX	
		XXXXXXXXXXXX	DDMMMYYYY/HH:MM	XXXXX	XX - XX	
		XXXXXXXXXXXX	DDMMMYYYY/HH:MM	XXXXX	XX - XX	
		XXXXXXXXXXXX	DDMMMYYYY/HH:MM	XXXXX	XX - XX	
###-###	XXXXXXXXXXX (XXXXX)	XXXXXXXXXXXX	DDMMMYYYY/HH:MM	XXXXX	XX - XX	
		XXXXXXXXXXXX	DDMMMYYYY/HH:MM	XXXXX	XX - XX	
		XXXXXXXXXXXX	DDMMMYYYY/HH:MM	XXXXX	XX - XX	
		XXXXXXXXXXXX	DDMMMYYYY/HH:MM	XXXXX	XX - XX	
		XXXXXXXXXXXX	DDMMMYYYY/HH:MM	XXXXX	XX - XX	
		XXXXXXXXXXXX	DDMMMYYYY/HH:MM	XXXXX	XX - XX	
###-###	XXXXXXXXXXX (XXXXX)	XXXXXXXXXXXX	DDMMMYYYY/HH:MM	XXXXX	XX - XX	
		XXXXXXXXXXXX	DDMMMYYYY/HH:MM	XXXXX	XX - XX	
		XXXXXXXXXXXX	DDMMMYYYY/HH:MM	XXXXX	XX - XX	
		XXXXXXXXXXXX	DDMMMYYYY/HH:MM	XXXXX	XX - XX	
		XXXXXXXXXXXX	DDMMMYYYY/HH:MM	XXXXX	XX - XX	

SF = Screen failure subject.

<< Programming Note: Include all results where LBCAT = "ARUP LABORATORIES" and LBSPEC in ("PLASMA", "SERUM")>>

<< Programming Note: The following will have the same layout as listing 16.2.6.1. Include all results where LBCAT = "ARUP LABORATORIES" and LBSPEC = "URINE". >>

Listing 16.2.6.3
ARUP Laboratories: Urine Samples
All Subjects

Listing 16.2.6.4
Salivary Cortisol
All Subjects

Subject	Parameter (Unit)	Visit	Time Point	Date/Time of Collection	Result	Normal Range	Flag
###-### (SF)	XXXXXXXXXXX (XXXXX)	XXXXXXXXXXXX	XXXXXXXXXXXX	DDMMMYYYY/HH:MM	XXXXX	XX - XX	
		XXXXXXXXXXXX	XXXXXXXXXXXX	DDMMMYYYY/HH:MM	XXXXX	XX - XX	HIGH
		XXXXXXXXXXXX	XXXXXXXXXXXX	DDMMMYYYY/HH:MM	XXXXX	XX - XX	
		XXXXXXXXXXXX	XXXXXXXXXXXX	DDMMMYYYY/HH:MM	XXXXX	XX - XX	
		XXXXXXXXXXXX	XXXXXXXXXXXX	DDMMMYYYY/HH:MM	XXXXX	XX - XX	LOW
		XXXXXXXXXXXX	XXXXXXXXXXXX	DDMMMYYYY/HH:MM	XXXXX	XX - XX	
	XXXXXXXXXXX (XXXXX)	XXXXXXXXXXXX	XXXXXXXXXXXX	DDMMMYYYY/HH:MM	XXXXX	XX - XX	
		XXXXXXXXXXXX	XXXXXXXXXXXX	DDMMMYYYY/HH:MM	XXXXX	XX - XX	
		XXXXXXXXXXXX	XXXXXXXXXXXX	DDMMMYYYY/HH:MM	XXXXX	XX - XX	
		XXXXXXXXXXXX	XXXXXXXXXXXX	DDMMMYYYY/HH:MM	XXXXX	XX - XX	
		XXXXXXXXXXXX	XXXXXXXXXXXX	DDMMMYYYY/HH:MM	XXXXX	XX - XX	
		XXXXXXXXXXXX	XXXXXXXXXXXX	DDMMMYYYY/HH:MM	XXXXX	XX - XX	
###-###	XXXXXXXXXXX (XXXXX)	XXXXXXXXXXXX	XXXXXXXXXXXX	DDMMMYYYY/HH:MM	XXXXX	XX - XX	
		XXXXXXXXXXXX	XXXXXXXXXXXX	DDMMMYYYY/HH:MM	XXXXX	XX - XX	
		XXXXXXXXXXXX	XXXXXXXXXXXX	DDMMMYYYY/HH:MM	XXXXX	XX - XX	
		XXXXXXXXXXXX	XXXXXXXXXXXX	DDMMMYYYY/HH:MM	XXXXX	XX - XX	
		XXXXXXXXXXXX	XXXXXXXXXXXX	DDMMMYYYY/HH:MM	XXXXX	XX - XX	
		XXXXXXXXXXXX	XXXXXXXXXXXX	DDMMMYYYY/HH:MM	XXXXX	XX - XX	
###-###	XXXXXXXXXXX (XXXXX)	XXXXXXXXXXXX	XXXXXXXXXXXX	DDMMMYYYY/HH:MM	XXXXX	XX - XX	
		XXXXXXXXXXXX	XXXXXXXXXXXX	DDMMMYYYY/HH:MM	XXXXX	XX - XX	
		XXXXXXXXXXXX	XXXXXXXXXXXX	DDMMMYYYY/HH:MM	XXXXX	XX - XX	
		XXXXXXXXXXXX	XXXXXXXXXXXX	DDMMMYYYY/HH:MM	XXXXX	XX - XX	
		XXXXXXXXXXXX	XXXXXXXXXXXX	DDMMMYYYY/HH:MM	XXXXX	XX - XX	

SF = Screen failure subject.

<< Programming Note: Include all results where LBSPEC = "SALIVA" (includes LBCAT = "HORMONES" and "ARUP LABORATORIES"). >>

<< Programming Note: I am waiting to see how the salivary cortisol collection CRFs are mapped to see how best to list the data (SC1 = questions about shift work, travel, altered wake/sleep and LB_SC1 = smoking question) >>

<< <u>Programming Note</u>: The following will have the same layout as listing 16.2.6.2. Include all results where LBCAT in("HORMONES", "QUEST DIAGNOSTICS") and LBSPEC NE "SALIVA". >>

Listing 16.2.6.5
Hormones
All Subjects

Listing 16.2.6.6
Pharmacokinetic Samples
All Dosed Subjects

Subject Visit	Last Dose Prior to PK Sampling Date/Time	Sampling Time Point	Date/Time	Nevanimibe (<<unit>>)	If Not Collected, Specify Reason
###-###					
XXXXXXXXXXXXXXX	DDMMMYYYY/HH:MM	XXXXXXXXXXX	DDMMMYYYY/HH:MM	#######	
		XXXXXXXXXXX	DDMMMYYYY/HH:MM	#######	
		XXXXXXXXXXX	DDMMMYYYY/HH:MM	#######	
		XXXXXXXXXXX	DDMMMYYYY/HH:MM	#######	
XXXXXXXXXXXXXXX			NOT DONE		XXXXXXXXXXXXXXXXXXXXXXXXXXX
XXXXXXXXXXXXXXX	DDMMMYYYY/HH:MM	XXXXXXXXXXX	DDMMMYYYY/HH:MM	#######	
		XXXXXXXXXXX	DDMMMYYYY/HH:MM	#######	
		XXXXXXXXXXX	DDMMMYYYY/HH:MM	#######	
		XXXXXXXXXXX	DDMMMYYYY/HH:MM	#######	
XXXXXXXXXXXXXXX			NOT DONE		XXXXXXXXXXXXXXXXXXXXXXXXXXX

<<Programming Note: Include footnotes for the lower limits of quantitation if provided. Include columns for each metabolite provided, delete if not needed. >>

Listing 16.2.7.1
Adverse Events
All Subjects

Subject	TEAE?/ Onset Dose/ SAE?	Adverse Event/ Preferred Term/ System Organ Class	Start Date/Day End Date/Day	Duration (Days)	Severity/ Relationship to Study Drug	Action Taken with Study Drug	Outcome/ Other Action Taken
###-###	YES/ 250 mg/ NO	XXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXX	DDMMMYYYY/## DDMMMYYYY/##	##	XXXXXX/ XXXXXXXXXXXX	DOSE NOT CHANGED	XXXXXXX/ XXXXXXXXXXXXXX
	YES/ 1000 mg/ XXX	XXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXX	DDMMMYYYY/## DDMMMYYYY/##	##	XXXXXX/ XXXXXXXXXXXX	DRUG INTERRUPTED Last Dose: DDMMMYYYY Restart: DDMMMYYYY	XXXXXXX/ XXXXXXXXXXXXXX
###-###	NO/ Pre-dose/ XXX	XXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXX	DDMMMYYYY/## DDMMMYYYY/##	##	XXXXXX/ XXXXXXXXXXXX	XXXXXXXXXXXXX	XXXXXXX/ XXXXXXXXXXXXXX
###-###	YES/ 500 mg/ XXX	XXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXX	DDMMMYYYY/## DDMMMYYYY/##	##	XXXXXX/ XXXXXXXXXXXX	XXXXXXXXXXXXX	XXXXXXX/ XXXXXXXXXXXXXX

TEAEs are defined as any AE beginning on or after the first dose date of study drug.
Onset dose is the subject's Nevanimibe dose level on the reported start date of the event.
For AEs starting prior to first dose of study drug, day = start date/end date – first dose of study drug.
Otherwise, day = start date/end date – first dose date OF THE ONSET DOSE LEVEL +1.
Duration = end date – start date + 1.
AEs are coded using MedDRA dictionary version 18.0.

<<Programming Note: Refer to EC.ECCAT="EXCEPTION DOSE" for the date of last dose prior to interruption and the date of restart. If any additional free text is mapped to SUPPAE (e.g. outcome sequelae or specify other action taken), then list it with the text of the parent field. >>

Listing 16.2.8.1
Safety Laboratory Values: Chemistry
All Subjects

Subject	Parameter (Unit)	Visit	Date/Time of Collection	Result	Normal Range	Flag [1]
###-### (SF)	XXXXXXXXXXX (XXXXX)	XXXXXXXXXXXX	DDMMMYYYY/HH:MM	XXXXX	XX - XX	XX
		XXXXXXXXXXXX	DDMMMYYYY/HH:MM	XXXXX	XX - XX	XX
		XXXXXXXXXXXX	DDMMMYYYY/HH:MM	XXXXX	XX - XX	XX
		XXXXXXXXXXXX	DDMMMYYYY/HH:MM	XXXXX	XX - XX	XX
		XXXXXXXXXXXX	DDMMMYYYY/HH:MM	XXXXX	XX - XX	XX
		XXXXXXXXXXXX	DDMMMYYYY/HH:MM	XXXXX	XX - XX	XX
	XXXXXXXXXXX (XXXXX)	XXXXXXXXXXXX	DDMMMYYYY/HH:MM	XXXXX	XX - XX	XX
		XXXXXXXXXXXX	DDMMMYYYY/HH:MM	XXXXX	XX - XX	XX
		XXXXXXXXXXXX	DDMMMYYYY/HH:MM	XXXXX	XX - XX	XX
		XXXXXXXXXXXX	DDMMMYYYY/HH:MM	XXXXX	XX - XX	XX
		XXXXXXXXXXXX	DDMMMYYYY/HH:MM	XXXXX	XX - XX	XX
		XXXXXXXXXXXX	DDMMMYYYY/HH:MM	XXXXX	XX - XX	XX
###-###	XXXXXXXXXXX (XXXXX)	XXXXXXXXXXXX	DDMMMYYYY/HH:MM	XXXXX	XX - XX	XX
		XXXXXXXXXXXX	DDMMMYYYY/HH:MM	XXXXX	XX - XX	XX
		XXXXXXXXXXXX	DDMMMYYYY/HH:MM	XXXXX	XX - XX	XX
		XXXXXXXXXXXX	DDMMMYYYY/HH:MM	XXXXX	XX - XX	XX
		XXXXXXXXXXXX	DDMMMYYYY/HH:MM	XXXXX	XX - XX	XX
		XXXXXXXXXXXX	DDMMMYYYY/HH:MM	XXXXX	XX - XX	XX
###-###	XXXXXXXXXXX (XXXXX)	XXXXXXXXXXXX	DDMMMYYYY/HH:MM	XXXXX	XX - XX	XX
		XXXXXXXXXXXX	DDMMMYYYY/HH:MM	XXXXX	XX - XX	XX
		XXXXXXXXXXXX	DDMMMYYYY/HH:MM	XXXXX	XX - XX	XX
		XXXXXXXXXXXX	DDMMMYYYY/HH:MM	XXXXX	XX - XX	XX
		XXXXXXXXXXXX	DDMMMYYYY/HH:MM	XXXXX	XX - XX	XX

SF = Screen failure subject.
[1] Laboratory Flag: RH=Reference High, RL=Reference Low, NH=Notable High, NL=Notable Low, CH=Critical High, CL=Critical Low

Program Name: XXXXXXXX.sas Run Date: DDMMMYYYY HH:MM Clinical database last extracted: DDMMYYYY HH:MM

<< Programming Note: Including all non-missing LBORRES where LBCAT = "CHEMISTRY". Exclude LBTESTCD = "HCG" since that is a pregnancy test which is included in another listing. >>

Programming Note: The following listings will have the same layout as Listing 16.2.8.1.

Listing 16.2.8.2
Safety Laboratory Values: Hematology
Screened Subjects

Listing 16.2.8.3
Safety Laboratory Values: Lipids
Screened Subjects

Listing 16.2.8.4
Safety Laboratory Values: Coagulation
Screened Subjects

Listing 16.2.8.5
Safety Laboratory Values: Urinalysis
Screened Subjects

Listing 16.2.8.6
Safety Laboratory Values: Serology and Urine Drug Screen
Screened Subjects

Listing 16.2.8.7
Serum and Urine Pregnancy Test
All Subjects

Subject	Visit	Date of Last Menstrual Period	Collection Date/Time	Urine Test Result	Serum Test Result	Reason Not Done
###-### (SF)	XXXXXXXXXXXXXX	DDMMMYYYY	DDMMMYYYY/HH:MM	XXXXXXXX	XXXXXXXXXX	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
	XXXXXXXXXXXXXX	DDMMMYYYY	DDMMMYYYY/HH:MM	XXXXXXXX	XXXXXXXXXX	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
	XXXXXXXXXXXXXX	DDMMMYYYY	DDMMMYYYY/HH:MM	XXXXXXXX	XXXXXXXXXX	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
	XXXXXXXXXXXXXX	DDMMMYYYY	DDMMMYYYY/HH:MM	XXXXXXXX	XXXXXXXXXX	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
	XXXXXXXXXXXXXX	DDMMMYYYY	DDMMMYYYY/HH:MM	XXXXXXXX	XXXXXXXXXX	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
###-###	XXXXXXXXXXXXXX	DDMMMYYYY	DDMMMYYYY/HH:MM	XXXXXXXX	XXXXXXXXXX	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
	XXXXXXXXXXXXXX	DDMMMYYYY	DDMMMYYYY/HH:MM	XXXXXXXX	XXXXXXXXXX	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
	XXXXXXXXXXXXXX	DDMMMYYYY	DDMMMYYYY/HH:MM	XXXXXXXX	XXXXXXXXXX	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
	XXXXXXXXXXXXXX	DDMMMYYYY	DDMMMYYYY/HH:MM	XXXXXXXX	XXXXXXXXXX	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
	XXXXXXXXXXXXXX	DDMMMYYYY	DDMMMYYYY/HH:MM	XXXXXXXX	XXXXXXXXXX	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX

SF = Screen failure subject.

Program Name: XXXXXXXX.sas Run Date: DDMMMYYYY HH:MM Clinical database last extracted: DDMMYYYY HH:MM

<< Programming Note: Include all records where LB.LBTESTCD = "HCG" and LBNAM = null. >>

Listing 16.2.9.1
Vital Signs
All Subjects

Subject	Visit	Date Performed	SBP (mmHg)	DBP (mmHg)	HR (bpm)	Temperature (Units)	RR (bpm)	Weight (Units)	Height (Units)	BMI (kg/m^2)
###-### (SF)	XXXXXXXXXXXX	DDMMMYYYY	###	###	###	### (°F)	###	###.# (kg)	###.# (cm)	##.#
	XXXXXXXXXXXX	DDMMMYYYY	###	###	###	### (°F)	###	###.# (kg)	###.# (cm)	##.#
	XXXXXXXXXXXX	DDMMMYYYY	###	###	###	### (°C)	###	###.# (lb)	###.# (in)	##.#
###-###	XXXXXXXXXXXX	DDMMMYYYY	###	###	###	### (°F)	###	###.# (kg)	###.# (cm)	##.#
	XXXXXXXXXXXX	DDMMMYYYY	###	###	###	### (°F)	###	###.# (kg)	###.# (cm)	##.#
	XXXXXXXXXXXX	DDMMMYYYY	###	###	###	### (°C)	###	###.# (lb)	###.# (in)	##.#
###-###	XXXXXXXXXXXX	DDMMMYYYY	###	###	###	### (°F)	###	###.# (kg)	###.# (cm)	##.#
	XXXXXXXXXXXX	DDMMMYYYY	###	###	###	### (°F)	###	###.# (kg)	###.# (cm)	##.#
	XXXXXXXXXXXX	DDMMMYYYY	###	###	###	### (°C)	###	###.# (lb)	###.# (in)	##.#

SF = Screen failure subject.
SBP = systolic blood pressure. DBP = diastolic blood pressure. HR = heart rate (bpm = beats per minute).
RR = respiratory rate (bpm = breaths per minute). BMI = Body Mass Index.

Listing 16.2.9.2
12-Lead Electrocardiogram
All Subjects

Subject Visit	Date Performed	Heart Rate (beats/min)	---- Interval (msec) ----- PR	 QRS	 QT	 QTcF	 RR	Overall Interpretation	Describe Abnormality
###-### (SF)									
XXXXXXXXXXXXXXXXXX	DDMMMYYYY	###	###	###	###	###	###	NORMAL	XXXXXXXXXXXXXXXXXXXXXXXX
XXXXXXXXXXXXXXXXXX	DDMMMYYYY	###	###	###	###	###	###	ABNORMAL, NCS	XXXXXXXXXXXXXXXXXXXXXXXX
XXXXXXXXXXXXXXXXXX	DDMMMYYYY	###	###	###	###	###	###	ABNORMAL, CS	XXXXXXXXXXXXXXXXXXXXXXXX
XXXXXXXXXXXXXXXXXX	DDMMMYYYY	###	###	###	###	###	###	XXXXXXXXXXXXXXXXXX	XXXXXXXXXXXXXXXXXXXXXXXX
###-###									
XXXXXXXXXXXXXXXXXX	DDMMMYYYY	###	###	###	###	###	###	XXXXXXXXXXXXXXXXXX	XXXXXXXXXXXXXXXXXXXXXXXX
XXXXXXXXXXXXXXXXXX	DDMMMYYYY	###	###	###	###	###	###	XXXXXXXXXXXXXXXXXX	XXXXXXXXXXXXXXXXXXXXXXXX
XXXXXXXXXXXXXXXXXX	DDMMMYYYY	###	###	###	###	###	###	XXXXXXXXXXXXXXXXXX	XXXXXXXXXXXXXXXXXXXXXXXX
XXXXXXXXXXXXXXXXXX	DDMMMYYYY	###	###	###	###	###	###	XXXXXXXXXXXXXXXXXX	XXXXXXXXXXXXXXXXXXXXXXXX

SF = Screen failure subject. NCS = not clinically significant. CS = clinically significant.

Listing 16.2.9.3
Physical Examination
All Subjects

Subject	Visit	Date of Exam	Result	Describe Findings
###-### (SF)	XXXXXXXXXXXXXXX	DDMMMYYYY	NORMAL	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
	XXXXXXXXXXXXXXX	DDMMMYYYY	ABNORMAL NCS	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
	XXXXXXXXXXXXXXX	DDMMMYYYY	NO CHANGE FROM PREVIOUS EXAM	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
	XXXXXXXXXXXXXXX	DDMMMYYYY	ABNORMAL CS	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
	XXXXXXXXXXXXXXX	DDMMMYYYY	XXXXXXXXXXXXXXXXXXXXXXXXXXXX	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
	XXXXXXXXXXXXXXX	DDMMMYYYY	XXXXXXXXXXXXXXXXXXXXXXXXXXXX	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
###-###	XXXXXXXXXXXXXXX	DDMMMYYYY	XXXXXXXXXXXXXXXXXXXXXXXXXXXX	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
	XXXXXXXXXXXXXXX	DDMMMYYYY	XXXXXXXXXXXXXXXXXXXXXXXXXXXX	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
	XXXXXXXXXXXXXXX	DDMMMYYYY	XXXXXXXXXXXXXXXXXXXXXXXXXXXX	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
	XXXXXXXXXXXXXXX	DDMMMYYYY	XXXXXXXXXXXXXXXXXXXXXXXXXXXX	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
	XXXXXXXXXXXXXXX	DDMMMYYYY	XXXXXXXXXXXXXXXXXXXXXXXXXXXX	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
	XXXXXXXXXXXXXXX	DDMMMYYYY	XXXXXXXXXXXXXXXXXXXXXXXXXXXX	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
	XXXXXXXXXXXXXXX	DDMMMYYYY	XXXXXXXXXXXXXXXXXXXXXXXXXXXX	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX

SF = Screen failure subject. CS = Clinically significant. NCS = Not clinically significant.