DATA ANALYSIS PLAN

Protocol Title:	A Double-blind, Randomized, Parallel-group, Placebo-controlled Study of MLE4901 for the Treatment of Polycystic Ovary Syndrome (PCOS)
Protocol Number:	MLE4901-101
Date of Original Protocol:	19 May 2016
Global Amendment 1:	16 Feb 2017
Global Amendment 2:	08 Mar 2017
Product:	MLE4901
Phase of Study:	2b
Sponsor:	Millendo Therapeutics, Inc.
Data Analysis Plan	V1.0 / June 29, 2017

Protocol: A Double-blind, Randomized, Parallel-group, Placebo-controlled Study of MLE4901 for the Treatment of Polycystic Ovary Syndrome (PCOS)

Protocol Number: MLE4901-101

Current Protocol: Global Amendment 2 / 08 Mar 2017

DAP: V1.0 / June 29, 2017

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REVISION HISTORY

Version	Date	Description of Changes
1.0	June 29, 2017	Original version

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1 Introduction

This purpose of this document is to provide specifications for the tables and listings to be provided for Millendo Therapeutics Protocol MLE4901-101. Information regarding the study objectives and procedures can be found in the Protocol.

On June 6, 2017, Millendo Therapeutics elected to terminate the MLE4901-101 study due to the occurrence of several elevated transaminase levels >3xULN. A total of 55 subjects were randomized into the study prior to the termination of randomization. The available data from subjects who participated in the study will be used for safety summaries. Due to the limited data available, efficacy will not be summarized. Safety data includes adverse events (AEs), vital signs, 12-lead electrocardiograms (ECGs), transvaginal ultrasounds (TVUs), and clinical safety laboratory assessments. Safety data will be summarized and no formal statistical analysis of the safety data will be conducted. All safety summaries will be based on randomized subjects unless otherwise specified. Safety summaries will be based on observed values only. All available data will be listed.

1.1 Subject Disposition

Counts of subjects who screened, entered the lead-in period, and 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 by treatment and in total.

1.2 Demographic and Baseline Characteristics

Descriptive summaries of demographic and baseline characteristics will be presented by treatment and for total MLE4901 for all randomized subjects. Baseline measurements refer to data collected at Treatment Visit 1. If a value at Treatment Visit 1 is not available, the last measurement on or prior to randomization will be used as baseline.

Demographic and baseline characteristics include, but are not limited to: age at informed consent, sex, race, ethnicity, self-reported menstrual period stratification group (<4 per year, 4-6 per year), height at screening, baseline body weight, baseline body mass index (BMI), and BMI stratification group (22 to <35 kg/m^2, 35 to 45 kg/m^2). Continuous variables (age, height, weight, BMI) will be summarized by subject count, mean, standard deviation, median, minimum, and maximum. Categorical variables (race, sex, ethnicity, stratification groups) will be summarized by the number and percentage of subjects in the corresponding categories.

1.3 Prior and Concomitant Medications

Prior and concomitant medications will be coded with the World Health Organization Drug Dictionary and listed. All concomitant medications taken on or after randomization will be summarized for all randomized subjects by treatment and for total MLE4901.

1.4 Adverse Events

AEs will be coded and classified by system organ class and preferred term using the Medical Dictionary for Regulatory Activities (MedDRA). All AEs reported during the clinical study will be recorded on the electronic case report form (eCRF). All AEs, regardless of relationship to study drug or procedure, should be collected beginning from the time the subject signs the study

consent until the early termination/final visit or 30 days after the last dose of study drug, whichever is longer. AEs in study subjects include any change in the subject's condition. This includes symptoms, physical findings, or clinical syndromes.

AEs beginning on or after randomization will be summarized for all randomized subjects. An overview with counts of events and subjects will be provided treatment and for total MLE4901 for the incidence of AEs in the following categories:

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

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

There were no deaths during the study. Listings will be provided for any SAEs, and for any AEs leading to discontinuation from study. In addition, AEs beginning in the lead-in phase will be listed for all subjects who entered the lead-in phase.

1.5 Clinical Safety Laboratory Evaluations

Safety laboratory data (chemistry, hematology, metabolic, coagulation, and urinalysis) will be summarized by treatment and for total MLE4901 by each scheduled visit for all randomized subjects. Change from baseline will be summarized. Baseline measurements for each dose level refer to data collected at Treatment Visit 1. If a value at Treatment Visit 1 is not available, the last measurement on or prior to randomization will be used as baseline.

The number and frequency of randomized subjects with laboratory abnormalities on or after randomization will be summarized by treatment and for total MLE4901. Laboratory abnormalities include:

- ALT >3xULN
- AST >3xULN
- Total Bilirubin >2xULN
- (ALT or AST ≥3xULN) and Total Bilirubin >2xULN
- Creatinine >2xULN
- BUN >2xULN
- Glucose <50 mg/dL

- Glucose >200 mg/dL
- WBC <3 x10^3/uL
- Hemoglobin <10 g/dL
- Platelets <100 x10^3/uL

Shift tables from baseline to the worst post-baseline value will be presented for ALT and AST (>1xULN to 3xULN, >3 to 5xULN, >5 to 10xULN, >10 to 15xULN, >15 to 20xULN, >20xULN) and alkaline phosphatase and total bilirubin (>1xULN to 1.5xULN, >1.5xULN to 2xULN, >2xULN).

1.6 Vital Signs

Vital signs (systolic blood pressure, diastolic blood pressure, heart rate, respiratory rate, temperature, body weight, and BMI) will be summarized by treatment and for total MLE4901 by each scheduled visit for all randomized subjects. Change from baseline will be summarized. Baseline measurements for each dose level refer to data collected at Treatment Visit 1. If a value at Treatment Visit 1 is not available, the last measurement on or prior to randomization will be used as baseline.

1.7 12-Lead Electrocardiogram

ECG interpretations (normal, abnormal not clinically significant, abnormal clinically significant, not evaluable) will be tabulated by treatment and for total MLE4901 for all randomized subjects by scheduled visit. In addition, the worst result on or after randomization will be tabulated for the following categories:

Highest QTcF

- >450 msec
- >480 msec
- >500 msec

Highest QTcF Change from Baseline

- >30 msec
- >60 msec

1.8 Transvaginal Ultrasound Endometrial Thickness

Endometrial thickness assessed by TVU will be summarized by treatment and for total MLE4901 by each scheduled visit for all randomized subjects. Change from baseline will be summarized. Baseline measurements for each dose level refer to data collected at Screening. If a value at Screening is not available, the last measurement on or prior to randomization will be used as baseline.

2 Tables

Millendo Therapeutics, Inc.
Protocol MLE4901-101

Table 14.1.1.1
Subject Disposition
All Subjects

Category	Placebo BID n (%)	MLE4901 40 mg BID n (%)	MLE4901 60 mg BID n (%)	MLE4901 80 mg BID n (%)	Total MLE4901 n (%)	Total n (%)
Screened						##
Entered Lead-in Period						##
Randomized	##	##	##	##	##	##
Completed	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)
Early termination	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)
Primary reason for early termination:						
XXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)
XXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)
XXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)
XXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)
XXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)
XXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)

Note: Percentages are calculated with the number of randomized subjects as the denominator.

Program Name: XXXXXXXX.sas   Run Date: DDMMMYYYY HH:MM   Database last modified: DDMMYYYY HH:MM

<< <u>Programming Note</u>: Only reasons for withdrawal with total>0 will be displayed. Reasons will be sorted by descending total, then alphabetically. >>

Table 14.1.2.1
Summary of Demographic and Baseline Characteristics
All Randomized Subjects

Characteristic Category/Statistic	Placebo BID (N=##)	MLE4901 40 mg BID (N=##)	MLE4901 60 mg BID (N=##)	MLE4901 80 mg BID (N=##)	Total MLE4901 (N=###)
Age at Informed Consent					
n	##	##	##	##	##
Mean	##.#	##.#	##.#	##.#	##.#
Standard Deviation	##.##	##.##	##.##	##.##	##.##
Median	##.#	##.#	##.#	##.#	##.#
Minimum	##	##	##	##	##
Maximum	##	##	##	##	##
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	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)
Self-Reported Menstrual Period Stratification Group, n (%)					
<4 per year	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)
4-6 per year	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)

Note: Baseline is defined as the measurement at treatment visit 1. If missing, the last value on or prior to randomization will be used as baseline.

Table 14.1.2.1
Summary of Demographic and Baseline Characteristics
All Randomized Subjects

Characteristic Category/Statistic	Placebo BID (N=##)	MLE4901 40 mg BID (N=##)	MLE4901 60 mg BID (N=##)	MLE4901 80 mg BID (N=##)	Total MLE4901 (N=###)
Height at Screening (cm)					
n	##	##	##	##	##
Mean	##.##	##.##	##.##	##.##	##.##
Standard Deviation	##.###	##.###	##.###	##.###	##.###
Median	##.##	##.##	##.##	##.##	##.##
Minimum	##.#	##.#	##.#	##.#	##.#
Maximum	##.#	##.#	##.#	##.#	##.#
Baseline Weight (kg)					
n	##	##	##	##	##
Mean	##.##	##.##	##.##	##.##	##.##
Standard Deviation	##.###	##.###	##.###	##.###	##.###
Median	##.##	##.##	##.##	##.##	##.##
Minimum	##.#	##.#	##.#	##.#	##.#
Maximum	##.#	##.#	##.#	##.#	##.#
Baseline BMI (kg/m^2)					
n	##	##	##	##	##
Mean	##.##	##.##	##.##	##.##	##.##
Standard Deviation	##.###	##.###	##.###	##.###	##.###
Median	##.##	##.##	##.##	##.##	##.##
Minimum	##.#	##.#	##.#	##.#	##.#
Maximum	##.#	##.#	##.#	##.#	##.#
BMI Stratification Group, n (%)					
22 to <35 kg/m^2	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)
35 to 45 kg/m^2	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)

Note: Baseline is defined as the measurement at treatment visit 1. If missing, the last value on or prior to randomization will be used as baseline.

Table 14.1.3.1
Summary of Concomitant Medications
All Randomized Subjects

Anatomical Main Group Therapeutic Subgroup Pharmacological Subgroup Chemical Subgroup Chemical Substance	Placebo BID (N=##) n (%)	MLE4901 40 mg BID (N=##) n (%)	MLE4901 60 mg BID (N=##) n (%)	MLE4901 80 mg BID (N=##) n (%)	Total MLE4901 (N=###) n (%)
Subjects with any concomitant medications	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)
XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)
XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)
XXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)
XXXXXXXXXXXXXXXXXXXXXXXXXXXXX	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)
XXXXXXXXXXXXXXXXXXXXXXXXXXXX	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)
XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)
XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)
XXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)
XXXXXXXXXXXXXXXXXXXXXXXXXXXXX	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)
XXXXXXXXXXXXXXXXXXXXXXXXXXXX	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)

Note: Concomitant medications are those that are taken on or after randomization.
%=100*n/N, where n=number of subjects in treatment group in the specified category and N=number of subjects in treatment group.
At each level of summation (overall, anatomical main group, pharmacological subgroup, etc.), subjects reporting more than one concomitant medication are counted only once. A subject may contribute to more than one chemical substance. Medications are coded using the WHODrug dictionary March 2016E B2 version.

Program Name: XXXXXXXX.sas Run Date: DDMMMYYYY HH:MM Database last modified: DDMMYYYY HH:MM

<<<u>Programming Note</u>: Terms are sorted by ATC code though the code itself should not be presented (e.g., A11CA (Vitamin A, plain) should come before A11CB (Vitamin A and D in combination)). >>

Table 14.3.1.1
Overview of Adverse Events Beginning On or After Randomization
All Randomized Subjects

Category	Placebo BID (N=##) n (%) [#]	MLE4901 40 mg BID (N=##) n (%) [#]	MLE4901 60 mg BID (N=##) n (%) [#]	MLE4901 80 mg BID (N=##) n (%) [#]	Total MLE4901 (N=##) n (%) [#]
Subjects with any adverse event (AE)	## (###.#) ##	## (###.#) ##	## (###.#) ##	## (###.#) ##	## (###.#) ##
Maximum severity of AE					
Mild	## (###.#) N/A	## (###.#) N/A	## (###.#) N/A	## (###.#) N/A	## (###.#) N/A
Moderate	## (###.#) N/A	## (###.#) N/A	## (###.#) N/A	## (###.#) N/A	## (###.#) N/A
Severe	## (###.#) N/A	## (###.#) N/A	## (###.#) N/A	## (###.#) N/A	## (###.#) N/A
Subjects with any AE related to study treatment	## (###.#) ##	## (###.#) ##	## (###.#) ##	## (###.#) ##	## (###.#) ##
Subjects with any serious AE	## (###.#) ##	## (###.#) ##	## (###.#) ##	## (###.#) ##	## (###.#) ##
Subjects with any AE leading to discontinuation of study treatment	## (###.#) ##	## (###.#) ##	## (###.#) ##	## (###.#) ##	## (###.#) ##

Note: %=100*n/N, where n is the number of subjects in the specified category and N=number of subjects randomized in the treatment group. [#] = number of adverse events in the specified category. Only AEs that begin on or after randomization are included. AEs related to study drug are defined as those that are probably related, possibly related, or definitely related.

Table 14.3.1.2
Summary of Adverse Events Beginning On or After Randomization by System Organ Class and Preferred Term
All Randomized Subjects

Category	Placebo BID (N=##) n (%) [#]	MLE4901 40 mg BID (N=##) n (%) [#]	MLE4901 60 mg BID (N=##) n (%) [#]	MLE4901 80 mg BID (N=##) n (%) [#]	Total MLE4901 (N=##) n (%) [#]
Subjects with any adverse event (AE)	## (###.#) ##	## (###.#) ##	## (###.#) ##	## (###.#) ##	## (###.#) ##
XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	## (###.#) ##	## (###.#) ##	## (###.#) ##	## (###.#) ##	## (###.#) ##
XXXXXXXXXXXXXXXXXXXXXXXXXXXXX	## (###.#) ##	## (###.#) ##	## (###.#) ##	## (###.#) ##	## (###.#) ##
XXXXXXXXXXXXXXXXXXXXXXXXXXXXX	## (###.#) ##	## (###.#) ##	## (###.#) ##	## (###.#) ##	## (###.#) ##
XXXXXXXXXXXXXXXXXXXXXXXXXXXXX	## (###.#) ##	## (###.#) ##	## (###.#) ##	## (###.#) ##	## (###.#) ##
XXXXXXXXXXXXXXXXXXXXXXXXXXXXX	## (###.#) ##	## (###.#) ##	## (###.#) ##	## (###.#) ##	## (###.#) ##
XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	## (###.#) ##	## (###.#) ##	## (###.#) ##	## (###.#) ##	## (###.#) ##
XXXXXXXXXXXXXXXXXXXXXXXXXXXXX	## (###.#) ##	## (###.#) ##	## (###.#) ##	## (###.#) ##	## (###.#) ##
XXXXXXXXXXXXXXXXXXXXXXXXXXXXX	## (###.#) ##	## (###.#) ##	## (###.#) ##	## (###.#) ##	## (###.#) ##

Note: %=100*n/N, where n is the number of subjects in the specified category and N=number of subjects randomized in the treatment group. [#] = number of adverse events in the specified category. Only AEs that begin on or after randomization are included. 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 19.0.

Program Name: XXXXXXXX.sas Run Date: DDMMMYYYY HH:MM Database last modified: DDMMYYYY HH:MM

<< <u>Programming Note:</u> Table will be sorted by descending frequency 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 Adverse Events Beginning On or After Randomization by System Organ Class and Preferred Term
All Randomized Subjects

<< Programming Note: Replace

Subjects with any adverse event (AE)

With

Subjects with any adverse event (AE) related to study Drug

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

AEs related to study drug are defined as those that are probably related, possibly related, or definitely related.

Table 14.3.2.1
Listing of All Serious Adverse Events
All Randomized Subjects

Treatment Subject	SAE Specify	Adverse Event Verbatim Term/ Preferred Term/ System Organ Class	Start Date/Time/Day Stop Date/Time/Day	Severity	Relationship to Study Drug/ Action Taken with Study Drug	Other Actions Taken/ Outcome
Placebo BID						
###-###	#, #	XXXXXXXXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXXXXXXX	DDMMMYYYY/## DDMMMYYYY/##	XXXXXXXX	XXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXX	NONE/ XXXXXXXXXXXXXX
	#, #, #	XXXXXXXXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXXXXXXX	DDMMMYYYY/## DDMMMYYYY/##	XXXXXXXX	XXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXX	#, #/ XXXXXXXXXXXXXX
###-###	#, #	XXXXXXXXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXXXXXXX	DDMMMYYYY/## DDMMMYYYY/##	XXXXXXXX	XXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXX	#, #, #/ XXXXXXXXXXXXXX
MLE4901 40 mg BID						
MLE4901 60 mg BID						
MLE4901 80 mg BID						

Note: Only AEs that begin on or after randomization are included. AEs are coded using MedDRA dictionary version 19.0.
SAE Specify: 1 = congenital anomaly or birth defect, 2 = persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, 3 = death, 4 = hospitalization/prolongation of hospitalization, 5 = life threatening, 6 = other medical important event.
Day = start date/stop date – first dose of study drug + 1.
Other actions taken: 1 = Concomitant medication added, 2 = Concomitant procedure, 3 = Other

Table 14.3.2.2
Listing of All Adverse Events Leading to Discontinuation of Study Drug
All Randomized Subjects

Treatment / Subject	SAE? / Specify	Adverse Event Verbatim Term/ Preferred Term/ System Organ Class	Start Date/Time/Day / Stop Date/Time/Day	Severity	Relationship to Study Drug/ Action Taken with Study Drug	Other Actions Taken/ Outcome
Placebo BID						
###-###	XXX	XXXXXXXXXXXXXXXXXXXXXXXXX/	DDMMMYYYY/##	XXXXXXXX	XXXXXXXXXXXXXXXXXXXX/	NONE/
	#, #	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXXXXXX	DDMMMYYYY/##		XXXXXXXXXXXXXXXXXXXX	XXXXXXXXXXXXXX
	XXX	XXXXXXXXXXXXXXXXXXXXXXXXX/	DDMMMYYYY/##	XXXXXXXX	XXXXXXXXXXXXXXXXXXXX/	#, #/
	#, #, #	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXXXXXX	DDMMMYYYY/##		XXXXXXXXXXXXXXXXXXXX	XXXXXXXXXXXXXX
###-###	XXX	XXXXXXXXXXXXXXXXXXXXXXXXX/	DDMMMYYYY/##	XXXXXXXX	XXXXXXXXXXXXXXXXXXXX/	#, #, #/
	#, #	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXXXXXX	DDMMMYYYY/##		XXXXXXXXXXXXXXXXXXXX	XXXXXXXXXXXXXX
MLE4901 40 mg BID						
MLE4901 60 mg BID						
MLE4901 80 mg BID						

Note: Only AEs that begin on or after randomization are included. AEs are coded using MedDRA dictionary version 19.0.
SAE Specify: 1 = congenital anomaly or birth defect, 2 = persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, 3 = death, 4 = hospitalization/prolongation of hospitalization, 5 = life threatening, 6 = other medical important event.
Day = start date/stop date – first dose of study drug + 1.
Other actions taken: 1 = Concomitant medication added, 2 = Concomitant procedure, 3 = Other

Table 14.3.2.3
Listing of Adverse Events Beginning in the Lead-in Phase
All Subjects Who Entered Lead-in Period

Treatment / Subject	SAE? / Specify	Adverse Event Verbatim Term/ Preferred Term/ System Organ Class	Start Date/Time/Day / Stop Date/Time/Day	Severity	Relationship to MPA/ Action Taken with MPA	Other Actions Taken/ Outcome
Placebo BID						
###-###	XXX	XXXXXXXXXXXXXXXXXXXXXXXXXX/	DDMMMYYYY/##	XXXXXXXX	XXXXXXXXXXXXXXXXXXXX/	NONE/
	#, #	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXXXXXXX	DDMMMYYYY/##		XXXXXXXXXXXXXXXXXXX	XXXXXXXXXXXXXXXX
	XXX	XXXXXXXXXXXXXXXXXXXXXXXXXX/	DDMMMYYYY/##	XXXXXXXX	XXXXXXXXXXXXXXXXXXXX/	#, #/
	#, #, #	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXXXXXXX	DDMMMYYYY/##		XXXXXXXXXXXXXXXXXXX	XXXXXXXXXXXXXXXXX
###-###	XXX	XXXXXXXXXXXXXXXXXXXXXXXXXX/	DDMMMYYYY/##	XXXXXXXX	XXXXXXXXXXXXXXXXXXXX/	#, #, #/
	#, #	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXXXXXXXX	DDMMMYYYY/##		XXXXXXXXXXXXXXXXXXX	XXXXXXXXXXXXXXXX
MLE4901 40 mg BID						
MLE4901 60 mg BID						
MLE4901 80 mg BID						

Note: Only AEs that begin on or after first dose of medroxyprogesterone acetate (MPA) and prior to randomization are included.
AEs are coded using MedDRA dictionary version 19.0.
SAE Specify: 1 = congenital anomaly or birth defect, 2 = persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, 3 = death, 4 = hospitalization/prolongation of hospitalization, 5 = life threatening, 6 = other medical important event.
Day = start date/stop date – first dose date of MPA + 1.
Other actions taken: 1 = Concomitant medication added, 2 = Concomitant procedure, 3 = Other

Table 14.3.3.1
Summary of Abnormal Safety Laboratory Parameters
All Randomized Subjects

Category	Placebo BID (N=##) n/N' (%)	MLE4901 40 mg BID (N=##) n/N' (%)	MLE4901 60 mg BID (N=##) n/N' (%)	MLE4901 80 mg BID (N=##) n/N' (%)	Total MLE4901 (N=###) n/N' (%)
ALT >3xULN	##/## (###.#)	##/## (###.#)	##/## (###.#)	##/## (###.#)	##/## (###.#)
AST >3xULN	##/## (###.#)	##/## (###.#)	##/## (###.#)	##/## (###.#)	##/## (###.#)
Total Bilirubin (T.Bili) >2xULN	##/## (###.#)	##/## (###.#)	##/## (###.#)	##/## (###.#)	##/## (###.#)
(ALT or AST >=3xULN) and T.Bili >2xULN	##/## (###.#)	##/## (###.#)	##/## (###.#)	##/## (###.#)	##/## (###.#)
Creatinine >2xULN	##/## (###.#)	##/## (###.#)	##/## (###.#)	##/## (###.#)	##/## (###.#)
BUN >2xULN	##/## (###.#)	##/## (###.#)	##/## (###.#)	##/## (###.#)	##/## (###.#)
Glucose <50 mg/dL	##/## (###.#)	##/## (###.#)	##/## (###.#)	##/## (###.#)	##/## (###.#)
Glucose >200 mg/dL	##/## (###.#)	##/## (###.#)	##/## (###.#)	##/## (###.#)	##/## (###.#)
WBC <3 x10^3/uL	##/## (###.#)	##/## (###.#)	##/## (###.#)	##/## (###.#)	##/## (###.#)
Hemoglobin <10 g/dL	##/## (###.#)	##/## (###.#)	##/## (###.#)	##/## (###.#)	##/## (###.#)
Platelets <100 x10^3/uL	##/## (###.#)	##/## (###.#)	##/## (###.#)	##/## (###.#)	##/## (###.#)

Note: %=100*n/N', where n=number of subjects with a value in the category on or after randomization and N'=number of subjects with a result on or after randomization for the specified parameter.

Table 14.3.3.2
Shift Table of ALT, AST, Alkaline Phosphatase, and Total Bilirubin
All Randomized Subjects

Parameter/ Treatment	Baseline	Worst Post-Baseline Value: Normal or Low n (%)	>1 to 3xULN n (%)	>3 to 5xULN n (%)	>5 to 10xULN n (%)	>10 to 15xULN n (%)	>15 to 20xULN n (%)	>20xULN n (%)	Missing n (%)	Total n (%)
ALT										
Placebo BID (N=#)	Normal or Low	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
	>1 - 3xULN	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
	>3 - 5xULN	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
	>5 - 10xULN	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
	>10 - 15xULN	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
	>15 - 20xULN	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
	>20xULN	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
	Missing	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
	Total	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (100.0)
MLE4901 40 mg BID (N=#)	Normal or Low	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
	>1 - 3xULN	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
	>3 - 5xULN	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
	>5 - 10xULN	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
	>10 - 15xULN	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
	>15 - 20xULN	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
	>20xULN	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
	Missing	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
	Total	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (100.0)
MLE4901 60 mg BID (N=#)	Normal or Low	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
	>1 - 3xULN	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
	>3 - 5xULN	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
	>5 - 10xULN	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
	>10 - 15xULN	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
	>15 - 20xULN	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
	>20xULN	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
	Missing	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
	Total	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (100.0)

Note: Baseline is defined as the measurement at treatment visit 1. If missing, the last value on or prior to randomization will be used as baseline.

Table 14.3.3.2
Shift Table of ALT, AST, Alkaline Phosphatase, and Total Bilirubin
All Randomized Subjects

Parameter/ Treatment	Baseline	Worst Post-Baseline Value: Normal or Low n (%)	>1 to 3xULN n (%)	>3 to 5xULN n (%)	>5 to 10xULN n (%)	>10 to 15xULN n (%)	>15 to 20xULN n (%)	>20xULN n (%)	Missing n (%)	Total n (%)
ALT										
MLE4901 80 mg BID (N=#)	Normal or Low	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
	>1 - 3xULN	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
	>3 - 5xULN	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
	>5 - 10xULN	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
	>10 - 15xULN	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
	>15 - 20xULN	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
	>20xULN	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
	Missing	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
	Total	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (100.0)
Total MLE4901 (N=#)	Normal or Low	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
	>1 - 3xULN	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
	>3 - 5xULN	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
	>5 - 10xULN	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
	>10 - 15xULN	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
	>15 - 20xULN	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
	>20xULN	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
	Missing	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
	Total	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (100.0)

Note: Baseline is defined as the measurement at treatment visit 1. If missing, the last value on or prior to randomization will be used as baseline.

<< Programming Note: Repeat these two pages for AST. >>

Table 14.3.3.2
Shift Table of ALT, AST, Alkaline Phosphatase, and Total Bilirubin
All Randomized Subjects

Parameter/ Treatment	Baseline	Worst Post-Baseline Value: Normal or Low n (%)	>1 to 1.5xULN n (%)	>1.5 to 2xULN n (%)	>2xULN n (%)	Missing n (%)	Total n (%)
ALP							
Placebo BID (N=#)	Normal or Low	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
	>1 - 1.5xULN	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
	>1.5 - 2xULN	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
	>2xULN	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
	Missing	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
	Total	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (100.0)
MLE4901 40 mg BID (N=#)	Normal or Low	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
	>1 - 1.5xULN	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
	>1.5 - 2xULN	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
	>2xULN	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
	Missing	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
	Total	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (100.0)
MLE4901 60 mg BID (N=#)	Normal or Low	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
	>1 - 1.5xULN	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
	>1.5 - 2xULN	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
	>2xULN	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
	Missing	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
	Total	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (100.0)

Note: Baseline is defined as the measurement at treatment visit 1. If missing, the last value on or prior to randomization will be used as baseline.

Table 14.3.3.2
Shift Table of ALT, AST, Alkaline Phosphatase, and Total Bilirubin
All Randomized Subjects

Parameter/ Treatment	Baseline	Worst Post-Baseline Value: Normal or Low n (%)	>1 to 1.5xULN n (%)	>1.5 to 2xULN n (%)	>2xULN n (%)	Missing n (%)	Total n (%)
ALP							
MLE4901 80 mg BID (N=#)	Normal or Low	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
	>1 - 1.5xULN	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
	>1.5 – 2xULN	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
	>2xULN	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
	Missing	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
	Total	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (100.0)
Total MLE4901 (N=#)	Normal or Low	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
	>1 - 1.5xULN	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
	>1.5 – 2xULN	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
	>2xULN	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
	Missing	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
	Total	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (100.0)

Note: Baseline is defined as the measurement at treatment visit 1. If missing, the last value on or prior to randomization will be used as baseline.

Program Name: XXXXXXXX.sas Run Date: DDMMMYYYY HH:MM Database last modified: DDMMYYYY HH:MM

<< Programming Note: Repeat these two pages for ALP and Total Bilirubin. In other words, Pages 1-2 = ALT, Pages 3-4 = AST, Pages 5-6 = ALP, and Pages 7-8 = Total Bilirubin.>>

<< Programming Note: The following tables will have the same layout as Table 14.3.4.1: >>

Table 14.3.3.3
Summary of Safety Laboratory Parameters by Visit: Chemistry
All Randomized Subjects

Table 14.3.3.4
Summary of Safety Laboratory Parameters by Visit: Hematology
All Randomized Subjects

Table 14.3.3.5
Summary of Safety Laboratory Parameters by Visit: Metabolic
All Randomized Subjects

Table 14.3.3.6
Summary of Safety Laboratory Parameters by Visit: Coagulation
All Randomized Subjects

Table 14.3.3.7
Summary of Safety Laboratory by Visit: Urinalysis
All Randomized Subjects

Parameter (Unit) Visit Result/Statistic	Placebo BID (N=##)	MLE4901 40 mg BID (N=##)	MLE4901 60 mg BID (N=##)	MLE4901 80 mg BID (N=##)	Total MLE4901 (N=###)
XXXXXXXXXX (XXXXX), n (%)					
Screening	N'=##	N'=##	N'=##	N'=##	N'=##
XXXXXXXXXX	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)
XXXXXXXXXX	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)
XXXXXXXXXX	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)
XXXXXXXXXX	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)
Treatment Visit 1	N'=##	N'=##	N'=##	N'=##	N'=##
XXXXXXXXXX	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)
XXXXXXXXXX	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)
Treatment Visit 7/EoT	N'=##	N'=##	N'=##	N'=##	N'=##
XXXXXXXXXX	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)
XXXXXXXXXX	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)
XXXXXXXXXX	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)
XXXXXXXXXX	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)
XXXXXXXXXX (XXXXX)					
Screening					
n	##	##	##	##	##
Mean	##.##	##.##	##.##	##.##	##.##
Standard Deviation	##.###	##.###	##.###	##.###	##.###
Median	##.##	##.##	##.##	##.##	##.##
Minimum	##.#	##.#	##.#	##.#	##.#
Maximum	##.#	##.#	##.#	##.#	##.#

Note: %=n/N', where N' is the number of subjects with a result at the specified visit. EoT = End of Treatment

<< Programming Note: pH and Specific Gravity will be summarized as continuous parameters (mean, SD, etc.). All others will be summarized categorically with counts and percentages. >>

Table 14.3.4.1
Summary of Vital Signs by Visit
All Randomized Subjects

Parameter (Unit) Visit Statistic	Placebo BID (N=##)	MLE4901 40 mg BID (N=##)	MLE4901 60 mg BID (N=##)	MLE4901 80 mg BID (N=##)	Total MLE4901 (N=###)
XXXXXXXXXX (XXXXX)					
Screening					
n	##	##	##	##	##
Mean	##.##	##.##	##.##	##.##	##.##
Standard Deviation	##.###	##.###	##.###	##.###	##.###
Median	##.##	##.##	##.##	##.##	##.##
Minimum	##.#	##.#	##.#	##.#	##.#
Maximum	##.#	##.#	##.#	##.#	##.#
Lead-in Visit 1					
n	##	##	##	##	##
Mean	##.##	##.##	##.##	##.##	##.##
Standard Deviation	##.###	##.###	##.###	##.###	##.###
Median	##.##	##.##	##.##	##.##	##.##
Minimum	##.#	##.#	##.#	##.#	##.#
Maximum	##.#	##.#	##.#	##.#	##.#
Lead-in Visit 2					
n	##	##	##	##	##
Mean	##.##	##.##	##.##	##.##	##.##
Standard Deviation	##.###	##.###	##.###	##.###	##.###
Median	##.##	##.##	##.##	##.##	##.##
Minimum	##.#	##.#	##.#	##.#	##.#
Maximum	##.#	##.#	##.#	##.#	##.#
Baseline					
n	##	##	##	##	##
Mean	##.##	##.##	##.##	##.##	##.##
Standard Deviation	##.###	##.###	##.###	##.###	##.###
Median	##.##	##.##	##.##	##.##	##.##
Minimum	##.#	##.#	##.#	##.#	##.#
Maximum	##.#	##.#	##.#	##.#	##.#

Note: Baseline is defined as the measurement at treatment visit 1. If missing, the last value on or prior to randomization will be used as baseline. n'=number of subjects with a measurement at both baseline and the specified visit.

Table 14.3.4.1
Summary of Vital Signs by Visit
All Randomized Subjects

Parameter (Unit) Visit Statistic	Placebo BID (N=##)	MLE4901 40 mg BID (N=##)	MLE4901 60 mg BID (N=##)	MLE4901 80 mg BID (N=##)	Total MLE4901 (N=###)
XXXXXXXXXX (XXXXX)					
Treatment Visit 2					
n	##	##	##	##	##
Mean	##.##	##.##	##.##	##.##	##.##
Standard Deviation	##.###	##.###	##.###	##.###	##.###
Median	##.##	##.##	##.##	##.##	##.##
Minimum	##.#	##.#	##.#	##.#	##.#
Maximum	##.#	##.#	##.#	##.#	##.#
Change from Baseline to Treatment Visit 2					
n'	##	##	##	##	##
Mean	##.##	##.##	##.##	##.##	##.##
Standard Deviation	##.###	##.###	##.###	##.###	##.###
Median	##.##	##.##	##.##	##.##	##.##
Minimum	##.#	##.#	##.#	##.#	##.#
Maximum	##.#	##.#	##.#	##.#	##.#
Treatment Visit 3					
n	##	##	##	##	##
Mean	##.##	##.##	##.##	##.##	##.##
Standard Deviation	##.###	##.###	##.###	##.###	##.###
Median	##.##	##.##	##.##	##.##	##.##
Minimum	##.#	##.#	##.#	##.#	##.#
Maximum	##.#	##.#	##.#	##.#	##.#
Change from Baseline to Treatment Visit 3					
n'	##	##	##	##	##
Mean	##.##	##.##	##.##	##.##	##.##
Standard Deviation	##.###	##.###	##.###	##.###	##.###
Median	##.##	##.##	##.##	##.##	##.##
Minimum	##.#	##.#	##.#	##.#	##.#
Maximum	##.#	##.#	##.#	##.#	##.#

Note: Baseline is defined as the measurement at treatment visit 1. If missing, the last value on or prior to randomization will be used as baseline. n'=number of subjects with a measurement at both baseline and the specified visit.

<< Programming Note: Include all scheduled visits through Follow Up Visit 2/EoS. Include all vital signs in the following order: systolic BP, diastolic BP, heart rate, respiratory rate, temperature, weight, and BMI. >>

Table 14.3.4.2
Summary of Abnormal 12-Lead ECG
All Randomized Subjects

Parameter/Category	Placebo BID (N=##) n (%)	MLE4901 40 mg BID (N=##) n (%)	MLE4901 60 mg BID (N=##) n (%)	MLE4901 80 mg BID (N=##) n (%)	Total MLE4901 (N=###) n (%)
Highest QTcF	N'=##	N'=##	N'=##	N'=##	N'=##
>450 msec	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)
>480 msec	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)
>500 msec	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)
Highest QTcF Change from Baseline	N'=##	N'=##	N'=##	N'=##	N'=##
>30 msec	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)
>60 msec	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)
Overall Interpretation, Screening	N'=##	N'=##	N'=##	N'=##	N'=##
Normal	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)
Abnormal Not Clinically Significant	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)
Abnormal Clinically Significant	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)
Not Evaluable	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)
Overall Interpretation, Treatment Visit 1	N'=##	N'=##	N'=##	N'=##	N'=##
Normal	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)
Abnormal Not Clinically Significant	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)
Abnormal Clinically Significant	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)
Not Evaluable	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)
Overall Interpretation, Treatment Visit 5	N'=##	N'=##	N'=##	N'=##	N'=##
Normal	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)
Abnormal Not Clinically Significant	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)
Abnormal Clinically Significant	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)
Not Evaluable	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)
Overall Interpretation, Treatment Visit 7/EoT	N'=##	N'=##	N'=##	N'=##	N'=##
Normal	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)
Abnormal Not Clinically Significant	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)
Abnormal Clinically Significant	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)
Not Evaluable	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)

Note: %=100*n/N', where n=number of subjects with a value in the category on or after randomization and N'=number of subjects with a result on or after randomization for the specified parameter. EoT = End of Treatment

Table 14.3.4.3
Summary of Transvaginal Ultrasound Endometrial Thickness
All Randomized Subjects

Parameter (Unit) Visit Statistic	Placebo BID (N=##)	MLE4901 40 mg BID (N=##)	MLE4901 60 mg BID (N=##)	MLE4901 80 mg BID (N=##)	Total MLE4901 (N=###)
XXXXXXXXXX (XXXXX)					
Baseline					
n	##	##	##	##	##
Mean	##.##	##.##	##.##	##.##	##.##
Standard Deviation	##.###	##.###	##.###	##.###	##.###
Median	##.##	##.##	##.##	##.##	##.##
Minimum	##.#	##.#	##.#	##.#	##.#
Maximum	##.#	##.#	##.#	##.#	##.#
Treatment Visit 7/EoT					
n	##	##	##	##	##
Mean	##.##	##.##	##.##	##.##	##.##
Standard Deviation	##.###	##.###	##.###	##.###	##.###
Median	##.##	##.##	##.##	##.##	##.##
Minimum	##.#	##.#	##.#	##.#	##.#
Maximum	##.#	##.#	##.#	##.#	##.#
Change from Baseline to Treatment Visit 7/EoT					
n'	##	##	##	##	##
Mean	##.##	##.##	##.##	##.##	##.##
Standard Deviation	##.###	##.###	##.###	##.###	##.###
Median	##.##	##.##	##.##	##.##	##.##
Minimum	##.#	##.#	##.#	##.#	##.#
Maximum	##.#	##.#	##.#	##.#	##.#

Note: Baseline is defined as the measurement at Screening. If missing, the last value on or prior to randomization will be used as baseline. n'=number of subjects with a measurement at both baseline and the specified visit. EoT = End of Treatment

3 Listings

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Listing 16.2.9.4	Papanicolaou (PAP) Test	All Subjects
Listing 16.2.9.5	Pregnancy Test	All Subjects