An Open-Label, Single-Arm Study of the Safety, Efficacy, and Pharmacokinetic Behavior of Leuprolide Mesylate for Injectable Suspension (LMIS 50 mg) in Subjects with Advanced Prostate Carcinoma – SAFETY EXTENSION

Protocol No.: FP01C-13-001-EX

STATISTICAL ANALYSIS PLAN

Version: 1.0
Date: 22Apr2016
Biostatistician: [redacted]

Confidentiality Statement

Approval of Statistical Analysis Plan
Protocol No : FP01C-13-001-EX

The undersigned approved the SAP Version 1.0, dated 22-Apr-2016 as final. Programming of the tables, figures and listings based upon the specifications within this document can proceed.

Foresee Pharmaceuticals Co., Ltd. Approval:

[redacted]	[redacted]	Apr 26, 2016
Signature (Title: SVP and Head of Development)	**Print Name**	**Date**

QPS-Qualitix Approval:

[redacted]	[redacted]	26 Apr 2016
Signature (Supervisor)	**Print Name**	**Date**

Please Note:

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1. INTRODUCTION

This is a multi-center, open-label, single-arm safety extension study. All subjects will be males with advanced prostate carcinoma that have completed 12 months of therapy with LMIS 50 mg under Protocol FP01C-13-001, judged by investigators to be candidates for continued medical androgen ablation therapy, and all subjects will continue to receive LMIS 50 mg.

This statistical analysis plan (SAP) is based on protocol version 1.0, dated 01Oct2015. The SAP provides details of data handling procedures and statistical analysis methods for safety evaluations. It also outlines statistical programming specifications for tables, listings and figures, and other details on the analyses not provided in the study protocol.

2. STUDY OBJECTIVE

Determine the long term safety and tolerability of LMIS 50 mg for up to 1 year under Protocol FP01C-13-001-EX (2 years of total exposure) in subjects with advanced prostate carcinoma.

3. STUDY DESIGN

3.1 Overall Trial Design

This is a multi-center, open-label, single-arm safety extension study. All subjects will be males with advanced prostate carcinoma that have completed 12 months of therapy with LMIS 50 mg under Protocol FP01C-13-001, judged by investigators to be candidates for continued medical androgen ablation therapy, and all subjects will continue to receive LMIS 50 mg in an unblinded fashion.

All AE(s) and SAE(s) which occur during the study period will be recorded on the CRFs and followed until resolution, until the events are considered stable, or otherwise explained. In addition, SAEs will be recorded and reported as required by both local and international regulatory requirements.

For early termination subjects, phone contacts should be performed at 3 and 6 months after the last injection of study drug to collect drug-related AEs, concomitant medication or non-drug therapy received for AE treatment, disease progression status, and subject survival status.

3.2 Randomization

Not applicable.

3.3 Blinding

Not applicable.

3.4 Assessments Schedule

	Scrn[1] (Subjects from FP01C-13-001 who completed study more than 28 days ago)	Scrn[2] (Subjects who completed the study within the last 28 days)	Treatment				ET[4]/EOS
Visit	1	1	2	3	4	5	6
Day (from completion of 12 months of treatment with LMIS 50 mg under FP01C-13-001)	-28-0	-28-0	0	84	168[3]	252	336
Informed consent	X	X					
Inclusion/Exclusion criteria	X	X					
Demographics	X	X					
Vital signs and height and weight[5] (resting 3 minutes)	X	X	X	X	X	X	X
ECOG PS	X	X					
Physical Exam	X			X	X	X	X
12-Lead ECG (Supine 5 minutes)	X				X		X
Laboratory							
Hematology[6]	X			X	X	X	X
Biochemistry[7] (Fasting)	X			X	X	X	X
Urinalysis[8]	X			X	X	X	X
HgbA1c (Fasting)	X						X
PSA	X			X	X	X	X
Testosterone	X				X[9]		
Study treatment			X		X		
Concomitant treatments			X	X	X	X	X
Adverse events	X	X	X	X	X	X	X

Scrn: Screening; EOS: End of study; ET: Early termination; BP: Blood pressure; HR: Heart rate; RR: Respiratory rate; BT: Body temperature

1. If the patient completed 12 months of treatment with LMIS 50 mg more than 28 days prior to entering the Extension study, the testosterone level should be repeated and the repeat test should indicate that the patient maintains a castrate-level of testosterone. In addition, the ECOG, PE, ECG, laboratory and PSA tests should be repeated.

2. If the patient has completed 12 months of treatment with LMIS 50 mg under Protocol FP01C-13-001 within the last 28 days, they will be allowed to enter the Extension study without repeating the testosterone measurements, ECG, PE, laboratory and the PSA tests.

3 If the Day 168 (2nd injection, Visit 4) is delayed, have the subject return for subsequent visits according to the date when the first injection was received. DO NOT ADJUST THE TIMELINE DUE TO THE LATE INJECTION

4. For early termination subjects (ET), procedures indicated should be performed. In addition, phone contacts should be performed at 3 and 6 months after the last injection of study drug to collect drug-related AEs, concomitant medication or non-drug therapy received for AEs treatment, disease progression status, and subject survival status.

5. Vital signs include BP, HR, RR, and BT. Subject weight will be measured at Screening and EOS.

[6] Hematology tests include CBC, such as Hb, Hct, RBC count, WBC count with differential and platelet count.

[7] Biochemistry tests include ALT, AST, ALP, total bilirubin, BUN, Serum Cr, electrolytes (K, Na, Mg, Ca and P), blood glucose, and lipid profile (LDL, HDL, triglycerides)

[8] Urinalysis tests include pH, specific gravity, leukocyte, erythrocyte, protein.

[9] Testosterone Level test (Optional item depending on investigators' judgment)

3.5 Endpoints

Determine the safety and tolerability by:

1) Assessment of clinically significant abnormal lab data, including liver function (AST, ALT, ALP), renal function (BUN, Serum Cr), complete blood count with platelets, clinical chemistries (K, Na, Mg, Ca and P), urinalysis, serum glucose, lipid profile (LDL, HDL, triglycerides)and HgbA1c
2) Adverse event (AE) reporting
3) Clinically significant changes from baseline in 12-lead resting electrocardiograms (ECGs) per the Investigator’s judgment

The safety endpoints include:

- Adverse event (AE)
- Laboratory data
- Vital signs
- Physical examination
- 12-lead resting electrocardiograms (ECGs)

3.6 Interim Analysis

No interim analysis will be performed for this study.

4. GENERAL STATISTICAL ISSUES

In this section, all statistical analysis methods applied to the primary, secondary and other variables are as following:

4.1 Continuous endpoints

Descriptive statistics including number of observation, mean, median, standard deviation, standard error, minimum and maximum will be presented for the raw data. Paired T-test or Wilcoxon Signed Rank test will be used to assess the change from baseline.

4.2 Categorical endpoints

The count and percentages will be used to summarize the categorical data.

4.3Sample size estimation and power

This a Safety Extension Study to Protocol FP01C-13-001. No efficacy analysis will be conducted under this protocol. No sample size calculations have been conducted for this study. Since there are totally 137 subjects enrolled in Protocol FP01C-13-001 study, the maximum of subjects willing to join Safety Extension Study will be 137.

5. DATA HANDLING PROCEDURES

5.1 Coding System

All AEs will be coded according to the MedDRA dictionary version 18.1 or higher and be reported by System Organ Class, and Preferred Term. AE severities will be graded according to Common Terminology Criteria for Adverse Events (CTCAE) version 4.

Concomitant medications will be coded according to the WHO-DRL (ATC/DDD Index 2016),which includes the ATC code and Generic name.

5.2 Missing Data Handling

Any incomplete data will be considered as missing data, and no imputation will be done for missing data.

6. ANALYSIS OF STUDY POPULATIONS

The safety population will be used in the safety assessment for this study. The safety population will consist of any subject receiving at least one dose of LMIS 50 mg under protocol FP01C-13-001-EX.
The summary of population will be summarized as Table 14.1.4. Also, the listing for subjects excluded from analysis will be presented as Listing 16.2.3.

7. DISPOSITION OF PATIENTS AND STUDY COMPLETION

The completion status and the primary reason for discontinuation will be listed in Listing 16.2.1. The subject disposition and completion status will be summarized in Table 14.1.2. The inclusion criteria and exclusion criteria will be listed in Listing 16.2.2.1, and the

eligibility data will be listed in Listing 16.2.2.2. In addition, subject incomplete study will be listed in Table 14.1.3, and protocol violation list will be presented in Listing 16.2.2.3.

8. DEMOGRAPHICS AND OTHER BASELINE CHARACTERISTICS

By-subject listings of demographics and baseline characteristics will be prepared in Listing 16.2.4.1, and demographics and baseline characteristics will be summarized in Table 14.1.1.

8.1 Medical History

Tumor history data will be listed by subject in Listing 16.2.4.2; Previous treatment of sure malignant disease will be listed by subject in Listing 16.2.4.3; Medical history recorded prior to dosing will be listed by subject in Listing 16.2.4.4.

8.2 Concomitant Medication and Non-Drug Therapy

Concomitant medication and non-drug therapy will be listed in Listing 16.2.5.1.

8.3 Dose Administration

The study treatment date, time and the dose to be administered per protocol will be listed by subject in Listing 16.2.5.2.

9. EXTENT OF EXPOSURE AND DRUG COMPLIANCE

The treatment duration (days) is defined as (last administered date – first administered date + 1); and the study duration (days) is defined as (last visit date – first administered date + 1).

The treatment duration (days) and study duration (days) will be summarized by the number of observations (n), mean, median, standard deviation (SD), standard error, minimum and maximum. The summary results will be presented as Table 14.3.2. Also, the proportion of subjects received first and second administration has been provided as Table 14.3.2.

10. SAFETY ANALYSIS

10.1 Adverse Events

All AEs (whether treatment related or not) that occur before, during, or after dosing of the study medication will be recorded. The verbatim adverse event (AE) terms will be coded using the MedDRA dictionary, version18.1 or highest, and classified by System Organ

Class and Preferred Term.

Adverse events will be categorized as:

- Previous treatment-emergent adverse event (TEAE): The TEAEs are captured from previous FP01C-13-001 study.
- Newly treatment-emergent adverse event (TEAE): AEs occurring during or after the treatment period until the subject is off study, or before the first administration of study drug and worsen in severity for this FP01C-13-001-EX study.
  Total treatment-emergent adverse event (TEAE): The combination of previous TEAEs and Newly TEAEs.

Unless otherwise specified, all adverse event summaries will include the previous TEAEs, Newly TEAEs and Total TEAEs. The listing of all TEAEs will be provided in Listing 16.2.7.1.

All AEs will be summarized by CTCAE version 4 grade and MedDRA preferred terms. The severity will be graded as follows:

- Grade 1 Mild; asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated
- Grade 2 Moderate; minimal, local or noninvasive intervention indicated; limiting age-appropriate instrumental activities of daily living* (ADL)
- Grade 3 Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self-care ADL**
- Grade 4 Life-threatening consequences; urgent intervention indicated
- Grade 5 Death related to AE

Activities of Daily Living (ADL):

*Instrumental ADL refer to preparing meals, shopping for groceries or clothes, using the telephone, managing money, etc.

**Self-care ADL refer to bathing, dressing and undressing, feeding self, using the toilet, taking medications, and not bedridden.

The reasonable possibility of causation will be determined based on the investigator's clinical judgment as follows:

- **Definite**: A clinical event, including laboratory test abnormality, occurring in a plausible time relationship to drug administration, and which cannot be explained by concurrent disease or other drugs or chemicals.
- **Possible**: A clinical event, including laboratory test abnormality, with a reasonable time sequence to administration of the drug, but which could also be explained by concurrent

disease or other drugs or chemicals. Information on drug withdrawal may be lacking or unclear.

- **Unrelated**: A clinical event, including laboratory test abnormality, which is clearly not related to drug administration.

For purposes of the summary tables, AEs will be classified as either related or not related to study drug. A study drug-related AE is defined as any TEAE that is assessed as 'Definite' or 'Possible' to study drug. An AE not related to study drug is defined as any AE that is assessed as 'Unrelated' to study drug.

Frequency counts will be tabulated and displayed by the MedDRA System Organ Class and Preferred Term.

A general summary of all TEAEs will be provided in Table 14.3.1.1. This summary will present the numbers and percentages of subjects according to the following categories:

- TEAEs
- TEAEs by severity
- TEAEs by relationship
- Drug-related AEs
- Drug-related AEs by severity
- SAEs

Other summary tables for adverse events will include:
Table 14.3.1.2: Summary of Incidence of TEAEs
Table 14.3.1.3: Summary of Incidence of TEAEs by Severity
Table 14.3.1.4: Summary of Incidence of Drug-Related Adverse Events
Table 14.3.1.5: Summary of Incidence of Drug-Related Adverse Events by Severity

The additional tables of AEs with incidence rate >5% are provided as Table 14.3.1.7~ Table 14.3.1.10. In addition, TEAEs leading to discontinuation will be provided in Listing 16.2.7.2.

10.2 Serious Adverse Event

A SAE is any experience that suggests a signification hazard, contraindication, side effect or precaution. With respect to human clinical experience, this includes any event which:

- results in death
- is life-threatening
- requires inpatient hospitalization or prolongation of hospitalization, unless

hospitalization is for:

- routine treatment or monitoring of the studied indication, not associated with any deterioration in condition.
- elective or pre-planned treatment for a pre-existing condition that is unrelated to the indication under study and has not worsened since the start of study drug
- treatment on an emergency outpatient basis for an event not fulfilling any of the definitions of a SAE given above and not resulting in hospital admission
- social reasons and respite care in the absence of any deterioration in the subject's general condition

- results in persistent or significant disability/incapacity or
- is a congenital anomaly/birth defect
- is a significant or important medical event that, based on appropriate medical judgment, may jeopardize the subject or may require intervention to prevent one of the other outcomes listed above.

A listing of all serious adverse events and serious adverse events report will be provided in Listing 16.2.7.3, and the summary of SAEs will be presented as Table 14.3.1.6.

10.3 Laboratory Evaluation

Clinical laboratory tests, including standard hematology, chemistry, and urinalysis:

Hematology

CBC, including Hb, Hct, RBC count, WBC count, WBC differential, platelet count and HgbA1c

Chemistry

ALT, AST, ALP, total bilirubin, BUN, Serum Cr, electrolytes (K, Na, Mg, Ca and P), blood glucose, lipid profile (LDL, HDL, triglycerides)

Urinalysis

pH, specific gravity, leukocyte, erythrocyte, protein

PSA Tumor Marker

PSA level

Testosterone Level

Testosterone level

Clinical laboratory data (hematology, biochemistry, and urinalysis) will be listed in Listings

16.2.8.2-16.2.8.4. Observations outside the normal range will be flagged. The abnormal values will be flagged with 'L' (low) for values below the lower limit of the laboratory's normal range or 'H' (high) for values above the upper limit of the laboratory's normal range. Clinically significant laboratory results will be marked as well. All original and repeated values will be listed.

The observed values of clinical laboratory data (hematology, biochemistry, and urinalysis) will be summarized for baseline, end of treatment, end of study, and change from baseline to end of treatment and end of study in Table 14.3.3.1~Table 14.3.3.3. Also, the clinical laboratory data transition status from baseline to end of treatment and end of study will be presented in Table 14.3.3.4~Table 14.3.3.6.

The PSA levels will be listed by subject in Listing 16.2.8.5; the testosterone level will be listed by subject in Listing 16.2.8.6.

Abnormal laboratory values of hematology, biochemistry and urinalysis will be listed in Listing16.2.8.1.

10.4 Vital Signs and Physical Examination

Individual subject listings of measured values for physical examinations, vital signs, and body weight data will be presented. The vital signs (blood pressure, heart rate, respiratory rate and body temperature) and body height, weight data will be presented in Listing 16.2.9, and physical examination will be presented in Listing 16.2.10, and the summary results of vital signs for baseline, end of treatment, end of study, and change from baseline to end of treatment and end of study will be presented as Table 14.3.4. In addition, the summary results of physical examination will be presented as Table 14.3.5.1, and the physical examination transition status will be presented as Table 14.3.5.2.

10.5 Other Variables Related to Safety

ECOG

The observed values of ECOG performance status will be listed in Listing 16.2.11.

Electrocardiograms (ECGs)

Electrocardiogram will be listed by subject in Listing 16.2.12. The observed values are included heart rate, RR interval, PR interval, QRS duration, QT interval and overall ECG result. In addition, the summary results of electrocardiogram will be presented as Table 14.3.6.1, and the overall ECG result transition status will be presented as Table 14.3.6.2.

Telephone Contact

The telephone contact included survival status and AEs check will be listed in Listing 16.2.13.

Unscheduled visit

The unscheduled visit data will be listed in Listing 16.2.14.

11. COMPUTER METHODS

The data analysis for this study will be generated using SAS® software, Version 9.3 of the SAS System for Windows 7. Copyright© 2013 SAS Institute Inc. SAS and all other SAS Institute Inc. product or service names are registered trademarks or trademarks of SAS Institute Inc., Cary, NC, USA. In addition, graphs will be created by Microsoft Excel 2007 if necessary.

Table of Content

Table 14.1.1: Summary of Demographics and Baseline Characteristics (Safety Population)

Variables / Status	Total (N=XX)
Age (years)*	
n	nn
mean (SD)	xx.x (xx.x)
SE	xx.x
median (min, max)	xx.x (xx.x, xx.x)
Gender	
Male	nn (xx.x%)
Race	
White	nn (xx.x%)
Black	nn (xx.x%)
Asian	nn (xx.x%)
American Indian or Alaska Native	nn (xx.x%)
Native Hawaiian or Pacific Islander	nn (xx.x%)
Other	nn (xx.x%)
Diagnosis (years)**	
n	nn
mean (SD)	xx.x (xx.x)
SE	xx.x
median (min, max)	xx.x (xx.x, xx.x)
TNM	
T_N_M_	nn (xx.x%)
Staging	
III	nn (xx.x%)
IV	nn (xx.x%)
ECOG performance status	
0	nn (xx.x%)
1	nn (xx.x%)
2	nn (xx.x%)

*The age (years) is calculated as (Date of informed consent - Date of birth)/365.25.
**The diagnosis age (years) is calculated as (Date of informed consent - Date of diagnosis)/365.25.
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Table 14.1.2: Summary of Disposition Status (Safety Population)

Variables / Status	Total (N=XX)
Enter by visit	
Screening (V1)	nn (xx.x%)
Day 0 (V2)	nn (xx.x%)
Day 84 (V3)	nn (xx.x%)
Day 168 (V4)	nn (xx.x%)
Day 252 (V5)	nn (xx.x%)
Day 336 (V6/EOS)	nn (xx.x%)
Complete the study	
Yes	nn (xx.x%)
No	nn (xx.x%)
Reason for withdrawal*	
Lost to follow-up	nn (xx.x%)
Subject withdrew consent	nn (xx.x%)
Treating with the prohibited medications will be needed	nn (xx.x%)
Adverse event	nn (xx.x%)
Protocol violation	nn (xx.x%)
Lack of efficacy	nn (xx.x%)
Persistent non-castrate testosterone levels judged by the investigator	nn (xx.x%)
Other	nn (xx.x%)

Percentage of the primary withdrawal reason = 100%[The number of subject(s) in the category / The number of subject(s) who did not complete study]
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Table 14.1.3: List of Subject Incomplete Study (Safety Population)

Subject No.	Primary Withdraw Reason	Comment

Table 14.1.4: Summary of Study Population (Enrolled Subjects)

Variables Status	Total (N=XX)
Safety population	
Included	nn (xx.x%)
Excluded	nn (xx.x%)

Table 14.3.1.1: Summary of TEAEs (Safety Population)

	Previous TEAEs (N=XX)			Newly TEAEs (N=XX)			Total TEAEs (N=XX)		
Variables / Status	**E**	**n**	**(%)**	**E**	**n**	**(%)**	**E**	**n**	**(%)**
TEAEs									
	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
TEAEs by severity									
Mild	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
Moderate	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
Severe	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
Life-threatening	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
Death	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
TEAEs by relationship									
Definite	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
Possible	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
Unrelated	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
Drug-related AEs*									
	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
Drug-related AEs* by severity									
Mild	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
Moderate	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
Severe	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
Life-threatening	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
Death	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
SAEs									
	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)

E is the number of events, n is the number of subjects, and the AE percentage: 100%*The number of subjects with event (n) / Total number of subjects in Safety population (N)
*Relationship to study drug: AE related to study drug will include AEs classified as 'Definite', or 'Possible'. AEs not related to study drug will include AEs that is 'Unrelated'.
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Table 14.3.1.2: Summary of Incidence of TEAEs (Safety Population)

	Previous TEAEs (N=XX)			Newly TEAEs (N=XX)			Total TEAEs (N=XX)		
System Organ Class / Preferred Term	**E**	**n**	**(%)**	**E**	**n**	**(%)**	**E**	**n**	**(%)**
System Organ Class 1									
Preferred Term 1	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
Preferred Term 2	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
System Organ Class 2									
Preferred Term 1	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
Preferred Term 2	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)

E is the number of events, n is the number of subjects, and the AE percentage: 100%*The number of subjects with event (n) / Total number of subjects in Safety population (N)
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Table 14.3.1.3: Summary of Incidence of TEAEs by Severity (Safety Population)

		Previous TEAEs (N=XX)			Newly TEAEs (N=XX)			Total TEAEs (N=XX)		
System Organ Class	Preferred Term	E	n	(%)	E	n	(%)	E	n	(%)
Mild AE										
System Organ Class 1	Preferred Term 1	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
System Organ Class 1	Preferred Term 2	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
System Organ Class 2	Preferred Term 1	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
System Organ Class 2	Preferred Term 2	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
Moderate AE										
System Organ Class 1	Preferred Term 1	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
System Organ Class 1	Preferred Term 2	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
System Organ Class 2	Preferred Term 1	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
System Organ Class 2	Preferred Term 2	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
Severe AE										
System Organ Class 1	Preferred Term 1	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
System Organ Class 1	Preferred Term 2	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
System Organ Class 2	Preferred Term 1	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
System Organ Class 2	Preferred Term 2	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
Life-threatening AE										
System Organ Class 1	Preferred Term 1	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
System Organ Class 1	Preferred Term 2	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
System Organ Class 2	Preferred Term 1	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
System Organ Class 2	Preferred Term 2	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
Death AE										
System Organ Class 1	Preferred Term 1	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
System Organ Class 1	Preferred Term 2	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
System Organ Class 2	Preferred Term 1	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
System Organ Class 2	Preferred Term 2	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)

E is the number of events, n is the number of subjects, and the AE percentage: 100%*The number of subjects with event (n) / Total number of subjects in Safety population (N)
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Table 14.3.1.4: Summary of Incidence of Drug-Related AEs (Safety Population)

	Previous TEAEs (N=XX)			Newly TEAEs (N=XX)			Total TEAEs (N=XX)		
System Organ Class / Preferred Term	**E**	**n**	**(%)**	**E**	**n**	**(%)**	**E**	**n**	**(%)**
System Organ Class 1									
Preferred Term 1	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
Preferred Term 2	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
System Organ Class 2									
Preferred Term 1	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
Preferred Term 2	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)

E is the number of events, n is the number of subjects, and the AE percentage: 100%*The number of subjects with event (n) / Total number of subjects in Safety population (N)
[Program: \\Foresee\FP01C-13-001\SAP\Table\S_AE.sas]

Table 14.3.1.5: Summary of Incidence of Drug-Related AEs by Severity (Safety Population)

		Previous TEAEs (N=XX)			Newly TEAEs (N=XX)			Total TEAEs (N=XX)		
System Organ Class	Preferred Term	E	n	(%)	E	n	(%)	E	n	(%)
Mild AE										
System Organ Class 1	Preferred Term 1	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
System Organ Class 1	Preferred Term 2	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
System Organ Class 2	Preferred Term 1	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
System Organ Class 2	Preferred Term 2	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
Moderate AE										
System Organ Class 1	Preferred Term 1	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
System Organ Class 1	Preferred Term 2	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
System Organ Class 2	Preferred Term 1	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
System Organ Class 2	Preferred Term 2	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
Severe AE										
System Organ Class 1	Preferred Term 1	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
System Organ Class 1	Preferred Term 2	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
System Organ Class 2	Preferred Term 1	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
System Organ Class 2	Preferred Term 2	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
Life-threatening AE										
System Organ Class 1	Preferred Term 1	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
System Organ Class 1	Preferred Term 2	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
System Organ Class 2	Preferred Term 1	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
System Organ Class 2	Preferred Term 2	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
Death AE										
System Organ Class 1	Preferred Term 1	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
System Organ Class 1	Preferred Term 2	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
System Organ Class 2	Preferred Term 1	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
System Organ Class 2	Preferred Term 2	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)

E is the number of events, n is the number of subjects, and the AE percentage: 100%*The number of subjects with event (n) / Total number of subjects in Safety population (N)
[Program: \\Foresee\FP01C-13-001\SAP\Table\S_AE.sas]

Table 14.3.1.6: Summary of Incidence of SAEs (Safety Population)

	Previous TEAEs (N=XX)			Newly TEAEs (N=XX)			Total TEAEs (N=XX)		
System Organ Class / Preferred Term	**E**	**n**	**(%)**	**E**	**n**	**(%)**	**E**	**n**	**(%)**
System Organ Class 1									
Preferred Term 1	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
Preferred Term 2	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
System Organ Class 2									
Preferred Term 1	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
Preferred Term 2	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)

E is the number of events, n is the number of subjects, and the AE percentage: 100%*The number of subjects with event (n) / Total number of subjects in Safety population (N)
[Program: \\Foresee\FP01C-13-001\SAP\Table\S_AE.sas]

Table 14.3.1.7: Summary of Incidence of TEAEs >5% (Safety Population)

	Previous TEAEs (N=XX)			Newly TEAEs (N=XX)			Total TEAEs (N=XX)		
System Organ Class / Preferred Term	**E**	**n**	**(%)**	**E**	**n**	**(%)**	**E**	**n**	**(%)**
System Organ Class 1									
Preferred Term 1	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
Preferred Term 2	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
System Organ Class 2									
Preferred Term 1	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
Preferred Term 2	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)

E is the number of events, n is the number of subjects, and the AE percentage: 100%*The number of subjects with event (n) / Total number of subjects in Safety population (N)
[Program: \\Foresee\FP01C-13-001\SAP\Table\S_AE.sas]

Table 14.3.1.8: Summary of Incidence of TEAEs by Severity >5% (Safety Population)

		Previous TEAEs (N=XX)			Newly TEAEs (N=XX)			Total TEAEs (N=XX)		
System Organ Class	Preferred Term	E	n	(%)	E	n	(%)	E	n	(%)
Mild AE										
System Organ Class 1	Preferred Term 1	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
System Organ Class 1	Preferred Term 2	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
System Organ Class 2	Preferred Term 1	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
System Organ Class 2	Preferred Term 2	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
Moderate AE										
System Organ Class 1	Preferred Term 1	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
System Organ Class 1	Preferred Term 2	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
System Organ Class 2	Preferred Term 1	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
System Organ Class 2	Preferred Term 2	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
Severe AE										
System Organ Class 1	Preferred Term 1	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
System Organ Class 1	Preferred Term 2	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
System Organ Class 2	Preferred Term 1	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
System Organ Class 2	Preferred Term 2	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
Life-threatening AE										
System Organ Class 1	Preferred Term 1	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
System Organ Class 1	Preferred Term 2	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
System Organ Class 2	Preferred Term 1	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
System Organ Class 2	Preferred Term 2	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
Death AE										
System Organ Class 1	Preferred Term 1	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
System Organ Class 1	Preferred Term 2	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
System Organ Class 2	Preferred Term 1	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
System Organ Class 2	Preferred Term 2	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)

E is the number of events, n is the number of subjects, and the AE percentage: 100%*The number of subjects with event (n) / Total number of subjects in Safety population (N)
[Program: \\Foresee\FP01C-13-001\SAP\Table\S_AE.sas]

Table 14.3.1.9: Summary of Incidence of Drug-Related AEs >5% (Safety Population)

	Previous TEAEs (N=XX)			Newly TEAEs (N=XX)			Total TEAEs (N=XX)		
System Organ Class / Preferred Term	**E**	**n**	**(%)**	**E**	**n**	**(%)**	**E**	**n**	**(%)**
System Organ Class 1									
Preferred Term 1	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
Preferred Term 2	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
System Organ Class 2									
Preferred Term 1	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
Preferred Term 2	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)

E is the number of events, n is the number of subjects, and the AE percentage: 100%*The number of subjects with event (n) / Total number of subjects in Safety population (N)
[Program: \\Foresee\FP01C-13-001\SAP\Table\S_AE.sas]

Table 14.3.1.10: Summary of Incidence of Drug-Related AEs by Severity >5% (Safety Population)

		Previous TEAEs (N=XX)			Newly TEAEs (N=XX)			Total TEAEs (N=XX)		
System Organ Class	Preferred Term	E	n	(%)	E	n	(%)	E	n	(%)
Mild AE										
System Organ Class 1	Preferred Term 1	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
System Organ Class 1	Preferred Term 2	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
System Organ Class 2	Preferred Term 1	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
System Organ Class 2	Preferred Term 2	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
Moderate AE										
System Organ Class 1	Preferred Term 1	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
System Organ Class 1	Preferred Term 2	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
System Organ Class 2	Preferred Term 1	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
System Organ Class 2	Preferred Term 2	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
Severe AE										
System Organ Class 1	Preferred Term 1	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
System Organ Class 1	Preferred Term 2	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
System Organ Class 2	Preferred Term 1	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
System Organ Class 2	Preferred Term 2	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
Life-threatening AE										
System Organ Class 1	Preferred Term 1	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
System Organ Class 1	Preferred Term 2	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
System Organ Class 2	Preferred Term 1	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
System Organ Class 2	Preferred Term 2	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
Death AE										
System Organ Class 1	Preferred Term 1	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
System Organ Class 1	Preferred Term 2	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
System Organ Class 2	Preferred Term 1	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)
System Organ Class 2	Preferred Term 2	E	nn	(xx.x%)	E	nn	(xx.x%)	E	nn	(xx.x%)

E is the number of events, n is the number of subjects, and the AE percentage: 100%*The number of subjects with event (n) / Total number of subjects in Safety population (N)
[Program: \\Foresee\FP01C-13-001\SAP\Table\S_AE.sas]

Table 14.3.2: Summary of Study Medication (Safety Population)

Variables / Status	Total (N=XX)
Received first administration	
Yes	nn (xx.x%)
No	nn (xx.x%)
Received second administration	
Yes	nn (xx.x%)
No	nn (xx.x%)
Treatment duration (days)	
n	nn
mean (SD)	xx.x (xx.x)
SE	xx.x
median (min, max)	xx.x (xx.x, xx.x)
Study duration (days)	
n	nn
mean (SD)	xx.x (xx.x)
SE	xx.x
median (min, max)	xx.x (xx.x, xx.x)

Treatment duration (days) is defined as (last administered date – first administered date + 1); and study duration (days) is defined as (last visit date – first administereddate + 1).
[Program: \\Foresee\FP01C-13-001\SAP\Table\S_EX.sas]

Table 14.3.3.1: Summary of Laboratory Assessments - Hematology (Safety Population)

Variables / Status	Total (N=XX)
Hematology at Screening (V1)	
n	nn
mean (SD)	xx.x (xx.x)
SE	nn (xx.x%)
median (min, max)	xx.x (xx.x, xx.x)
Normal	nn (xx.x%)
Abnormal - NCS	nn (xx.x%)
Abnormal - CS	nn (xx.x%)
Not Done	nn (xx.x%)
Hematology on Day 168 (V4)	
n	nn
mean (SD)	xx.x (xx.x)
SE	nn (xx.x%)
median (min, max)	xx.x (xx.x, xx.x)
Normal	nn (xx.x%)
Abnormal - NCS	nn (xx.x%)
Abnormal - CS	nn (xx.x%)
Not Done	nn (xx.x%)
Hematology on Day 336 (V6/EOS)	
n	nn
mean (SD)	xx.x (xx.x)
SE	nn (xx.x%)
median (min, max)	xx.x (xx.x, xx.x)
Normal	nn (xx.x%)
Abnormal - NCS	nn (xx.x%)
Abnormal - CS	nn (xx.x%)
Not Done	nn (xx.x%)
Hematology change on Day 168 (V4)	
n	nn

*Paired T test or Wilcoxon signed rank test will be used to test the change from baseline for continuous variables.
[Program: \\Foresee\FP01C-13-001\SAP\Table\S_LB.sas]

Table 14.3.3.1: Summary of Laboratory Assessments - Hematology (Safety Population)

Variables / Status	Total (N=XX)
mean (SD)	xx.x (xx.x)
SE	nn (xx.x%)
median (min, max)	xx.x (xx.x, xx.x)
P-value*	x.xxxx
Hematology change on Day 336 (V6/EOS)	
n	nn
mean (SD)	xx.x (xx.x)
SE	nn (xx.x%)
median (min, max)	xx.x (xx.x, xx.x)
P-value*	x.xxxx

*Paired T test or Wilcoxon signed rank test will be used to test the change from baseline for continuous variables.
[Program: \\Foresee\FP01C-13-001\SAP\Table\S_LB.sas]

Table 14.3.3.2: Summary of Laboratory Assessments - Biochemistry (Safety Population)

Variables / Status	Total (N=XX)
Biochemistry at Screening (V1)	
n	nn
mean (SD)	xx.x (xx.x)
SE	nn (xx.x%)
median (min, max)	xx.x (xx.x, xx.x)
Normal	nn (xx.x%)
Abnormal - NCS	nn (xx.x%)
Abnormal - CS	nn (xx.x%)
Not Done	nn (xx.x%)
Biochemistry on Day 168 (V4)	
n	nn
mean (SD)	xx.x (xx.x)
SE	nn (xx.x%)
median (min, max)	xx.x (xx.x, xx.x)
Normal	nn (xx.x%)
Abnormal - NCS	nn (xx.x%)
Abnormal - CS	nn (xx.x%)
Not Done	nn (xx.x%)
Biochemistry on Day 336 (V6/EOS)	
n	nn
mean (SD)	xx.x (xx.x)
SE	nn (xx.x%)
median (min, max)	xx.x (xx.x, xx.x)
Normal	nn (xx.x%)
Abnormal - NCS	nn (xx.x%)
Abnormal - CS	nn (xx.x%)
Not Done	nn (xx.x%)
Biochemistry change on Day 168 (V4)	
n	nn

*Paired T test or Wilcoxon signed rank test will be used to test the change from baseline for continuous variables.
[Program: \\Foresee\FP01C-13-001\SAP\Table\S_LB.sas]

Table 14.3.3.2: Summary of Laboratory Assessments - Biochemistry (Safety Population)

Variables / Status	Total (N=XX)
mean (SD)	xx.x (xx.x)
SE	nn (xx.x%)
median (min, max)	xx.x (xx.x, xx.x)
P-value*	x.xxxx
Biochemistry change on Day 336 (V6/EOS)	
n	nn
mean (SD)	xx.x (xx.x)
SE	nn (xx.x%)
median (min, max)	xx.x (xx.x, xx.x)
P-value*	x.xxxx

*Paired T test or Wilcoxon signed rank test will be used to test the change from baseline for continuous variables.
[Program: \\Foresee\FP01C-13-001\SAP\Table\S_LB.sas]

Table 14.3.3.3: Summary of Laboratory Assessments - Urinalysis (Safety Population)

Variables / Status	Total (N=XX)
Urinalysis at Screening (V1)	
n	nn
mean (SD)	xx.x (xx.x)
SE	nn (xx.x%)
median (min, max)	xx.x (xx.x, xx.x)
Normal	nn (xx.x%)
Abnormal - NCS	nn (xx.x%)
Abnormal - CS	nn (xx.x%)
Not Done	nn (xx.x%)
Urinalysis on Day 168 (V4)	
n	nn
mean (SD)	xx.x (xx.x)
SE	nn (xx.x%)
median (min, max)	xx.x (xx.x, xx.x)
Normal	nn (xx.x%)
Abnormal - NCS	nn (xx.x%)
Abnormal - CS	nn (xx.x%)
Not Done	nn (xx.x%)
Urinalysis on Day 336 (V6/EOS)	
n	nn
mean (SD)	xx.x (xx.x)
SE	nn (xx.x%)
median (min, max)	xx.x (xx.x, xx.x)
Normal	nn (xx.x%)
Abnormal - NCS	nn (xx.x%)
Abnormal - CS	nn (xx.x%)
Not Done	nn (xx.x%)
Urinalysis change on Day 168 (V4)	
n	nn

*Paired T test or Wilcoxon signed rank test will be used to test the change from baseline for continuous variables.
[Program: \\Foresee\FP01C-13-001\SAP\Table\S_LB.sas]

Table 14.3.3.3: Summary of Laboratory Assessments - Urinalysis (Safety Population)

Variables / Status	Total (N=XX)
mean (SD)	xx.x (xx.x)
SE	nn (xx.x%)
median (min, max)	xx.x (xx.x, xx.x)
P-value*	x.xxxx
Urinalysis change on Day 336 (V6/EOS)	
n	nn
mean (SD)	xx.x (xx.x)
SE	nn (xx.x%)
median (min, max)	xx.x (xx.x, xx.x)
P-value*	x.xxxx

*Paired T test or Wilcoxon signed rank test will be used to test the change from baseline for continuous variables.
[Program: \\Foresee\FP01C-13-001\SAP\Table\S_LB.sas]

Table 14.3.3.4: Summary of Laboratory Assessments Transition Status - Hematology (Safety Population)

	Screening (V1)			
Variables / Status	**Normal**	**Abnormal - NCS**	**Abnormal - CS**	**Not Done**
Hematology on Day 168 (V4)				
Normal	nn (xx.x%)	nn (xx.x%)	nn (xx.x%)	nn (xx.x%)
Abnormal - NCS	nn (xx.x%)	nn (xx.x%)	nn (xx.x%)	nn (xx.x%)
Abnormal - CS	nn (xx.x%)	nn (xx.x%)	nn (xx.x%)	nn (xx.x%)
Not Done	nn (xx.x%)	nn (xx.x%)	nn (xx.x%)	nn (xx.x%)
Hematology on Day 336 (V6/EOS)				
Normal	nn (xx.x%)	nn (xx.x%)	nn (xx.x%)	nn (xx.x%)
Abnormal - NCS	nn (xx.x%)	nn (xx.x%)	nn (xx.x%)	nn (xx.x%)
Abnormal - CS	nn (xx.x%)	nn (xx.x%)	nn (xx.x%)	nn (xx.x%)
Not Done	nn (xx.x%)	nn (xx.x%)	nn (xx.x%)	nn (xx.x%)

Table 14.3.3.5: Summary of Laboratory Assessments Transition Status - Biochemistry (Safety Population)

	Screening (V1)			
Variables / Status	**Normal**	**Abnormal - NCS**	**Abnormal - CS**	**Not Done**
Biochemistry on Day 168 (V4)				
Normal	nn (xx.x%)	nn (xx.x%)	nn (xx.x%)	nn (xx.x%)
Abnormal - NCS	nn (xx.x%)	nn (xx.x%)	nn (xx.x%)	nn (xx.x%)
Abnormal - CS	nn (xx.x%)	nn (xx.x%)	nn (xx.x%)	nn (xx.x%)
Not Done	nn (xx.x%)	nn (xx.x%)	nn (xx.x%)	nn (xx.x%)
Biochemistry on Day 336 (V6/EOS)				
Normal	nn (xx.x%)	nn (xx.x%)	nn (xx.x%)	nn (xx.x%)
Abnormal - NCS	nn (xx.x%)	nn (xx.x%)	nn (xx.x%)	nn (xx.x%)
Abnormal - CS	nn (xx.x%)	nn (xx.x%)	nn (xx.x%)	nn (xx.x%)
Not Done	nn (xx.x%)	nn (xx.x%)	nn (xx.x%)	nn (xx.x%)

Table 14.3.3.6: Summary of Laboratory Assessments Transition Status - Urinalysis (Safety Population)

	Screening (V1)			
Variables / Status	**Normal**	**Abnormal - NCS**	**Abnormal - CS**	**Not Done**
Urinalysis on Day 168 (V4)				
Normal	nn (xx.x%)	nn (xx.x%)	nn (xx.x%)	nn (xx.x%)
Abnormal - NCS	nn (xx.x%)	nn (xx.x%)	nn (xx.x%)	nn (xx.x%)
Abnormal - CS	nn (xx.x%)	nn (xx.x%)	nn (xx.x%)	nn (xx.x%)
Not Done	nn (xx.x%)	nn (xx.x%)	nn (xx.x%)	nn (xx.x%)
Urinalysis on Day 336 (V6/EOS)				
Normal	nn (xx.x%)	nn (xx.x%)	nn (xx.x%)	nn (xx.x%)
Abnormal - NCS	nn (xx.x%)	nn (xx.x%)	nn (xx.x%)	nn (xx.x%)
Abnormal - CS	nn (xx.x%)	nn (xx.x%)	nn (xx.x%)	nn (xx.x%)
Not Done	nn (xx.x%)	nn (xx.x%)	nn (xx.x%)	nn (xx.x%)

Table 14.3.4: Summary of Vital Signs (Safety Population)

Variables / Status	Total (N=XX)
SBP (mmHg) on Day 0 (V2)	
n	nn
mean (SD)	xx.x (xx.x)
SE	nn (xx.x%)
median (min, max)	xx.x (xx.x, xx.x)
SBP (mmHg) on Day 168 (V4)	
n	nn
mean (SD)	xx.x (xx.x)
SE	nn (xx.x%)
median (min, max)	xx.x (xx.x, xx.x)
SBP (mmHg) on Day 336 (V6/EOS)	
n	nn
mean (SD)	xx.x (xx.x)
SE	nn (xx.x%)
median (min, max)	xx.x (xx.x, xx.x)
SBP (mmHg) change on Day 168 (V4)	
n	nn
mean (SD)	xx.x (xx.x)
SE	nn (xx.x%)
median (min, max)	xx.x (xx.x, xx.x)
P-value*	x.xxxx
SBP (mmHg) change on Day 336 (V6/EOS)	
n	nn
mean (SD)	xx.x (xx.x)
SE	nn (xx.x%)
median (min, max)	xx.x (xx.x, xx.x)
P-value*	x.xxxx

*Paired T test or Wilcoxon signed rank test will be used to test the change from baseline for continuous variables.
[Program: \\Foresee\FP01C-13-001\SAP\Table\S_VS.sas]

Table 14.3.4: Summary of Vital Signs (Safety Population)

Variables / Status	Total (N=XX)
DBP (mmHg) change on Day 168 (V4)	
n	nn
mean (SD)	xx.x (xx.x)
SE	nn (xx.x%)
median (min, max)	xx.x (xx.x, xx.x)
DBP (mmHg) change on Day 336 (V6/EOS)	
n	nn
mean (SD)	xx.x (xx.x)
SE	nn (xx.x%)
median (min, max)	xx.x (xx.x, xx.x)
DBP (mmHg) on Day 0 (V2)	
n	nn
mean (SD)	xx.x (xx.x)
SE	nn (xx.x%)
median (min, max)	xx.x (xx.x, xx.x)
DBP (mmHg) on Day 168 (V4)	
n	nn
mean (SD)	xx.x (xx.x)
SE	nn (xx.x%)
median (min, max)	xx.x (xx.x, xx.x)
DBP (mmHg) on Day 336 (V6/EOS)	
n	nn
mean (SD)	xx.x (xx.x)
SE	nn (xx.x%)
median (min, max)	xx.x (xx.x, xx.x)
Heart rate (beats/min) change on Day 168 (V4)	
n	nn

*Paired T test or Wilcoxon signed rank test will be used to test the change from baseline for continuous variables.
[Program: \\Foresee\FP01C-13-001\SAP\Table\S_VS.sas]

Table 14.3.4: Summary of Vital Signs (Safety Population)

Variables / Status	Total (N=XX)
mean (SD)	xx.x (xx.x)
SE	nn (xx.x%)
median (min, max)	xx.x (xx.x, xx.x)
Heart rate (beats/min) change on Day 336 (V6/EOS)	
n	nn
mean (SD)	xx.x (xx.x)
SE	nn (xx.x%)
median (min, max)	xx.x (xx.x, xx.x)
Heart rate (beats/min) on Day 0 (V2)	
n	nn
mean (SD)	xx.x (xx.x)
SE	nn (xx.x%)
median (min, max)	xx.x (xx.x, xx.x)
Heart rate (beats/min) on Day 168 (V4)	
n	nn
mean (SD)	xx.x (xx.x)
SE	nn (xx.x%)
median (min, max)	xx.x (xx.x, xx.x)
Heart rate (beats/min) on Day 336 (V6/EOS)	
n	nn
mean (SD)	xx.x (xx.x)
SE	nn (xx.x%)
median (min, max)	xx.x (xx.x, xx.x)
Body temperature (ºC) change on Day 168 (V4)	
n	nn
mean (SD)	xx.x (xx.x)
SE	nn (xx.x%)
median (min, max)	xx.x (xx.x, xx.x)

*Paired T test or Wilcoxon signed rank test will be used to test the change from baseline for continuous variables.
[Program: \\Foresee\FP01C-13-001\SAP\Table\S_VS.sas]

Table 14.3.4: Summary of Vital Signs (Safety Population)

Variables / Status	Total (N=XX)
Body temperature (ºC) change on Day 336 (V6/EOS)	
n	nn
mean (SD)	xx.x (xx.x)
SE	nn (xx.x%)
median (min, max)	xx.x (xx.x, xx.x)
Body temperature (ºC) on Day 0 (V2)	
n	nn
mean (SD)	xx.x (xx.x)
SE	nn (xx.x%)
median (min, max)	xx.x (xx.x, xx.x)
Body temperature (ºC) on Day 168 (V4)	
n	nn
mean (SD)	xx.x (xx.x)
SE	nn (xx.x%)
median (min, max)	xx.x (xx.x, xx.x)
Body temperature (ºC) on Day 336 (V6/EOS)	
n	nn
mean (SD)	xx.x (xx.x)
SE	nn (xx.x%)
median (min, max)	xx.x (xx.x, xx.x)
Respiratory rate (/min) change on Day 168 (V4)	
n	nn
mean (SD)	xx.x (xx.x)
SE	nn (xx.x%)
median (min, max)	xx.x (xx.x, xx.x)
Respiratory rate (/min) change on Day 336 (V6/EOS)	
n	nn

*Paired T test or Wilcoxon signed rank test will be used to test the change from baseline for continuous variables.
[Program: \\Foresee\FP01C-13-001\SAP\Table\S_VS.sas]

Table 14.3.4: Summary of Vital Signs (Safety Population)

Variables / Status	Total (N=XX)
mean (SD)	xx.x (xx.x)
SE	nn (xx.x%)
median (min, max)	xx.x (xx.x, xx.x)
Respiratory rate (/min) on Day 0 (V2)	
n	nn
mean (SD)	xx.x (xx.x)
SE	nn (xx.x%)
median (min, max)	xx.x (xx.x, xx.x)
Respiratory rate (/min) on Day 168 (V4)	
n	nn
mean (SD)	xx.x (xx.x)
SE	nn (xx.x%)
median (min, max)	xx.x (xx.x, xx.x)
Respiratory rate (/min) on Day 336 (V6/EOS)	
n	nn
mean (SD)	xx.x (xx.x)
SE	nn (xx.x%)
median (min, max)	xx.x (xx.x, xx.x)
Weight (kg) at Screening (V1)	
n	nn
mean (SD)	xx.x (xx.x)
SE	nn (xx.x%)
median (min, max)	xx.x (xx.x, xx.x)
Weight (kg) change on Day 336 (V6/EOS)	
n	nn
mean (SD)	xx.x (xx.x)
SE	nn (xx.x%)
median (min, max)	xx.x (xx.x, xx.x)

*Paired T test or Wilcoxon signed rank test will be used to test the change from baseline for continuous variables.
[Program: \\Foresee\FP01C-13-001\SAP\Table\S_VS.sas]

Table 14.3.4: Summary of Vital Signs (Safety Population)

Variables / Status	Total (N=XX)
Weight (kg) on Day 336 (V6/EOS)	
n	nn
mean (SD)	xx.x (xx.x)
SE	nn (xx.x%)
median (min, max)	xx.x (xx.x, xx.x)

*Paired T test or Wilcoxon signed rank test will be used to test the change from baseline for continuous variables.
[Program: \\Foresee\FP01C-13-001\SAP\Table\S_VS.sas]

Table 14.3.5.1: Summary of Physical Examination (Safety Population)

Variables / Status	Total (N=XX)
Physical examination category at Screening (V1)	
Normal	nn (xx.x%)
Abnormal	nn (xx.x%)
Not Done	nn (xx.x%)
Physical examination category on Day 168 (V4)	
Normal	nn (xx.x%)
Abnormal	nn (xx.x%)
Not Done	nn (xx.x%)
Physical examination category on Day 336 (V6/EOS)	
Normal	nn (xx.x%)
Abnormal	nn (xx.x%)
Not Done	nn (xx.x%)

Table 14.3.5.2: Summary of Physical Examination Transition Status (Safety Population)

	Screening (V1)		
	Total (N=XX)		
Variables / Status	Normal	Abnormal	Not Done
Physical examination category on Day 168 (V4)			
Normal	nn (xx.x%)	nn (xx.x%)	nn (xx.x%)
Abnormal	nn (xx.x%)	nn (xx.x%)	nn (xx.x%)
Not Done	nn (xx.x%)	nn (xx.x%)	nn (xx.x%)
Physical examination category on Day 336 (V6/EOS)			
Normal	nn (xx.x%)	nn (xx.x%)	nn (xx.x%)
Abnormal	nn (xx.x%)	nn (xx.x%)	nn (xx.x%)
Not Done	nn (xx.x%)	nn (xx.x%)	nn (xx.x%)

Table 14.3.6.1: Summary of ECG (Safety Population)

Variables / Status	Total (N=XX)
HR (bpm) at Screening (V1)	
n	nn
mean (SD)	xx.x (xx.x)
SE	xx.x
median (min, max)	xx.x (xx.x, xx.x)
HR (bpm) on Day 168 (V4)	
n	nn
mean (SD)	xx.x (xx.x)
SE	xx.x
median (min, max)	xx.x (xx.x, xx.x)
HR (bpm) on Day 336 (V6/EOS)	
n	nn
mean (SD)	xx.x (xx.x)
SE	xx.x
median (min, max)	xx.x (xx.x, xx.x)
HR (bpm) change on Day 168 (V4)	
n	nn
mean (SD)	xx.x (xx.x)
SE	xx.x
median (min, max)	xx.x (xx.x, xx.x)
P-value*	x.xxxx
HR (bpm) change on Day 336 (V6/EOS)	
n	nn
mean (SD)	xx.x (xx.x)
SE	xx.x
median (min, max)	xx.x (xx.x, xx.x)
P-value*	x.xxxx

*Paired T test or Wilcoxon signed rank test will be used to test the change from baseline for continuous variables.
[Program: \\Foresee\FP01C-13-001\SAP\Table\S_EG.sas]

Table 14.3.6.1: Summary of ECG (Safety Population)

Variables / Status	Total (N=XX)
RR (msec) at Screening (V1)	
n	nn
mean (SD)	xx.x (xx.x)
SE	xx.x
median (min, max)	xx.x (xx.x, xx.x)
RR (msec) change on Day 168 (V4)	
n	nn
mean (SD)	xx.x (xx.x)
SE	xx.x
median (min, max)	xx.x (xx.x, xx.x)
RR (msec) on Day 168 (V4)	
n	nn
mean (SD)	xx.x (xx.x)
SE	xx.x
median (min, max)	xx.x (xx.x, xx.x)
RR (msec) change on Day 336 (V6/EOS)	
n	nn
mean (SD)	xx.x (xx.x)
SE	xx.x
median (min, max)	xx.x (xx.x, xx.x)
P-value*	x.xxxx
RR (msec) on Day 336 (V6/EOS)	
n	nn
mean (SD)	xx.x (xx.x)
SE	xx.x
median (min, max)	xx.x (xx.x, xx.x)
P-value*	x.xxxx

*Paired T test or Wilcoxon signed rank test will be used to test the change from baseline for continuous variables.
[Program: \\Foresee\FP01C-13-001\SAP\Table\S_EG.sas]

Table 14.3.6.1: Summary of ECG (Safety Population)

Variables / Status	Total (N=XX)
QRS (msec) at Screening (V1)	
n	nn
mean (SD)	xx.x (xx.x)
SE	xx.x
median (min, max)	xx.x (xx.x, xx.x)
QRS (msec) change on Day 168 (V4)	
n	nn
mean (SD)	xx.x (xx.x)
SE	xx.x
median (min, max)	xx.x (xx.x, xx.x)
QRS (msec) on Day 168 (V4)	
n	nn
mean (SD)	xx.x (xx.x)
SE	xx.x
median (min, max)	xx.x (xx.x, xx.x)
QRS (msec) change on Day 336 (V6/EOS)	
n	nn
mean (SD)	xx.x (xx.x)
SE	xx.x
median (min, max)	xx.x (xx.x, xx.x)
P-value*	x.xxxx
QRS (msec) on Day 336 (V6/EOS)	
n	nn
mean (SD)	xx.x (xx.x)
SE	xx.x
median (min, max)	xx.x (xx.x, xx.x)
P-value*	x.xxxx

*Paired T test or Wilcoxon signed rank test will be used to test the change from baseline for continuous variables.
[Program: \\Foresee\FP01C-13-001\SAP\Table\S_EG.sas]

Table 14.3.6.1: Summary of ECG (Safety Population)

Variables / Status	Total (N=XX)
PR (msec) at Screening (V1)	
n	nn
mean (SD)	xx.x (xx.x)
SE	xx.x
median (min, max)	xx.x (xx.x, xx.x)
PR (msec) on Day 168 (V4)	
n	nn
mean (SD)	xx.x (xx.x)
SE	xx.x
median (min, max)	xx.x (xx.x, xx.x)
PR (msec) on Day 336 (V6/EOS)	
n	nn
mean (SD)	xx.x (xx.x)
SE	xx.x
median (min, max)	xx.x (xx.x, xx.x)
PR (msec) change on Day 168 (V4)	
n	nn
mean (SD)	xx.x (xx.x)
SE	xx.x
median (min, max)	xx.x (xx.x, xx.x)
P-value*	x.xxxx
PR (msec) change on Day 336 (V6/EOS)	
n	nn
mean (SD)	xx.x (xx.x)
SE	xx.x
median (min, max)	xx.x (xx.x, xx.x)
P-value*	x.xxxx

*Paired T test or Wilcoxon signed rank test will be used to test the change from baseline for continuous variables.
[Program: \\Foresee\FP01C-13-001\SAP\Table\S_EG.sas]

Table 14.3.6.1: Summary of ECG (Safety Population)

Variables / Status	Total (N=XX)
QT (msec) at Screening (V1)	
n	nn
mean (SD)	xx.x (xx.x)
SE	xx.x
median (min, max)	xx.x (xx.x, xx.x)
QT (msec) change on Day 168 (V4)	
n	nn
mean (SD)	xx.x (xx.x)
SE	xx.x
median (min, max)	xx.x (xx.x, xx.x)
QT (msec) on Day 168 (V4)	
n	nn
mean (SD)	xx.x (xx.x)
SE	xx.x
median (min, max)	xx.x (xx.x, xx.x)
QT (msec) on Day 336 (V6/EOS)	
n	nn
mean (SD)	xx.x (xx.x)
SE	xx.x
median (min, max)	xx.x (xx.x, xx.x)
QT (msec) change on Day 336 (V6/EOS)	
n	nn
mean (SD)	xx.x (xx.x)
SE	xx.x
median (min, max)	xx.x (xx.x, xx.x)
P-value*	x.xxxx
Overall Interpretation at Screening (V1)	

*Paired T test or Wilcoxon signed rank test will be used to test the change from baseline for continuous variables.
[Program: \\Foresee\FP01C-13-001\SAP\Table\S_EG.sas]

Table 14.3.6.1: Summary of ECG (Safety Population)

Variables / Status	Total (N=XX)
Normal	nn (xx.x%)
Abnormal-NCS	nn (xx.x%)
Abnormal-CS	nn (xx.x%)
Overall Interpretation on Day 168 (V4)	
Normal	nn (xx.x%)
Abnormal-NCS	nn (xx.x%)
Abnormal-CS	nn (xx.x%)
Overall Interpretation on Day 336 (V6/EOS)	
Normal	nn (xx.x%)
Abnormal-NCS	nn (xx.x%)
Abnormal-CS	nn (xx.x%)

*Paired T test or Wilcoxon signed rank test will be used to test the change from baseline for continuous variables.
[Program: \\Foresee\FP01C-13-001\SAP\Table\S_EG.sas]

Table 14.3.6.2: Summary of ECG Transition Status (Safety Population)

	Screening (V1)		
	Total (N=XX)		
Variables / Status	Normal	Abnormal-NCS	Abnormal-CS
Overall Interpretation on Day 168 (V4)			
Normal	nn (xx.x%)	nn (xx.x%)	nn (xx.x%)
Abnormal-NCS	nn (xx.x%)	nn (xx.x%)	nn (xx.x%)
Abnormal-CS	nn (xx.x%)	nn (xx.x%)	nn (xx.x%)
Overall Interpretation on Day 336 (V6/EOS)			
Normal	nn (xx.x%)	nn (xx.x%)	nn (xx.x%)
Abnormal-NCS	nn (xx.x%)	nn (xx.x%)	nn (xx.x%)
Abnormal-CS	nn (xx.x%)	nn (xx.x%)	nn (xx.x%)

Table of Content

Listing 16.2.1: Subject Disposition

Subject No.	Visit	Date of Visit (dd-mmm-yyyy)	Unable or Unwilling to Return for the Early Termination Visit	Date of Last Contact (dd-mmm-yyyy)	Complete the Study	Primary Withdraw Reason	Protocol Violation, Specify	Other, Specify

Listing 16.2.2.1: Inclusion Criteria and Exclusion Criteria

	Inclusion Criteria					Exclusion Criteria						
Subject No.	#1	#2	#3	#4	#5	#1	#2	#3	#4	#5	#6	#7

Listing 16.2.2.2: Eligibility

			If Yes		If No			
Subject No.	Visit	Eligible to Study	Randomization No.	Medication No.	Check the Reason	Inclusion Criteria No.	Exclusion Criteria No.	Other, Specify

Listing 16.2.2.3: Protocol Deviations

Subject No.	Visit	CRF Page	Field	Description	Reason	Major PD/ Minor PD/ Progress Note

Listing 16.2.3: Patients Excluded from the Safety Analysis

Subject No.	Safety Population	Reason for Exclusion

Listing 16.2.4.1: Demographics

Subject No.	Date of Informed Consent Signed (dd-mmm-yyyy)	Date of Birth (dd-mmm-yyyy)	Age*	Ethnicity	Race**	Sex

*The age (years) is calculated as (Date of informed consent - Date of birth)/365.25.
** If otther, specify.

Listing 16.2.4.2: Tumor History

	Prostate Carcinoma History				Other Tumor History						
Subject No.	First Diagnosis Date (dd-mmm-yyyy)	T_N_M_	Stage	Date of Last Relapse/ Progression (dd-mmm-yyyy) or N/A	None	Tumor History	First Diagnosis Date (dd-mmm-yyyy)	T_N_M_	Stage	Date of Last Relapse/ Progression (dd-mmm-yyyy) or N/A	Date of Resolved (dd-mmm-yyyy) or Ongoing

Listing 16.2.4.3: Previous Treatment of Malignant Disease

Subject No.	None	Treatment	Start Date (dd-mmm-yyyy)	End Date (dd-mmm-yyyy)

Listing 16.2.4.4: Medical History

Subject No.	Any Medical History	Medical History/ Surgery History	Onset Date (dd-mmm-yyyy)	Resolution Date (dd-mmm-yyyy) or Ongoing

Listing 16.2.5.1: Concomitant Medication and Non-Drug Therapy

Subject No.	None	Medication/ Non-Drug Therapy	Code*	Single Dose/ Unit	Freq.	Route	Reason	Indication	Start Date (dd-mmm-yyyy)	End Date (dd-mmm-yyyy) or Ongoing

*Code: WHO ATC (Anatomical Therapeutic Chemical) Code.

Listing 16.2.5.2: Study Treatment

Subject No.	Visit	Date (dd-mmm-yyyy)	Time (HHMM)	Not Done	If Not Done, Reason	Actually Administrated Dose (mg)	Administrated Site	If Any Protocol Deviation, Please Specify

Listing 16.2.7.1: Adverse Events

Subject No.	None	AE No.	Adverse Event	Preferred Term	Onset Date (dd-mmm-yyyy)	Onset Time (HHMM)	Onset Day*	Resolution Date (dd-mmm-yyyy)	Resolution Time (HHMM)	Ongoing	Severity	Serious AE	Relationship	Action Taken	Treatment Required	Outcome

*Onset Day is defined as: Date of onset - Date of first administration + 1.

Listing 16.2.7.2: Adverse Events Lead to Discontinuation

Subject No.	AE No.	Adverse Event	Preferred Term	Onset Date (dd-mmm-yyyy)	Onset Time (HHMM)	Onset Day*	Resolution Date (dd-mmm-yyyy)	Resolution Time (HHMM)	Ongoing	Severity	Serious AE	Relationship	Action Taken	Treatment Required	Outcome

*Onset Day is defined as: Date of onset - Date of first administration + 1.

Listing 16.2.7.3: Serious Adverse Events

Subject No.	AE No.	Adverse Event	Preferred Term	Onset Date (dd-mmm-yyyy)	Onset Time (HHMM)	Onset Day*	Resolution Date (dd-mmm-yyyy)	Resolution Time (HHMM)	Ongoing	Severity	Serious AE	Relationship	Action Taken	Treatment Required	Outcome

*Onset Day is defined as: Date of onset - Date of first administration + 1.

Listing 16.2.8.1: Laboratory Test Abnormality

Subject No.	Visit	Sampling Date (dd-mmm-yyyy)	Category	Item	Result	Units	Normal Range	Judgment	Flag*	If Any Protocol Deviation, Please Specify

*Flag for Out-of-Range Values: 'L' (low)- below the lower limit of normal range; 'H' (high)- above the upper limit of normal range.

Listing 16.2.8.2: Laboratory Test - Hematology

Subject No.	Visit	Sampling Date or N/A (dd-mmm-yyyy)	Item	Result	Units	Normal Range	Judgment	Flag*	If Any Protocol Deviation, Please Specify

*Flag for Out-of-Range Values: 'L' (low)- below the lower limit of normal range; 'H' (high)- above the upper limit of normal range.

Listing 16.2.8.3: Laboratory Test - Biochemistry

Subject No.	Visit	Sampling Date or N/A (dd-mmm-yyyy)	Item	Result	Units	Normal Range	Judgment	Flag*	If Any Protocol Deviation, Please Specify

*Flag for Out-of-Range Values: 'L' (low)- below the lower limit of normal range; 'H' (high)- above the upper limit of normal range.

Listing 16.2.8.4: Laboratory Test - Urinalysis

Subject No.	Visit	Sampling Date or N/A (dd-mmm-yyyy)	Item	Result	Units	Normal Range	Judgment	Flag*	If Any Protocol Deviation, Please Specify

*Flag for Out-of-Range Values: 'L' (low)- below the lower limit of normal range; 'H' (high)- above the upper limit of normal range.

Listing 16.2.8.5: PSA Tumor Marker

Subject No.	Visit	Sampling Date (dd-mmm-yyyy)	N/A or Not Done	Result	If Any Protocol Deviation, Please Specify

Listing 16.2.8.6: Testosterone Level

Subject No.	Visit	Sampling Date (dd-mmm-yyyy)	N/A or Not Done	Result	If Any Protocol Deviation, Please Specify

Listing 16.2.9: Vital Signs

Subject No.	Visit	Not Done	Body Height (cm)	Body Weight (kg)	Body Pressure (mmHg)	Heart Rate (beats/min)	Respiratory Rate (/min)	Body Temperature (℃)	If Any Protocol Deviation, Please Specify

Listing 16.2.10: Physical Examination

Subject No.	Visit	N/A	Category	Other Abnormal Findings	Result	Abnormal Findings	If Any Protocol Deviation, Please Specify

Listing 16.2.11: ECOG Performance Status

Subject No.	Visit	Perform Date (dd-mmm-yyyy)	Not Done	ECOG Performance Status	If Any Protocol Deviation, Please Specify

Listing 16.2.12: Electrocardiography (ECG)

Subject No.	Visit	Perform Date (dd-mmm-yyyy)	N/A or Not Done	HR (bpm)	RR (msec)	QRS (msec)	PR (msec)	QT (msec)	Overall Interpretation	If Abnormal, Please Specify	If Any Protocol Deviation, Please Specify

Listing 16.2.13: Telephone Contact

		Date of Contact		Survival Status					AEs Check
Subject No.	Telephone Contact 1 /Telephone Contact 1	Date of Contact (dd-mmm-yyyy)	Contact Failure or N/A	Subject Alive	Date of Death (dd-mmm-yyyy)	Reason for Death	Prostate Carcinoma Progress	Date of Progression (dd-mmm-yyyy)	Data Collected*

*Were all necessary data collected from the subject and the medical chart (if available)?

Listing 16.2.14: Unscheduled Assessments

Subject No.	Visit	None	Assessment	Perform Date (dd-mmm-yyyy)	Result	Judgment