Statistical Analysis Plan

Study Title

A prospective, multicenter, Phase-IV clinical trial to assess safety of Durvalumab in Indian adult patients with locally advanced, unresectable non-small cell lung cancer (NSCLC)

Protocol/ Study Number :	D133HC00003
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LIST OF ABBREVIATION

Abbreviation	Term

AE	Adverse Event
CRF	case report form (electronic/paper)
CSA	clinical study agreement
CSR	clinical study report
CTCAE	Common Terminology Criteria for Adverse Event
DAE	discontinuation of investigational product due to Adverse Event
DNA	deoxyribonucleic acid
EC	ethics committee, synonymous to institutional review board (IRB) and independent ethics committee (IEC)
GCP	Good Clinical Practice
ICH	International Conference on Harmonisation
International Co-ordinating investigator	If a study is conducted in several countries the International Co-ordinating Investigator is the Investigator co-ordinating the investigators and/or activities internationally.
IVRS	interactive voice response system
IWRS	interactive web response system
LSLV	last subject last visit
LIMS	laboratory information management system
OAE	other significant Adverse Event
PI	principal investigator
SAE	serious Adverse Event
SAP	statistical analysis plan
WBDC	web based data capture

1. INTRODUCTION

The purpose of this document is to provide a description of the statistical methods and procedures to be implemented for the analysis of data from D133HC00003 study. This document is based on protocol version 4.1 Dated 12-Oct-2022.

The statistical planning and conduct of analysis of the data from this study will follow the principles defined in relevant ICH-E9 guidelines. Any change from the planned analysis as described in the protocol, are detailed here, and any differences described here supersede the analysis as presented in the protocol.

2. Study Objective and Design

2.1 Study Objective

2.1.1 Primary Objective

To assess the safety of durvalumab among locally advanced unresectable non-small cell lung carcinoma in Indian patients

2.1.2 Secondary Objective

Not Applicable

2.2 Study Description

2.2.1 Study Design

This is a Phase IV, open-label, single arm, multi-center, prospective study to be conducted in India. Two cohorts of patients will be included in the current study patients with locally advanced, unresectable NSCLC whose disease has not progressed following platinum-based chemoradiation therapy (N= 100). Potential patients will undergo eligibility determination within 7 days prior to first dose. Patients who meet the protocol-defined inclusion/exclusion criteria will be prospectively enrolled in a sequential manner at 10 centres in India. All enrolled patients will be treated with durvalumab administered intravenously over 60 minutes at 10 mg/kg every 2 weeks. The treatment period for this study is 20 weeks, which corresponds to 10 doses of study drug administration. Treatment will continue as long as clinical benefit is observed for a maximum of 20 weeks or either of the criteria defined in section 7 are met, whichever is earlier. Patients who are observed to continue to receive clinical benefit from durvalumab at end of Week 20 will continue treatment in post-trial phase . Any patient who discontinues treatment with durvalumab before end of Week 20 on study will be followed for 90 days after discontinuation of study drug or until the start of alternate treatment intervention, whichever is earlier. Safety will be evaluated throughout the evaluation phase and during the follow up of patients who discontinue treatment before end of Week 20 by physical exams including vital signs, AE/SAE monitoring, laboratory evaluations and recording of concomitant medications.

2.2.2 Inclusion Criteria

Patients are eligible to be included in the study only if all of the following inclusion criteria and none of the exclusion criteria apply:

1. Provision of signed, written and dated informed consent prior to any study specific Procedures

2. Male or female aged 18 years or older

3. As per local prescribing information and in view of positive benefit-risk assessment, patient prescribed Durvalumab treatment as per independent clinical judgment of treating physician for either treatment for locally advanced, unresectable non-small cell lung carcinoma whose disease has not progressed following platinum-based chemoradiation therapy (N= 100)

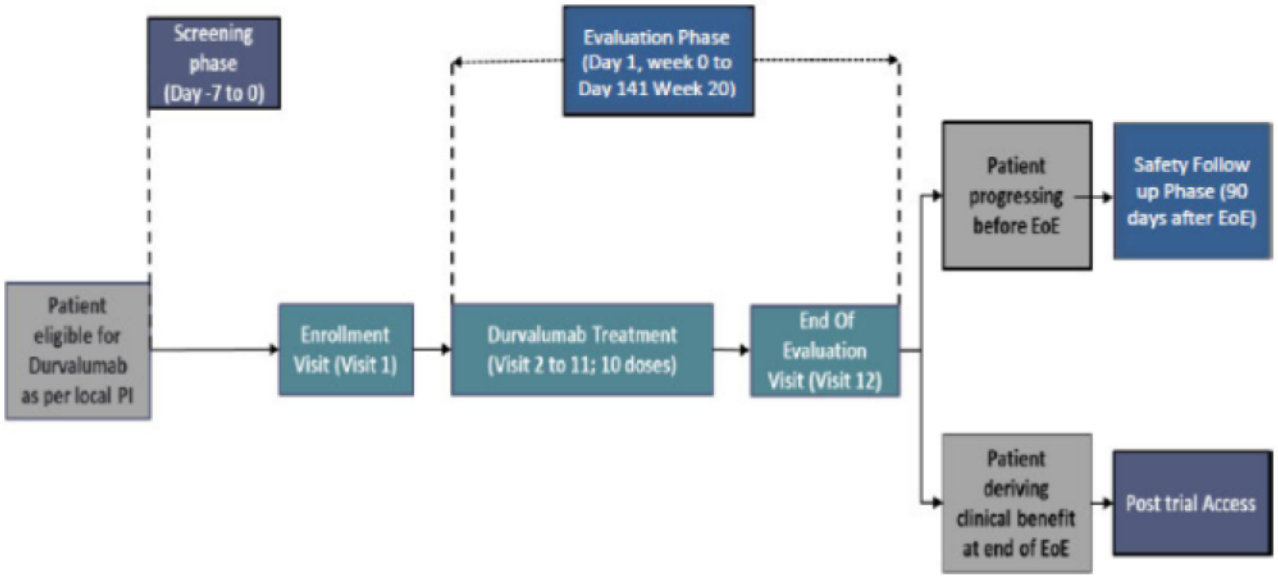
2.2.3 Exclusion Criteria

1. Concurrent enrolment in another clinical study, unless it is an observational (non-interventional) clinical study or the follow-up period of an interventional study
2. Current or prior use of immunosuppressive medication within 14 days before the first dose of study drug, with the exceptions of intranasal and inhaled corticosteroids or systemic corticosteroids at physiological doses, which are not to exceed 10 mg/day of prednisone, or an equivalent corticosteroid. Systemic steroid administration required to manage toxicities arising from radiation therapy delivered as part of the chemoradiation therapy for locally advanced NSCLC is allowed.
3. Prior exposure to any anti-PD-1 or anti-PD-L1 antibody including durvalumab.
4. **For NSCLC cohort only**:
   a. Mixed small cell and non-small cell lung cancer histology
   b. Any unresolved toxicity CTCAE >Grade 2 from the prior chemoradiation therapy.
   c. Patients with ≥Grade 2 pneumonitis from prior chemoradiation therapy
5. Active or prior documented autoimmune disease within the past 2 years, inflammatory bowel disease (eg, Crohn's disease, ulcerative colitis), primary immunodeficiency, organ transplant that requires therapeutic immunosuppression, hypersensitivity to study drug or any excipient, leptomeningeal carcinomatosis, tuberculosis.

   NOTE: Patients with vitiligo, Grave's disease, or psoriasis not requiring systemic treatment (within the past 2 years) are not excluded.
6. Female patients who are pregnant, breast-feeding or male or female patients of reproductive potential who are not employing an effective method of birth control

7. Any condition that, in the opinion of the investigator, would interfere with evaluation of the study drug or interpretation of patient safety or study results.

2.2.4 Study Flow chart



2.2.5 Study Plan

Dose		1	2	3	4	5	6	7	8	9	10		
Days (± 3 days of windows period)	-7 to 0	1	15	29	43	57	71	85	99	113	127	141	230
Week (1st day of week)		0	2	4	6	8	10	12	14	16	18	Last day of week 20	
Visit	1	2	3	4	5	6	7	8	9	10	11	12	13
	Screening Period	Evaluation Phase											Follow-up period
	Screening Visit	Evaluation Visit (2-11)										End of Evaluation Visit	End of Study Visit
Informed Consent Form	X												
Eligibility Criteria	X	X											
Demography and history of tobacco and alcohol use	X												
Medical and surgical history (including all treatments for NSCLC/mUC)	X												
Physical examination	X	X	Targeted physical exam (based on symptoms)									X	
Vital signs (pre and post-infusion vital signs assessments; see Section 6.4.8)		X	X	X	X	X	X	X	X	X	X	X	
Urine Pregnancy Test	X												
Weight		X		X		X		X		X			
World Health Organization performance status	X	X	X	X	X	X	X	X	X	X	X	X	
Concomitant medications	X	X	X	X	X	X	X	X	X	X	X	X	
Disease Characteristics Assessment		X			X			X			X	X	
Adverse event/serious adverse event assessment		X	X	X	X	X	X	X	X	X	X	X	X
Electrocardiogram (before dosing of IP)		X				X				X			
Haematology		X	X	X	X	X	X	X	X	X	X	X	
Serum chemistry (LFT, RFT, Electrolytes)		X	X	X	X	X	X	X	X	X	X	X	
Urine Routine and microscopy		X	X	X	X	X	X	X	X	X	X	X	
Thyroid function tests (TSH, T3 and T4)[a]		X				X				X		X	
IP Administration		X	X	X	X	X	X	X	X	X	X		

a. Except screening visit, free T3 and free T4 will only be measured if TSH is abnormal or if there is clinical suspicion of an AE related to the endocrine system.

2.3 Randomization

Not Applicable

2.4 Blinding and Un-Blinding

Not Applicable

2.5 Interim Analysis

No interim analyses is planned for this study.

3. Population Analysis Set

3.1 Enrolled Analysis Set

The enrolled population is defined as all screened patients who provided written informed consent at screening assessment, satisfied all the eligibility criteria and enrolled into the study.

3.2 Safety Analysis Set

All the patients who are enrolled into the study and received at least one dose of investigational product as an IV infusion.

4. Sample Size and Power Calculations

The primary endpoint of the trial is to demonstrate the safety profile of durvalumab in routine clinical practice as assessed by the incidence of Adverse Events (AEs) (Serious and Non-serious AEs) observed during trial. Based on the Durvalumab historic data, estimated proportion of 31% for Adverse Events prevalence rate. With a sample size of 83, would be able to achieve the 10% precision of the estimates with the 95% level of confidence. Approximately 120 participants will be screened to achieve around 100 participants enrolled in the study.

Scenario#	estimated proportion	Precision	Confidence level	Required sample size
1	31%	.15	95%	37
2	31%	.14	95%	42
3	31%	.13	95%	49
4	31%	.12	95%	58
5	31%	.11	95%	68
6	31%	.10	95%	83

5. Patient Characteristics and Study Conduct Summaries

5.1 General Considerations

Statistical Analysis will be performed using SAS (version 9.4 or higher) software (SAS Institute Inc USA). Categorical variables will be summarized with the frequency, percentage of Patients in each category. Continuous variables will be summarized descriptively with the number of Patients, mean, standard deviation, median, minimum and maximum values.

5.2 Decimal Point

Unless otherwise noted, means, median, will be presented to one decimal place more than the measured value, the same decimal as the measured value, percentages and 95% confidence intervals will be presented to two decimal places and p-value will be presented to three decimal place. Percentages after zero counts will not be displayed and percentages equating to 100% will be presented as 100%, without any decimal places.

5.3 Disposition of Patients

Patient disposition table will be based on all Enrolled Analysis Set who consented to participate in the study. The following summaries will be included in the disposition table: total number of Patient Enrolled in the study, total number of Patients screened in the study, number of Patients who failed screening, number and percentage of Patients who completed the study and number and percentage of Patients who discontinued from the study with reason for discontinuation.

5.4 Demographic and Baseline Characteristics

Demographic and baseline characteristics will be summarized based on the Enrolled Analysis Set.

Descriptive summaries will be provided for the demographic and baseline characteristics. Demographic characteristics and baseline characteristics such as age, Gender and Weight, etc. will be summarized and tabulated for Enrolled Analysis Set.

All the continuous variables will be summarized by n, mean, standard deviation, median, minimum and maximum values. All the categorical variables will be summarized as frequency, percentage of Patients.

5.5 Medical/Surgical History

Medical History will be summarized based on the Enrolled Population.

Descriptive summaries will be provided for the Medical/Surgical History.

All the continuous variables will be summarized by n, mean, standard deviation, minimum, median and maximum values. All the categorical variables will be summarized as frequency, percentage of Patients.

5.6 Radiation Treatment

Radiation Treatment will be summarized based on the Enrolled Population.

Descriptive summaries will be provided for the Radiation Treatment.

All the continuous variables will be summarized by n, mean, standard deviation, minimum, median and maximum values. All the categorical variables will be summarized as frequency, percentage of Patients.

6. Endpoints Analysis Strategy

6.1 Endpoints Analysis

6.1.1 Primary Endpoint

Adverse Events (AEs), Serious Adverse Events (SAEs), and AEs of Special Interest (AESI) including interstitial lung disease/pneumonitis-like events, and on-study deaths.

6.1.2 Secondary Endpoint

Not Applicable

6.2 Efficacy Hypothesis

There is no statistical hypothesis to be tested in this study.

6.3 Statistical Methods for Efficacy Analysis

Statistical Analysis will be performed using SAS (version 9.4 or higher) software (SAS Institute Inc USA). Categorical variables will be summarized with the frequency and percentage of Patients in each category. Continuous variables will be summarized descriptively with the number of Patients, mean, standard deviation, minimum, median and maximum values.

6.3.1 Primary Endpoint Analysis

The primary analysis for primary endpoint will be based on Safety Analysis Set.

Primary Endpoint evaluations will include Adverse Events (AEs), Serious Adverse Events (SAEs), Adverse Events of Special Interest (AESI) including interstitial lung disease/pneumonitis-like events and on study Deaths.

Adverse Events (AEs), Serious Adverse Events (SAEs), Adverse Events of Special Interest (AESI) including interstitial lung disease/pneumonitis-like events and on study Deaths will be summarized using Frequency, Percentages.

Physical Examination will include General Appearance, Respiratory system, Cardiovascular system, Abdomen, Skin, Heent, Neck, Lymph node, Thyroid, Musculo-skeletal system, Genital/Rectal and Neurological System. Physical Examination will be summarized based on the Safety Analysis Set.

Descriptive summaries will be provided for the Physical Examination.

All the continuous variables will be summarized by n, mean, standard deviation, minimum, median and maximum values. All the categorical variables will be summarized as frequency, percentage.

Vital Signs will include Pulse rate, Respiratory rate, Systolic Blood Pressure, Diastolic Blood Pressure, Oxygen Saturation and Temperature. Vital Signs will be summarized based on the Safety Analysis Set.

Vital Signs will be summarised by number of observations, arithmetic mean, SD, median, minimum and maximum values.

12-Lead Electrocardiogram will include Heart rate, QRS, PR, RR, QT and QTcF. 12-Lead Electrocardiogram will be summarized based on the Safety Analysis Set.

12-Lead Electrocardiogram will be summarised by number of observations, arithmetic mean, SD, median, minimum and maximum values.

6.3.2 Secondary Endpoint Analysis

Not applicable

7. References

- AstraZeneca Pharma India Limited Block N1, 12th Floor, Manyata Embassy Business Park Rachenahalli, Outer Ring Road, Bangalore-560045.
- ICH E3 Guideline
- ICH E9; STATISTICAL PRINCIPLES FOR CLINICAL TRIALS

8. Mock Shells

Tables

Table 14.1.1.1 Patient Disposition (Enrolled Analysis Set)

	Durvalumab n (%)
Number of Patients Screened [1], n	xxx
Number of Screen failure Patients [2], n	xx
Number of Subjects Eligibility Criteria met	xxx
Number of Subjects Withdrawal/Discontinued before Study Enrolment	xx
Reason:	
xxxxxxxxx	xx
Xxxxx xxxxxxx	xx
Number of Patient Enrolled into the Study	xxx
Number of Patients Completed the study	xx (xx.xx)
Number of Patients Discontinued from the study	xx (xx.xx)
Reason for Discontinuation:	
Patient Decision	xx (xx.xx)
Adverse Event	xx (xx.xx)
Severe non-compliance to study protocol that, in the opinion of the investigator or sponsor, warrants withdrawal	xx (xx.xx)
Any AE that meets criteria for discontinuation	xx (xx.xx)
An AE related to study drug that is ≥Grade 3, with the exception of toxicities that do not meet criteria for discontinuation	xx (xx.xx)
≥Grade 3 infusion reaction	xx (xx.xx)
Initiation of alternative anticancer therapy including another investigational agent	xx (xx.xx)
Disease progression as per investigator's clinical and imaging assessment	xx (xx.xx)
Pregnancy or intent to become pregnant	xx (xx.xx)
Use of prohibited concomitant medication	xx (xx.xx)
Study terminated by sponsor	xx (xx.xx)
Death	xx (xx.xx)
Clinically significant abnormal laboratory value(s)	xx (xx.xx)
Other	xx (xx.xx)
xxxxxx	xx (xx.xx)
xxxxxx	xx (xx.xx)

- [1] Patients who provided informed consent; [2] patients who did not satisfied the eligibility criteria i.e., Inclusion or exclusion criteria.
- The small "n" in summary statistics represents the number of patients in the row category.
- Percentages in are based on the number of patients enrolled into the study.
- Source: Listing 16.1.1.1 and Listing 16.1.1.
- Table Name: xxxxxxxx

Table 14.1.1.2 Summary of Analysis Population Set (Enrolled Analysis Set)

	Durvalumab N = xxx n (%)
Enrolled Analysis Set	xx (xx.xx)
Safety Analysis Set	xx (xx.xx)

- The Capital "N" in the column header represents the total number of patients in Enrolled Analysis Set.
- The small "n" in summary statistics represents the total number of patients in the row category.
- Percentages are based on the total number patients in Enrolled Analysis Set.
- Enrolled Analysis Set: The enrolled population is defined as all screened patients who provided written informed consent at screening assessment, satisfied all the eligibility criteria and enrolled into the study.
- Safety Population: All the patients who are enrolled into the study and received at least one dose of investigational product as an IV infusion.
- Source: Listing 16.1.1.4
- Table Name: xxxxxxxx

Table 14.1.1.3 Summary of Protocol Deviation (Enrolled Analysis Set)

	Durvalumab N = xxx n (%)
Patient undergone any Protocol Deviation	
Yes	xx (xx.xx)
No	xx (xx.xx)
Protocol Deviation	
Restrictions	xx (xx.xx)
Enrolment/IE Criteria	xx (xx.xx)
Out of visit window	xx (xx.xx)
IP Administration	xx (xx.xx)
Drug accountability	xx (xx.xx)
Noncompliance	xx (xx.xx)
Use of prohibited medication	xx (xx.xx)
Safety assessment	xx (xx.xx)
Other	xx (xx.xx)
Other 1	xx (xx.xx)
Other n	xx (xx.xx)
Action Taken	
Patient continued in the study	xx (xx.xx)
Patient Discontinued in the study	xx (xx.xx)
Retraining	xx (xx.xx)
Other	xx (xx.xx)
Other 1	xx (xx.xx)
Other n	xx (xx.xx)

- The Capital "N" in the column header represents the total number of patients in Enrolled Analysis Set.
- The small "n" represents the total number of patients in the row category.
- Percentages are based on number of patients in Enrolled Analysis Set.
- Patients may have more than one protocol deviation.
- Source: Listing 16.1.1.3

Table 14.1.2 Summary of Demographic and Baseline Characteristics (Enrolled Analysis Set)

Demographic and Baseline Variables	N = xx
Age (Years)	
n	Xx
Missing	Xx
Mean (SD)	xx.x (xx.xx)
Median	xx.x
(min, max)	(xx.xx, xx.xx)
Gender, n (%)	
Male	xx (xx.xx)
Female	xx (xx.xx)
Missing	xx (xx.xx)
Height (cm)	
N	Xx
Missing	Xx
Mean (SD)	xx.x (xx.xx)
Median	xx.x
(min, max)	(xx.xx, xx.xx)
Weight (Kg)	
n	Xx
Missing	Xx
Mean (SD)	xx.x (xx.xx)
Median	xx.x
(min, max)	(xx.xx, xx.xx)
Race, n (%)	
Indian	xx (xx.xx)
Other	xx (xx.xx)
Other 1	xx (xx.xx)
Other n	xx (xx.xx)

- The Capital "N" in the column header represents the total number of patients in Enrolled Analysis Set.
- The small "n" in summary statistics represents the total number of patients.
- Percentages are based on number of patients in Enrolled Analysis Set.
- SD = Standard Deviation, min=minimum, max=maximum
- Source: Listing 16.1.2

Table 14.1.3 Summary of Significant Medical/Surgical History (Enrolled Analysis Set)

System Organ Class Preferred Term	Durvalumab N = xx n (%)
Number of patient with at least one medical/Surgical history	xx (xx.xx)
System Organ Class 1	xx (xx.xx)
Preferred Term 1	xx (xx.xx)
Preferred Term 2	xx (xx.xx)
System Organ Class 2	xx (xx.xx)
Preferred Term 1	xx (xx.xx)
Preferred Term 2	xx (xx.xx)
System Organ Class 3	xx (xx.xx)
Preferred Term 1	xx (xx.xx)
Preferred Term 2	xx (xx.xx)

- The Capital "N" in the column header represents the total number of patients in Enrolled Analysis Set.
- The small "n" in summary statistic represents the total number of patients in the row category.
- Percentages are based on number of patients in Enrolled Analysis Set.
- System Organ Class and Preferred term are coded using standards of MedDRA version xx.x
- Patient having a medical history of similar SOC/PT more than once will be counted only once.
- Source: Listing 16.1.3
- Table Name: xxxx
- Programmer's Note 1: The above table will be continued for all other SOC and PT terms.
- Programmers Note 2: SOC and PT will be sorted in descending order of frequency.

Table 14.1.4.1 Summary of Alcohol consumption and drug abuse (Enrolled Analysis Set)

	Durvalumab N = xx n (%)
Number of patients with significant history of alcoholism or drug abuse	xx (xx.xx)
Alcohol	
Current	xx (xx.xx)
Past	xx (xx.xx)
Never	xx (xx.xx)
Drug	
Current	xx (xx.xx)
Past	xx (xx.xx)
Never	xx (xx.xx)

- The Capital "N" in the column header represents the total number of patients in Enrolled Analysis Set.
- The small "n" in summary statistic represents the total number of patients in the row category.
- =Percentages are based on total number of patients in Enrolled Analysis Set.
- Source: Listing 16.1.6.1
- Table number: xxxxx

Table 14.1.4.2 Summary of History of Tobacco (Enrolled Analysis Set)

	Durvalumab N = xxx
	n (%)
Smoking History	
Current	xx (xx.xx)
Past	xx (xx.xx)
Never	xx (xx.xx)

- The Capital "N" in the column header represents the total number of patients in Enrolled Analysis Set.
- The small "n" in summary statistic represents the total number of patients in the row category.
- Percentages are based on total number of patients in Enrolled Analysis Set.
- Source: Listing 16.1.6.2
- Table Name: xxxxx

Table 14.1.5.1 Summary of IP Administration (Enrolled Analysis Set)

	Durvalumab N = xx
Visit 2	
Total Dose Administered(mg/mL)	
n	Xx
Missing	Xx
Mean (SD)	xx.x (xx.xx)
Median	xx.x
(min, max)	(xx.xx, xx.xx)
Dose interrupted during infusion, n (%)	
No	xx (xx.xx)
Yes	xx (xx.xx)
Dose Restarted, n (%)	
Yes	xx (xx.xx)
No	xx (xx.xx)

- The Capital "N" in the column header represents the total number of patients in Enrolled Analysis Set.
- The small "n" in summary statistic represents the total number of patients in the row category.
- Percentages are based on number of patients in Enrolled Analysis Set.
- SD = Standard Deviation, min=minimum, max=maximum
- Source: Listing 16.1.4.1 and Listing 16.1.4.2
- Table Name: xxxxx
- Programmer Note: Continue the above table from Visit 2 to Visit 11.

Table 14.1.5.2 Summary of Study drug Administration accountability (Enrolled Analysis Set)

	N = xx
At Visit 11,	
Dose Reduced in any of the Visit , n (%)	
Yes	xx (xx.xx)
No	xx (xx.xx)
Dosing Completed, n (%)	
Yes	xx (xx.xx)
No	xx (xx.xx)
Number of IV Dose administered in the treatment period	
n	Xx
Missing	Xx
Mean (SD)	xx.x (xx.xx)
Median	xx.x
(min, max)	(xx.xx, xx.xx)
Unused IP returned, n (%)	
Yes	xx (xx.xx)
No	xx (xx.xx)
Compliance (%)	
n	Xx
Missing	Xx
Mean (SD)	xx.x (xx.xx)
Median	xx.x
(min, max)	(xx.xx, xx.xx)

- The Capital "N" in the column header represents the total number of patients in Enrolled Analysis Set.
- The small "n" represents the total number of patients in the row category.
- All Percentages rows are based on number of patients in Enrolled Analysis Set.
- SD = Standard Deviation, min=minimum, max=maximum
- Source: Listing 16.1.4.3
- Table Name: xxxxx

Table 14.1.6 Summary of Disease Characteristics Assessment (Enrolled Analysis Set)

	Durvalumab N = xx n (%)
At Visit x	
Disease Stage of NSCLC	
Stage IIIA	xx (xx.xx)
Stage IIIB	xx (xx.xx)
Stage IIIC	xx (xx.xx)

- The Capital "N" in the column header represents the total number of patients in Enrolled Analysis Set.
- The small "n" in summary statistic represents the total number of patients in the row category.
- Percentages are based on total number of patients in Enrolled Analysis Set.
- Programmer Note:- Visit x : Visit 2, Visit 5, Visit 8, Visit 11 and Visit 12.
- Source: Listing 16.1.5
- Table Name: xxxx

Table 14.1.7 Summary of Radiation Treatment (Enrolled Analysis Set)

	N = xx
Clinical Stage of NSCLC	
Stage IIIA	xx (xx.xx)
Stage IIIB	xx (xx.xx)
Stage IIIC	xx (xx.xx)
Pathological staging of NSCLC done	
No	xx (xx.xx)
Yes	xx (xx.xx)
Stage IIIA	xx (xx.xx)
Stage IIIB	xx (xx.xx)
Stage IIIC	xx (xx.xx)
Histology of Tumor	
Squamous	xx (xx.xx)
Non-squamous	xx (xx.xx)
Technique of Radiation	
Sequential	
IMRT	xx (xx.xx)
IGRT	xx (xx.xx)
Proton	xx (xx.xx)
SBRT	xx (xx.xx)
Other	xx (xx.xx)
Other 1	xx (xx.xx)
Other 2	xx (xx.xx)
Concurrent	
IMRT	xx (xx.xx)
IGRT	xx (xx.xx)
Proton	xx (xx.xx)
SBRT	xx (xx.xx)
Other	xx (xx.xx)
Other 1	xx (xx.xx)
Other 2	xx (xx.xx)
Dose of Radiation (Gy)	
n	Xx
Missing	Xx
Mean (SD)	xx.x (xx.xx)
Median	xx.x
(min, max)	(xx.xx, xx.xx)
Induction chemotherapy given	
Yes	xx (xx.xx)
No	xx (xx.xx)
If Yes, Number of cycles	
n	Xx

Mean (SD)	xx.x (xx.xx)
Median	xx.x
(min, max)	(xx.xx, xx.xx)
Type of Chemotherapy	
Sequential	
Concurrent	
Number of cycles (Sequential)	
n	Xx
Missing	Xx
Mean (SD)	xx.x (xx.xx)
Median	xx.x
(min, max)	(xx.xx, xx.xx)
Number of cycles (Concurrent)	
n	Xx
Missing	Xx
Mean (SD)	xx.x (xx.xx)
Median	xx.x
(min, max)	(xx.xx, xx.xx)
Tumor response assessment done on imaging (days)	
n	Xx
Missing	Xx
Mean (SD)	xx.x (xx.xx)
Median	xx.x
(min, max)	(xx.xx, xx.xx)
Performance status at time of initiation of CRT	
n	Xx
Missing	Xx
Mean (SD)	xx.x (xx.xx)
Median	xx.x
(min, max)	(xx.xx, xx.xx)

- The Capital "N" in the column header represents the total number Enrolled Analysis Set.
- The small "n" represents the total number of patients in the row category.
- Percentages are based on total number of Enrolled Analysis Set.
- SD = Standard Deviation, min=minimum, max=maximum
- Source: Listing 16.1.9.1 and Listing 16.1.9.2

Table 14.1.8 Summary of WHO Performance Status (Safety Analysis Set)

	N = xx
Visit 1	
WHO Performance Grade	
0 = Fully active, able to carry on all pre-disease performance without restriction	xx (xx.xx)
1 = Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature	xx (xx.xx)
2 = Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light housework, office work	xx (xx.xx)
3 = Capable of only limited self-care, confined to bed or chair more than 50% of waking hours	xx (xx.xx)
4 = Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair	xx (xx.xx)
5 = Dead	xx (xx.xx)
Visit x	
WHO Performance Grade	
0 = Fully active, able to carry on all pre-disease performance without restriction	xx (xx.xx)
1 = Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature	xx (xx.xx)
2 = Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light housework, office work	xx (xx.xx)
3 = Capable of only limited self-care, confined to bed or chair more than 50% of waking hours	xx (xx.xx)
4 = Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair	xx (xx.xx)
5 = Dead	xx (xx.xx)
Patients performance grade changed, since last visit	
Yes	xx (xx.xx)
No	xx (xx.xx)

- The Capital "N" in the column header represents the total number of patients in Safety Analysis Set.
- The small "n" in summary statistic represents the total number of patients in the row category.
- Percentages are based on total number of patients in Safety Analysis Set.
- Programmer Note: Visit x- Visit 2 up to Visit 13.
- Source: Listing 16.1.10
- Table Name: xxxxx

Table 14.2.1.1 Adverse Events (Safety Analysis Set)

	Durvalumab (N=xxx) n (%) E
Any Adverse Event	xx (xx.xx) xx
Any Serious Adverse Event	xx (xx.xx) xx
Any Treatment Emergent Adverse Event	xx (xx.xx) xx
Any Serious Treatment Emergent Adverse Event	xx (xx.xx) xx
Treatment Emergent Adverse Event related to IMP	xx (xx.xx) xx
Treatment Emergent Adverse Event leading to IMP discontinuation	xx (xx.xx) xx
Treatment Emergent Adverse Event leading to Death	xx (xx.xx) xx

- The capital "N" in the column header represents the total number of patients in Safety Analysis Set.
- The small "n' in summary represents the number of patients in row category.
- TEAE are those adverse events which occurred after first dose of study medication.
- Note: Adverse events were coded using MedDRA version xx.x
- If a Patient has multiple occurrences of an AE, the Patient is presented only once in the respective patient count column (n) for the corresponding AE. Events are counted each time in the event (E)
- Source: Listing 16.3.1.1 and Listing 16.3.1.2

Table 14.2.1.2 Summary of Adverse Event (Safety Analysis Set)

	Durvalumab (N=xxx) n (%) E
Any Adverse Event reported	xx (xx.xx) xx
Severity as per CTCAE grade	
Mild	xx (xx.xx) xx
Moderate	xx (xx.xx) xx
Severe	xx (xx.xx) xx
Life Threatening	xx (xx.xx) xx
Death	xx (xx.xx) xx
Action Taken to Study Drug	
No Change in IP	xx (xx.xx) xx
IP Temporarily Interrupted	xx (xx.xx) xx
IP Permanently Discontinued	xx (xx.xx) xx
Other	xx (xx.xx) xx
Treatment Given	
Yes	xx (xx.xx) xx
No	xx (xx.xx) xx
Relationship with Study Drug	
Related	xx (xx.xx) xx
Not Related	xx (xx.xx) xx
Outcome	
Resolved	xx (xx.xx) xx
Recovered/ Resolved with Sequelae	xx (xx.xx) xx
Recovering/ Resolving	xx (xx.xx) xx
Not Recovered/ Not Resolved	xx (xx.xx) xx
Fatal/ result in death	xx (xx.xx) xx
Unknown	xx (xx.xx) xx
Serious Adverse Event	
Yes	xx (xx.xx) xx
No	xx (xx.xx) xx
Seriousness Criteria	
Death	xx (xx.xx) xx
Life-threatening	xx (xx.xx) xx
Inpatient hospitalization or prolongation of existing hospitalization	xx (xx.xx) xx

Persistent or significant disability/ incapacity	xx (xx.xx) xx
Congenital anomaly/Birth Defect	xx (xx.xx) xx
Important medical events	xx (xx.xx) xx
Therapy Discontinued	
Yes	xx (xx.xx) xx
No	xx (xx.xx) xx

- The Capital "N" in the column header represents the total number Safety Analysis Set.
- The small "n" represents the total number of patients in the row category.
- All Percentages rows are based on number of Safety Analysis Set.
- TEAE = treatment-emergent adverse event; E = number of TEAE
- All Percentages are based on the total number of Safety Analysis Set.
- Source: Listing 16.3.1.1 and Listing 16.3.1.2

Table 14.2.1.3 Summary of Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set)

	Durvalumab (N=xxx)
	n (%) E
Any TEAE	xx (xx.xx) xx
System Organ Class 1	xx (xx.xx) xx
Preferred Term 1	xx (xx.xx) xx
Preferred Term 2	xx (xx.xx) xx
System Organ Class 2	xx (xx.xx) xx
Preferred Term 1	xx (xx.xx) xx
Preferred Term 2	xx (xx.xx) xx

- TEAE = treatment-emergent adverse event; N = number of Patients in the Safety Analysis Set; n = number of Patients with TEAE; E = number of TEAE
- All Percentages are based on the number of patients in Safety Analysis Set.
- System Organ Class and Preferred term are coded using MedDRA version xx.x
- System Organ classes and preferred term are sorted by descending frequency. Preferred terms are sorted by descending frequency within system organ class.
- Source: Listing 16.3.1.1 and Listing 16.3.1.2

Table 14.2.1.4 Summary of Serious Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set)

	Durvalumab (N=xxx)
	n (%) E
Any Serious TEAE	xx (xx.xx) xx
System Organ Class 1	xx (xx.xx) xx
Preferred Term 1	xx (xx.xx) xx
Preferred Term 2	xx (xx.xx) xx
System Organ Class 2	xx (xx.xx) xx
Preferred Term 1	xx (xx.xx) xx
Preferred Term 2	xx (xx.xx) xx

- TEAE = treatment-emergent adverse event; N = number of Patients in the Safety Analysis Set; n = number of Patients with TEAE; E = number of TEAE
- All Percentages are based on the total number of patients in Safety Analysis Set.
- System Organ Class and Preferred term are coded using MedDRA version xx.x
- System Organ classes and preferred term are sorted by descending frequency. Preferred terms are sorted by descending frequency within system organ class.
- Source: Listing 16.3.1.1 and Listing 16.3.1.2

Table 14.2.1.5 Summary of Treatment Emergent Adverse Events leading to permanent discontinuation by System Organ Class and Preferred Term (Safety Analysis Set)

	Durvalumab (N=xxx)
	n (%) E
Any TEAE leading to permanent discontinuation	xx (xx.xx) xx
System Organ Class 1	xx (xx.xx) xx
Preferred Term 1	xx (xx.xx) xx
Preferred Term 2	xx (xx.xx) xx
System Organ Class 2	xx (xx.xx) xx
Preferred Term 1	xx (xx.xx) xx
Preferred Term 2	xx (xx.xx) xx

- TEAE = treatment-emergent adverse event; N = number of Patients in the Safety Analysis Set; n = number of Patients with TEAE; E = number of TEAE
- All Percentages are based on the total number of patients in Safety Analysis Set.
- System Organ Class and Preferred term are coded using MedDRA version xx.x
- System Organ classes and preferred term are sorted by descending frequency. Preferred terms are sorted by descending frequency within system organ class.
- Source: Listing 16.3.1.1 and Listing 16.3.1.2

Table 14.2.1.6 Summary of Treatment Emergent Adverse Events leading to Death by System Organ Class and Preferred Term (Safety Analysis Set)

	Durvalumab (N=xxx)
	n (%) E
Any TEAE leading to death	xx (xx.xx) xx
System Organ Class 1	xx (xx.xx) xx
Preferred Term 1	xx (xx.xx) xx
Preferred Term 2	xx (xx.xx) xx
System Organ Class 2	xx (xx.xx) xx
Preferred Term 1	xx (xx.xx) xx
Preferred Term 2	xx (xx.xx) xx

- TEAE = treatment-emergent adverse event; N = number of Patients in the Safety Analysis Set; n = number of Patients with TEAE; E = number of TEAE
- All Percentages are based on the total number of patients in Safety Analysis Set.
- System Organ Class and Preferred term are coded using MedDRA version xx.x
- System Organ classes and preferred term are sorted by descending frequency. Preferred terms are sorted by descending frequency within system organ class.
- Source: Listing 16.3.1.1 and Listing 16.3.1.2

Table 14.2.1.7 Summary of Treatment Emergent Adverse Event by System Organ Class, Preferred Term and Severity (Safety Analysis Set)

	Durvalumab (N=xxx)				
	Mild	Moderate	Severe	Life Threatening	Death
	n (%) E	n (%) E	n (%) E	n (%) E	n (%) E
Any TEAE	xx (xx.xx) xx	xx (xx.xx) xx	xx (xx.xx) xx	xx (xx.xx) xx	xx (xx.xx) xx
System Organ Class 1	xx (xx.xx) xx	xx (xx.xx) xx	xx (xx.xx) xx	xx (xx.xx) xx	xx (xx.xx) xx
Preferred Term 1	xx (xx.xx) xx	xx (xx.xx) xx	xx (xx.xx) xx	xx (xx.xx) xx	xx (xx.xx) xx
Preferred Term 2	xx (xx.xx) xx	xx (xx.xx) xx	xx (xx.xx) xx	xx (xx.xx) xx	xx (xx.xx) xx
System Organ Class 2	xx (xx.xx) xx	xx (xx.xx) xx	xx (xx.xx) xx	xx (xx.xx) xx	xx (xx.xx) xx
Preferred Term 1	xx (xx.xx) xx	xx (xx.xx) xx	xx (xx.xx) xx	xx (xx.xx) xx	xx (xx.xx) xx
Preferred Term 2	xx (xx.xx) xx	xx (xx.xx) xx	xx (xx.xx) xx	xx (xx.xx) xx	xx (xx.xx) xx

- TEAE = treatment-emergent adverse event; N = number of Patients in the Safety Analysis Set; n = number of Patients with TEAE; E = number of TEAE
- All Percentages are based on the total number of patients in Safety Analysis Set.
- System Organ Class and Preferred term are coded using MedDRA version xx.x
- System Organ classes and preferred term are sorted by descending frequency. Preferred terms are sorted by descending frequency within system organ class.
- Source: Listing 16.3.1.1 and Listing 16.3.1.2

Table 14.2.1.8 Summary of Treatment Emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	Durvalumab (N=xxx)
	Related
	n (%) E
Any Related TEAE	xx (xx.xx) xx
System Organ Class 1	xx (xx.xx) xx
Preferred Term 1	xx (xx.xx) xx
Preferred Term 2	xx (xx.xx) xx
System Organ Class 2	xx (xx.xx) xx
Preferred Term 1	xx (xx.xx) xx
Preferred Term 2	xx (xx.xx) xx

- TEAE = treatment-emergent adverse event; N = number of Patients in the Safety Analysis Set; n = number of Patients with TEAE; E = number of TEAE
- All Percentages are based on the total number of patients in Safety Analysis Set.
- System Organ Class and Preferred term are coded using MedDRA version xx.x
- System Organ classes and preferred term are sorted by descending frequency. Preferred terms are sorted by descending frequency within system organ class.
- Source: Listing 16.3.1.1 and Listing 16.3.1.2

Table 14.2.1.9 Summary of Serious Treatment Emergent Adverse Event by System Organ Class and Preferred Term (Safety Analysis Set)

	Durvalumab (N=xxx)
	Related
	n (%) E
Any Related Serious TEAE	xx (xx.xx) xx
System Organ Class 1	xx (xx.xx) xx
Preferred Term 1	xx (xx.xx) xx
Preferred Term 2	xx (xx.xx) xx
System Organ Class 2	xx (xx.xx) xx
Preferred Term 1	xx (xx.xx) xx
Preferred Term 2	xx (xx.xx) xx

- TEAE = treatment-emergent adverse event; N = number of Patients in the Safety Analysis Set; n = number of Patients with TEAE; E = number of TEAE
- All Percentages are based on the total number of patients in Safety Analysis Set.
- System Organ Class and Preferred term are coded using MedDRA version xx.x
- System Organ classes and preferred term are sorted by descending frequency. Preferred terms are sorted by descending frequency within system organ class.

- Source: Listing 16.3.1.1 and Listing 16.3.1.2

Table 14.2.1.10 Summary of Treatment Emergent Adverse Event by System Organ Class, Preferred Term and Relationship with Study Drug (Safety Analysis Set)

	Durvalumab (N=xxx)					
	Resolved	Resolve with Sequelae	Resolving	Not Resolved	Result in Death	Unknown
	n (%) E	n (%) E	n (%) E	n (%) E	n (%) E	n (%) E
Any TEAE	xx (xx.xx) xx	xx (xx.xx) xx	xx (xx.xx) xx	xx (xx.xx) xx	xx (xx.xx) xx	xx (xx.xx) xx
System Organ Class 1	xx (xx.xx) xx	xx (xx.xx) xx	xx (xx.xx) xx	xx (xx.xx) xx	xx (xx.xx) xx	xx (xx.xx) xx
Preferred Term 1	xx (xx.xx) xx	xx (xx.xx) xx	xx (xx.xx) xx	xx (xx.xx) xx	xx (xx.xx) xx	xx (xx.xx) xx
Preferred Term 2	xx (xx.xx) xx	xx (xx.xx) xx	xx (xx.xx) xx	xx (xx.xx) xx	xx (xx.xx) xx	xx (xx.xx) xx
System Organ Class 2	xx (xx.xx) xx	xx (xx.xx) xx	xx (xx.xx) xx	xx (xx.xx) xx	xx (xx.xx) xx	xx (xx.xx) xx
Preferred Term 1	xx (xx.xx) xx	xx (xx.xx) xx	xx (xx.xx) xx	xx (xx.xx) xx	xx (xx.xx) xx	xx (xx.xx) xx
Preferred Term 2	xx (xx.xx) xx	xx (xx.xx) xx	xx (xx.xx) xx	xx (xx.xx) xx	xx (xx.xx) xx	xx (xx.xx) xx

- TEAE = treatment-emergent adverse event; N = number of Patients in the Safety Analysis Set; n = number of Patients with TEAE; E = number of TEAE
- All Percentages are based on the total number of patients in Safety Analysis Set.
- System Organ Class and Preferred term are coded using MedDRA version xx.x
- System Organ classes and preferred term are sorted by descending frequency. Preferred terms are sorted by descending frequency within system organ class.
- Source: Listing 16.3.1.1 and Listing 16.3.1.2

Table 14.3.1 Summary of Physical Examination (Safety Analysis Set)

	Durvalumab N = xx n (%)
Visit x	
Patients Examination Done	
Yes	xx (xx.xx)
No	xx (xx.xx)
Missing	xx (xx.xx)
General Appearance	
Normal	xx (xx.xx)
Abnormal	xx (xx.xx)
If Abnormal	
NCS	xx (xx.xx)
CS	xx (xx.xx)
Respiratory	
Normal	xx (xx.xx)
Abnormal	xx (xx.xx)
If Abnormal	
NCS	xx (xx.xx)
CS	xx (xx.xx)
Cardiovascular	
Normal	xx (xx.xx)
Abnormal	xx (xx.xx)
If Abnormal	
NCS	xx (xx.xx)
CS	xx (xx.xx)
Abdomen	
Normal	xx (xx.xx)
Abnormal	xx (xx.xx)
If Abnormal	
NCS	xx (xx.xx)
CS	xx (xx.xx)
Skin	
Normal	xx (xx.xx)
Abnormal	xx (xx.xx)
If Abnormal	
NCS	xx (xx.xx)
CS	xx (xx.xx)
HEENT	
Normal	xx (xx.xx)
Abnormal	xx (xx.xx)
If Abnormal	
NCS	xx (xx.xx)
CS	xx (xx.xx)
Neck	
Normal	xx (xx.xx)
Abnormal	xx (xx.xx)

If Abnormal	
NCS	xx (xx.xx)
CS	xx (xx.xx)
Lymph Node	
Normal	xx (xx.xx)
Abnormal	xx (xx.xx)
If Abnormal	
NCS	xx (xx.xx)
CS	xx (xx.xx)
Thyroid	
Normal	xx (xx.xx)
Abnormal	xx (xx.xx)
If Abnormal	
NCS	xx (xx.xx)
CS	xx (xx.xx)
Musculo-skeletal	
Normal	xx (xx.xx)
Abnormal	xx (xx.xx)
If Abnormal	
NCS	xx (xx.xx)
CS	xx (xx.xx)
Genital/Rectal	
Normal	xx (xx.xx)
Abnormal	xx (xx.xx)
If Abnormal	
NCS	xx (xx.xx)
CS	xx (xx.xx)
Neurological	
Normal	xx (xx.xx)
Abnormal	xx (xx.xx)
If Abnormal	
NCS	xx (xx.xx)
CS	xx (xx.xx)
Others	
Normal	xx (xx.xx)
Abnormal	xx (xx.xx)
If Abnormal	
NCS	xx (xx.xx)
CS	xx (xx.xx)

- The Capital "N" in the column header represents the total number Safety Analysis Set.
- The small "n" represents the total number of patients in the row category.
- All Percentages rows are based on number of Safety Analysis Set.
- Programmer Note: Visit x – Visit 1 up to Visit 12.
- Source: Listing 16.3.2

Table 14.3.2 Summary of Vital Sign (Safety Analysis Set)

	N = xx
Visit x	
Examination Done, n (%)	
Yes	xx (xx.xx)
No	xx (xx.xx)
Missing	xx (xx.xx)
Systolic Blood Pressure (mmHg)	
n	Xx
Missing	Xx
Mean (SD)	xx.x (xx.xx)
Median	xx.x
(min, max)	(xx.xx, xx.xx)
Diastolic Blood Pressure (mmHg)	
n	Xx
Missing	Xx
Mean (SD)	xx.x (xx.xx)
Median	xx.x
(min, max)	(xx.xx, xx.xx)
Pulse Rate (beats/min)	
n	Xx
Missing	Xx
Mean (SD)	xx.x (xx.xx)
Median	xx.x
(min, max)	(xx.xx, xx.xx)
Respiratory Rate (breaths/min)	
n	Xx
Missing	Xx
Mean (SD)	xx.x (xx.xx)
Median	xx.x
(min, max)	(xx.xx, xx.xx)
Temperature (^{0}F)	
n	Xx
Missing	Xx
Mean (SD)	xx.x (xx.xx)
Median	xx.x
(min, max)	(xx.xx, xx.xx)
Oxygen Saturation (%)	
n	Xx
Missing	Xx
Mean (SD)	xx.x (xx.xx)
Median	xx.x
(min, max)	(xx.xx, xx.xx)
Weight (Kg)	
n	Xx
Missing	Xx

Mean (SD)	xx.x (xx.xx)
Median	xx.x
(min, max)	(xx.xx, xx.xx)

- The Capital "N" in the column header represents the total number Safety Analysis Set.
- The small "n" represents the total number of patients in the row category.
- Percentages in the "Examination Done" rows are based on number of Safety Analysis Set.
- SD = Standard Deviation, min=minimum, max=maximum
- Programmer Note: Visit x – Visit 2 up to Visit 12.
- Source: Listing 16.3.3

Table 14.3.3 Summary of 12-Lead Electrocardiogram (Safety Analysis Set)

	N = xx
Visit x	
Assessment Done, n (%)	
Yes	xx (xx.xx)
No	xx (xx.xx)
Missing	xx (xx.xx)
Heart rate (beats/min)	
n	Xx
Missing	Xx
Mean (SD)	xx.x (xx.xx)
Median	xx.x
(min, max)	(xx.xx, xx.xx)
QRS (ms)	
n	Xx
Missing	Xx
Mean (SD)	xx.x (xx.xx)
Median	xx.x
(min, max)	(xx.xx, xx.xx)
PR (ms)	
n	Xx
Missing	Xx
Mean (SD)	xx.x (xx.xx)
Median	xx.x
(min, max)	(xx.xx, xx.xx)
RR (ms)	
n	Xx
Missing	Xx
Mean (SD)	xx.x (xx.xx)
Median	xx.x
(min, max)	(xx.xx, xx.xx)
QT (ms)	
n	Xx
Missing	Xx
Mean (SD)	xx.x (xx.xx)
Median	xx.x
(min, max)	(xx.xx, xx.xx)
QTcF (ms)	
n	Xx
Missing	Xx
Mean (SD)	xx.x (xx.xx)
Median	xx.x
(min, max)	(xx.xx, xx.xx)

- The Capital "N" in the column header represents the total number Safety Analysis Set.
- The small "n" represents the total number of patients in the row category.
- Percentages in the "Assessment Done" rows are based on number of Safety Analysis Set.
- SD = Standard Deviation, min=minimum, max=maximum

- Programmer Note: Visit x – Visit 2, Visit 6 and Visit 10.
- Source: Listing 16.3.4

Table 14.3.4.1 Summary of Haematology (Safety Analysis Set)

	N = xx n (%)
Visit x	
Sample Collected	
Yes	xx (xx.xx)
No	xx (xx.xx)
Missing	xx (xx.xx)
Haematocrit	
Normal	xx (xx.xx)
Abnormal	xx (xx.xx)
If Abnormal	
CS	xx (xx.xx)
NCS	xx (xx.xx)
Haemoglobin	
Normal	xx (xx.xx)
Abnormal	xx (xx.xx)
If Abnormal	
CS	xx (xx.xx)
NCS	xx (xx.xx)
Basophils	
Normal	xx (xx.xx)
Abnormal	xx (xx.xx)
If Abnormal	
CS	xx (xx.xx)
NCS	xx (xx.xx)
Eosinophils	
Normal	xx (xx.xx)
Abnormal	xx (xx.xx)
If Abnormal	
CS	xx (xx.xx)
NCS	xx (xx.xx)
Monocytes	
Normal	xx (xx.xx)
Abnormal	xx (xx.xx)
If Abnormal	
CS	xx (xx.xx)
NCS	xx (xx.xx)
Absolute Neutrophil Count	
Normal	xx (xx.xx)
Abnormal	xx (xx.xx)
If Abnormal	
CS	xx (xx.xx)
NCS	xx (xx.xx)
Platelet count	
Normal	xx (xx.xx)
Abnormal	xx (xx.xx)
If Abnormal	
CS	xx (xx.xx)
NCS	xx (xx.xx)
Total Lymphocyte count	

Normal	xx (xx.xx)
Abnormal	xx (xx.xx)
If Abnormal	
CS	xx (xx.xx)
NCS	xx (xx.xx)
Differential Lymphocyte count	
Normal	xx (xx.xx)
Abnormal	xx (xx.xx)
If Abnormal	
CS	xx (xx.xx)
NCS	xx (xx.xx)

- The Capital "N" in the column header represents the total number Safety Analysis Set.
- The small "n" represents the total number of patients in the row category.
- All Percentages rows are based on number of Safety Analysis Set.
- NCS=Abnormal Not Clinically Significant and CS= Abnormal Clinically Significant
- Programmer Note: Visit x – Visit 2 up to Visit 12.
- Source: Listing 16.3.5

Table 14.3.4.2 Summary of Serum Chemistry (Safety Analysis Set)

	N = xx n (%)
Visit x	
Sample Collected	
Yes	xx (xx.xx)
No	xx (xx.xx)
Missing	xx (xx.xx)
Albumin	
Normal	xx (xx.xx)
Abnormal	xx (xx.xx)
If Abnormal	
CS	xx (xx.xx)
NCS	xx (xx.xx)
Glucose	
Normal	xx (xx.xx)
Abnormal	xx (xx.xx)
If Abnormal	
CS	xx (xx.xx)
NCS	xx (xx.xx)
Alkaline phosphatase	
Normal	xx (xx.xx)
Abnormal	xx (xx.xx)
If Abnormal	
CS	xx (xx.xx)
NCS	xx (xx.xx)
Lactate dehydrogenase	
Normal	xx (xx.xx)
Abnormal	xx (xx.xx)
If Abnormal	
CS	xx (xx.xx)
NCS	xx (xx.xx)
Alanine aminotransferase	
Normal	xx (xx.xx)
Abnormal	xx (xx.xx)
If Abnormal	
CS	xx (xx.xx)
NCS	xx (xx.xx)
Lipase	
Normal	xx (xx.xx)
Abnormal	xx (xx.xx)
If Abnormal	
CS	xx (xx.xx)
NCS	xx (xx.xx)
Aspartate amin-otransferase	
Normal	xx (xx.xx)
Abnormal	xx (xx.xx)
If Abnormal	
CS	xx (xx.xx)
NCS	xx (xx.xx)
Magnesium	

Normal	xx (xx.xx)
Abnormal	xx (xx.xx)
If Abnormal	
CS	xx (xx.xx)
NCS	xx (xx.xx)
Amylase	
Normal	xx (xx.xx)
Abnormal	xx (xx.xx)
If Abnormal	
CS	xx (xx.xx)
NCS	xx (xx.xx)
Potassium	
Normal	xx (xx.xx)
Abnormal	xx (xx.xx)
If Abnormal	
CS	xx (xx.xx)
NCS	xx (xx.xx)
Bicarbonate	
Normal	xx (xx.xx)
Abnormal	xx (xx.xx)
If Abnormal	
CS	xx (xx.xx)
NCS	xx (xx.xx)
Sodium	
Normal	xx (xx.xx)
Abnormal	xx (xx.xx)
If Abnormal	
CS	xx (xx.xx)
NCS	xx (xx.xx)
Calcium	
Normal	xx (xx.xx)
Abnormal	xx (xx.xx)
If Abnormal	
CS	xx (xx.xx)
NCS	xx (xx.xx)
Total bilirubin	
Normal	xx (xx.xx)
Abnormal	xx (xx.xx)
If Abnormal	
CS	xx (xx.xx)
NCS	xx (xx.xx)
Chloride	
Normal	xx (xx.xx)
Abnormal	xx (xx.xx)
If Abnormal	
CS	xx (xx.xx)
NCS	xx (xx.xx)
Total protein	
Normal	xx (xx.xx)
Abnormal	xx (xx.xx)
If Abnormal	
CS	xx (xx.xx)

NCS	xx (xx.xx)
Creatinine Clearance	
Normal	xx (xx.xx)
Abnormal	xx (xx.xx)
If Abnormal	
CS	xx (xx.xx)
NCS	xx (xx.xx)
Urea / Blood Urea/ Nitrogen	
Normal	xx (xx.xx)
Abnormal	xx (xx.xx)
If Abnormal	
CS	xx (xx.xx)
NCS	xx (xx.xx)
Gamma glutamyl transferase	
Normal	xx (xx.xx)
Abnormal	xx (xx.xx)
If Abnormal	
CS	xx (xx.xx)
NCS	xx (xx.xx)
Uric acid	
Normal	xx (xx.xx)
Abnormal	xx (xx.xx)
If Abnormal	
CS	xx (xx.xx)
NCS	xx (xx.xx)

- The Capital "N" in the column header represents the total number Safety Analysis Set.
- The small "n" represents the total number of patients in the row category.
- All Percentages rows are based on number of Safety Analysis Set.
- NCS=Abnormal Not Clinically Significant and CS= Abnormal Clinically Significant
- Programmer Note: Visit x – Visit 2 up to Visit 12.
- Source: Listing 16.3.6

Table 14.3.4.3 Summary of Urine Routine and Microscopy (Safety Analysis Set)

	N = xx n (%)
Visit x	
Sample Collected	
Yes	xx (xx.xx)
No	xx (xx.xx)
Missing	xx (xx.xx)
Specific gravity	
Normal	xx (xx.xx)
Abnormal	xx (xx.xx)
If Abnormal	
CS	xx (xx.xx)
NCS	xx (xx.xx)
pH	
Normal	xx (xx.xx)
Abnormal	xx (xx.xx)
If Abnormal	
CS	xx (xx.xx)
NCS	xx (xx.xx)
Glucose	
Normal	xx (xx.xx)
Abnormal	xx (xx.xx)
If Abnormal	
CS	xx (xx.xx)
NCS	xx (xx.xx)
Ketones	
Normal	xx (xx.xx)
Abnormal	xx (xx.xx)
If Abnormal	
CS	xx (xx.xx)
NCS	xx (xx.xx)
Bilirubin	
Normal	xx (xx.xx)
Abnormal	xx (xx.xx)
If Abnormal	
CS	xx (xx.xx)
NCS	xx (xx.xx)
Urobilinogen	
Normal	xx (xx.xx)
Abnormal	xx (xx.xx)
If Abnormal	
CS	xx (xx.xx)
NCS	xx (xx.xx)
RBC	
Normal	xx (xx.xx)
Abnormal	xx (xx.xx)
If Abnormal	
CS	xx (xx.xx)
NCS	xx (xx.xx)
Dysmorphic Red Blood Cells	

Normal	xx (xx.xx)
Abnormal	xx (xx.xx)
If Abnormal	
CS	xx (xx.xx)
NCS	xx (xx.xx)
Pus Cells	
Normal	xx (xx.xx)
Abnormal	xx (xx.xx)
If Abnormal	
CS	xx (xx.xx)
NCS	xx (xx.xx)
Crystals	
Normal	xx (xx.xx)
Abnormal	xx (xx.xx)
If Abnormal	
CS	xx (xx.xx)
NCS	xx (xx.xx)
Casts	
Normal	xx (xx.xx)
Abnormal	xx (xx.xx)
If Abnormal	
CS	xx (xx.xx)
NCS	xx (xx.xx)
Epithelial Cells	
Normal	xx (xx.xx)
Abnormal	xx (xx.xx)
If Abnormal	
CS	xx (xx.xx)
NCS	xx (xx.xx)
Protein	
Normal	xx (xx.xx)
Abnormal	xx (xx.xx)
If Abnormal	
CS	xx (xx.xx)
NCS	xx (xx.xx)

- The Capital "N" in the column header represents the total number Safety Analysis Set.
- The small "n" represents the total number of patients in the row category.
- All Percentages rows are based on number of Safety Analysis Set.
- NCS=Abnormal Not Clinically Significant and CS= Abnormal Clinically Significant
- Programmer Note: Visit x – Visit 2 up to Visit 12.
- Source: Listing 16.3.7

Table 14.3.4.4 Summary of Thyroid function test (Safety Analysis Set)

	N = xx n (%)
Visit x	
Sample Collected	
Yes	xx (xx.xx)
No	xx (xx.xx)
Missing	xx (xx.xx)
TSH	
Normal	xx (xx.xx)
Abnormal	xx (xx.xx)
If Abnormal	
CS	xx (xx.xx)
NCS	xx (xx.xx)
Tri iodothyronine	
Not applicable	xx (xx.xx)
Normal	xx (xx.xx)
Abnormal	xx (xx.xx)
If Abnormal	
CS	xx (xx.xx)
NCS	xx (xx.xx)
Tetra iodothyronine	
Not Applicable	xx (xx.xx)
Normal	xx (xx.xx)
Abnormal	
If Abnormal	
CS	xx (xx.xx)
NCS	xx (xx.xx)

- The Capital "N" in the column header represents the total number Safety Analysis Set.
- The small "n" represents the total number of patients in the row category.
- All Percentages rows are based on number of Safety Analysis Set.
- NCS=Abnormal Not Clinically Significant and CS= Abnormal Clinically Significant
- Programmer Note: Visit x – Visit 2, Visit 6, Visit 10 and Visit 12.
- Source: Listing 16.3.8

Table 14.3.5 Summary of Urine Pregnancy Test (Safety Analysis Set - Female)

Visit		Durvalumab N* = xx n (%)
Visit 1	**Numbe of patients' urine pregnancy test performed**	
	Yes	xx (xx.xx)
	No	xx (xx.xx)
	NA	xx (xx.xx)
	Result	

	Positive	xx (xx.xx)
	Negative	xx (xx.xx)
Visit 2	**Numbe of patients' urine pregnancy test performed**	
	Yes	xx (xx.xx)
	No	xx (xx.xx)
	NA	xx (xx.xx)
	Result	
	Positive	xx (xx.xx)
	Negative	xx (xx.xx)

- The Capital "N" in the column header represents the total number Enrolled Analysis Set.
- The small "n" represents the total number of patients in the row category.
- Percentages in the "Urine pregnancy test performed" rows are based on number of Enrolled Analysis Set.
- Percentages in the "Result" rows are based on number of patient urine pregnancy test performed.
- Source: Listing 16.1.7

Listings

Listing 16.1.1.1. Listing of Patient Informed Consent Details

Unique Patient ID	Informed Consent taken	Date and Time for Informed Consent	Subject vulnerable	Audio-visual consent taken
Xxxxxx	Yes/No	DD-MMM-YYYY/HH:MM	Yes/No	Yes/No
Xxxxxx	Yes/No	DD-MMM-YYYY/HH:MM	Yes/No	Yes/No
Xxxxxx	Yes/No	DD-MMM-YYYY/HH:MM	Yes/No	Yes/No
Xxxxxx	Yes/No	DD-MMM-YYYY/HH:MM	Yes/No	Yes/No
Xxxxxx	Yes/No	DD-MMM-YYYY/HH:MM	Yes/No	Yes/No

Listing 16.1.1.2 Listing of Patient Eligibility Criteria and Analysis Population Set

Unique Patient ID	Patients meet all Eligibility Criteria	Subject Enrolled into the Study	Enrolled Analysis Set	Safety Analysis Set
Xxxxxx	Yes/No	Yes/No	Yes/No	Yes/No
Xxxxxx	Yes/No	Yes/No	Yes/No	Yes/No
Xxxxxx	Yes/No	Yes/No	Yes/No	Yes/No
Xxxxxx	Yes/No	Yes/No	Yes/No	Yes/No
Xxxxxx	Yes/No	Yes/No	Yes/No	Yes/No

Listing 16.1.1.3 Listing of Patient Study Completion / Discontinuation

Unique Patient ID	Patient completed the study	Date of study completion/discontinuation	Primary reason of Discontinuation
xxxxxx	Yes/No	DD-MMM-YYYY	xxxx
xxxxxx	Yes/No	DD-MMM-YYYY	xxxx
xxxxxx	Yes/No	DD-MMM-YYYY	xxxx
xxxxxx	Yes/No	DD-MMM-YYYY	Other: xxxxx
xxxxxx	Yes/No	DD-MMM-YYYY	xxxx

Listing 16.1.1.4 Listing of Patient Protocol Deviation

Unique Patient ID	Patient undergone any Protocol Deviation	Sr. no	Deviation	Date of study Deviation	Description	Deviation Code	Action taken
xxxxxx	Yes/No	Xx	xxxx	DD-MMM-YYYY	xxxx	Xx	Xx
xxxxxx	Yes/No	Xx	xxxx	DD-MMM-YYYY	xxxx	Xx	Xx
xxxxxx	Yes/No	Xx	xxxx	DD-MMM-YYYY	xxxx	Xx	Xx
xxxxxx	Yes/No	Xx	xxxx	DD-MMM-YYYY	xxxx	Xx	Xx
xxxxxx	Yes/No	Xx	xxxx	DD-MMM-YYYY	xxxx	Xx	Xx

Listing 16.1.2 Listing of Patient Demographics Data

Unique Patient ID	Age / Gender	Date of Birth	Weight (kg)	Height (cm)	Race	If Other
xxxxxx	xx/xxx	DD-MMM-YYYY	xxx	xxx	Indian/Other	xxxx
xxxxxx	xx/xxx	DD-MMM-YYYY	xxx	xxx	Indian/Other	xxxx
xxxxxx	xx/xxx	DD-MMM-YYYY	xxx	xxx	Indian/Other	xxxx
xxxxxx	xx/xxx	DD-MMM-YYYY	xxx	xxx	Indian/Other	xxxx
xxxxxx	xx/xxx	DD-MMM-YYYY	xxx	xxx	Indian/Other	xxxx

Listing 16.1.3 Listing of Patient Medical / Surgical History

Unique Patient ID	MH. No	Medical/ Surgical history	Type of Condition	System Organ Class	Preferred Term	Start date	Stop date	Treatment Required	Ongoing
xxxxxx	xxx	xxx	xxx	xxx	xxx	DD-MMM-YYYY	DD-MMM-YYYY	Yes/No	xxx
xxxxxx	xxx	xxx	xxx	xxx	xxx	DD-MMM-YYYY	DD-MMM-YYYY	Yes/No	xxx
xxxxxx	xxx	xxx	xxx	xxx	xxx	DD-MMM-YYYY	DD-MMM-YYYY	Yes/No	xxx
xxxxxx	xxx	xxx	xxx	xxx	xxx	DD-MMM-YYYY	DD-MMM-YYYY	Yes/No	xxx
xxxxxx	xxx	xxx	xxx	xxx	xxx	DD-MMM-YYYY	DD-MMM-YYYY	Yes/No	xxx

Patients with at least one medical/ Surgical History have been listed.

Listing 16.1.4.1 Listing of Patient IP Administration I

Unique Patient ID	Visit	Date and Time of Infusion of IP	Days of completion of CRT durvalumab Started	Total Dose (mg/mL)	Stop Time of Infusion of IP
xxxxxx	xxx	DD-MMM-YYYY/HH:MM	xxx	xxx	xxx
xxxxxx	xxx	DD-MMM-YYYY/HH:MM	xxx	xxx	xxx
xxxxxx	xxx	DD-MMM-YYYY/HH:MM	xxx	xxx	xxx
xxxxxx	xxx	DD-MMM-YYYY/HH:MM	xxx	xxx	xxx
xxxxxx	xxx	DD-MMM-YYYY/HH:MM	xxx	xxx	xxx

Listing 16.1.4.2 Listing of Patient IP Administration II

Unique Patient ID	Visit	Dose interrupted during infusion	If yes	Interruption time	Dose Restated	If No	If Yes, Provide the restart time
xxxxxx	xxx	Yes/No	xxx	DD-MMM-YYYY	Yes/No	xxx	xxx
xxxxxx	xxx	Yes/No	xxx	DD-MMM-YYYY	Yes/No	xxx	xxx
xxxxxx	xxx	Yes/No	xxx	DD-MMM-YYYY	Yes/No	xxx	xxx
xxxxxx	xxx	Yes/No	xxx	DD-MMM-YYYY	Yes/No	xxx	xxx
xxxxxx	xxx	Yes/No	xxx	DD-MMM-YYYY	Yes/No	xxx	xxx

Listing 16.1.4.3. Listing of Patient Study Drug Administration Accountability

Unique Patient ID	Dose reduced in any of the visit	If yes	If Yes, Visit number	Dose Competed	If No	No. of IV Dose has to administered during treatment period	No. of IV Dose has to administered in the treatment period	Unused IP returned	Compliance (%)
xxxxxx	Yes/No	xxx	xxx	Yes/No	xxx	xxx	xxx	Yes/No	xxx
xxxxxx	Yes/No	xxx	xxx	Yes/No	xxx	xxx	xxx	Yes/No	xxx
xxxxxx	Yes/No	xxx	xxx	Yes/No	xxx	xxx	xxx	Yes/No	xxx
xxxxxx	Yes/No	xxx	xxx	Yes/No	xxx	xxx	xxx	Yes/No	xxx
xxxxxx	Yes/No	xxx	xxx	Yes/No	xxx	xxx	xxx	Yes/No	xxx

Listing 16.1.5 Listing of Patient Disease characteristics Assessment

Unique Patient ID	Visit	Disease Staging	Disease progressed since last visit
xxxxxx	xxx	xxx	Yes/No
xxxxxx	xxx	xxx	Yes/No
xxxxxx	xxx	xxx	Yes/No
xxxxxx	xxx	xxx	Yes/No
xxxxxx	xxx	xxx	Yes/No

Listing 16.1.6.1 Listing of Patient Alcohol consumption and drug abuse

Unique Patient ID	Patient have any significant history of alcoholism or drug abuse	If Yes, Alcohol	Quit date	If Yes, Drug abuse	Quit date
xxxxxx	Yes/No	xxx	DD-MMM-YYYY	xxx	DD-MMM-YYYY
xxxxxx	Yes/No	xxx	DD-MMM-YYYY	xxx	DD-MMM-YYYY
xxxxxx	Yes/No	xxx	DD-MMM-YYYY	xxx	DD-MMM-YYYY
xxxxxx	Yes/No	xxx	DD-MMM-YYYY	xxx	DD-MMM-YYYY
xxxxxx	Yes/No	xxx	DD-MMM-YYYY	xxx	DD-MMM-YYYY

Listing 16.1.6.2 Listing of Patient History of Tobacco

Unique Patient ID	Smoking History
xxxxxx	xxx
xxxxxx	xxx
xxxxxx	xxx
xxxxxx	xxx
xxxxxx	xxx

Listing 16.1.7 Listing of Patient Urine Pregnancy Test

Unique Patient ID	Visit	Urine pregnancy test performed	Date and Time of Assessment	Result
xxxxxx	Visit 1	Yes/No/NA	DD-MMM-YYYY	Positive/Negative
	Visit 2	Yes/No/NA	DD-MMM-YYYY	Positive/Negative
	-----	Yes/No/NA	DD-MMM-YYYY	Positive/Negative
xxxxxx	Visit 1	Yes/No/NA	DD-MMM-YYYY	Positive/Negative
	----	Yes/No/NA	DD-MMM-YYYY	Positive/Negative

Listing 16.1.8 Listing of Patient Prior/Concomitant Medications

Unique Patient ID	Medication Name (Generic)	ATC Drug Class	Standard Name	Start Date -End Date/Ongoing	Indication	Dosage Form	Dose (unit)	Route	Frequency
xxxxxx	xxxx	xxxx	xxxx	DDMMYYYY-DDMMYYYY	xxx	xx	xx (xx)	xxxx	xx
xxxxxx	Xxx xxx	xxxxx	xxxxx	DDMMYYYY-Ongoing	xxx	xxxx	xx (xx)	xxxx	xxxx
xxxxxx	Xxx xxxx	xxxx	xxxx	DDMMYYYY-DDMMYYYY	xx	xxx	xx (xx)	xxxx	xxx
xxxxxx	Xxxxx xxxxx	xxxx	xxxxx	DDMMYYYY-DDMMYYYY	xx	xxx	xx (xx)	xxxx	xx
xxxxxx	xxxxxxxxxx	xxxx	xxxx	DDMMYYYY-Ongoing	xx	xxx	xx (xx)	xxxx	xxx

Listing 16.1.9.1 Listing of Patient Radiation Treatment

Unique Patient ID	Clinical Stage of NSCLC	Pathological Staging of NSCLC done	Pathological Staging of NSCLC	Histology of Tumor	Technique of Radiation	Dose of Radiation	Chemotherapy given	If Yes	No. Of Cycles
xxxxxx	xxx	Yes/No	xxx	xxx	xxx	xxx	Yes/No	xxx	xxx
xxxxxx	xxx	Yes/No	xxx	xxx	xxx	xxx	Yes/No	xxx	xxx
xxxxxx	xxx	Yes/No	xxx	xxx	xxx	xxx	Yes/No	xxx	xxx
xxxxxx	xxx	Yes/No	xxx	xxx	xxx	xxx	Yes/No	xxx	xxx
xxxxxx	xxx	Yes/No	xxx	Xxx	Xxx	Xxx	Yes/No	Xxx	Xxx

Listing 16.1.9.2 Listing of Patient Radiation Treatment

Unique Patient ID	Type of Chemotherapy	Chemo regime	No. of Cycles	Days of CRT	Performance status at time of initiation of CRT
xxxxxx	xxx	xxx	xxx	xxx	xxx
xxxxxx	xxx	xxx	xxx	xxx	xxx
xxxxxx	xxx	xxx	xxx	xxx	xxx
xxxxxx	xxx	xxx	xxx	xxx	xxx
xxxxxx	xxx	xxx	xxx	xxx	xxx

Listing 16.1.10 Listing of Patient WHO Performance status

Unique Patient ID	Visit	Type	WHO Performance Grade	If there any changes in performance grade since last visit
xxxxxx	xxx	xxx	xxx	Yes/No
xxxxxx	xxx	xxx	xxx	Yes/No
xxxxxx	xxx	xxx	xxx	Yes/No
xxxxxx	xxx	xxx	xxx	Yes/No
xxxxxx	xxx	xxx	xxx	Yes/No

Listing 16.3.1.1 Listing of Patient Adverse Event

Unique Patient ID	Visit	Patient have any Adverse Event since screening visit	Patient have any Adverse Event since last visit
xxxxxx	xxx	Yes/No	Yes/No
xxxxxx	xxx	Yes/No	Yes/No
xxxxxx	xxx	Yes/No	Yes/No
xxxxxx	xxx	Yes/No	Yes/No
xxxxxx	xxx	Yes/No	Yes/No

Listing 16.3.1.2 Listing of Patient Adverse Event

Unique Patient ID	Adverse Event	AE No.	Adverse Event Term	System organ class	Preferred Term	Start Date and time	Stop Date and time	Severity as per CTCAE grade	Action taken
xxxxxx	Yes/No	xxx	xxx	xxx	xxx	DD-MMM-YYYY/HH:MM	DD-MMM-YYYY/HH:MM	xx	xxx
xxxxxx	Yes/No	xxx	xxx	xxx	xxx	DD-MMM-YYYY/HH:MM	DD-MMM-YYYY/HH:MM	Xx	xxx
xxxxxx	Yes/No	xxx	xxx	xxx	xxx	DD-MMM-YYYY/HH:MM	DD-MMM-YYYY/HH:MM	xx	xxx
xxxxxx	Yes/No	xxx	xxx	xxx	xxx	DD-MMM-YYYY/HH:MM	DD-MMM-YYYY/HH:MM	xx	xxx
xxxxxx	Yes/No	xxx	xxx	xxx	xxx	DD-MMM-YYYY/HH:MM	DD-MMM-YYYY/HH:MM	xx	xxx

Listing 16.3.1.3 Listing of Patient Adverse Event

Unique Patient ID	Adverse Event	AE No.	Adverse Event Term	Treatment given	Relationship with study Drug	Outcome	Serious AE	Therapy Discontinued
xxxxxx	Yes/No	xxx	xxx	Yes/No	xxx	xxx	Yes/No	Yes/No
xxxxxx	Yes/No	xxx	xxx	Yes/No	xxx	xxx	Yes/No	Yes/No
xxxxxx	Yes/No	xxx	xxx	Yes/No	xxx	xxx	Yes/No	Yes/No
xxxxxx	Yes/No	xxx	xxx	Yes/No	xxx	xxx	Yes/No	Yes/No
xxxxxx	Yes/No	xxx	xxx	Yes/No	xxx	xxx	Yes/No	Yes/No

Listing 16.3.2 Listing of Patient Physical Examination

Unique Patient ID	Visit	Examination done	Date and Time of Assessment	Physical Examination	Result	If Abnormal
xxxxxx	xxx	Yes/No	DD-MMM-YYYY/HH:MM	xxx	Normal/Abnormal	CS/NCS
xxxxxx	xxx	Yes/No	DD-MMM-YYYY/HH:MM	xxx	Normal/Abnormal	CS/NCS
xxxxxx	xxx	Yes/No	DD-MMM-YYYY/HH:MM	xxx	Normal/Abnormal	CS/NCS
xxxxxx	xxx	Yes/No	DD-MMM-YYYY/HH:MM	xxx	Normal/Abnormal	CS/NCS
xxxxxx	xxx	Yes/No	DD-MMM-YYYY/HH:MM	xxx	Normal/Abnormal	CS/NCS

Listing 16.3.3 Listing of Patient Vital Signs

Unique Patient ID	Visit	Examination Done	Date and Time of Assessment	Parameter	Result	Assessment Result	If Abnormal
xxxxxx	xxx	Yes/No	DD-MMM-YYYY/HH:MM	xxx	xxx	Normal/Abnormal	xxx
xxxxxx	xxx	Yes/No	DD-MMM-YYYY/HH:MM	xxx	xxx	Normal/Abnormal	xxx
xxxxxx	xxx	Yes/No	DD-MMM-YYYY/HH:MM	xxx	xxx	Normal/Abnormal	xxx
xxxxxx	xxx	Yes/No	DD-MMM-YYYY/HH:MM	xxx	xxx	Normal/Abnormal	xxx
xxxxxx	xxx	Yes/No	DD-MMM-YYYY/HH:MM	xxx	xxx	Normal/Abnormal	xxx

Listing 16.3.4 Listing of Patient 12-Lead electrocardiogram

Unique Patient ID	Visit	Assessment Done	Date and Time of ECG assessment	Parameter	Result	Unit	Interpretation
xxxxxx	xxx	Yes/No	DD-MMM-YYYY/HH:MM	xxx	xxx	xxx	xxx
xxxxxx	xxx	Yes/No	DD-MMM-YYYY/HH:MM	xxx	xxx	xxx	xxx
xxxxxx	xxx	Yes/No	DD-MMM-YYYY/HH:MM	xxx	xxx	xxx	xxx
xxxxxx	xxx	Yes/No	DD-MMM-YYYY/HH:MM	xxx	xxx	xxx	xxx
xxxxxx	xxx	Yes/No	DD-MMM-YYYY/HH:MM	xxx	xxx	xxx	xxx

Listing 16.3.5.1 Listing of Patient Haematology Parameters

Unique Patient ID	Visit	Sample Collected	Date and Time of sample collection	Lab Parameter	Result	Unit	Interpretation
xxxxxx	xxx	Yes/No	DD-MMM-YYYY/HH:MM	xxx	xxx	xxx	xxx
xxxxxx	xxx	Yes/No	DD-MMM-YYYY/HH:MM	xxx	xxx	xxx	xxx
xxxxxx	xxx	Yes/No	DD-MMM-YYYY/HH:MM	xxx	xxx	xxx	xxx
xxxxxx	xxx	Yes/No	DD-MMM-YYYY/HH:MM	xxx	xxx	xxx	xxx
xxxxxx	xxx	Yes/No	DD-MMM-YYYY/HH:MM	xxx	xxx	xxx	xxx

Listing 16.3.5.2 Listing of Patient Serum Chemistry Parameters

Unique Patient ID	Visit	Sample Collected	Date and Time of sample collection	Lab Parameter	Result	Unit	Interpretation
xxxxxx	xxx	Yes/No	DD-MMM-YYYY/HH:MM	xxx	xxx	xxx	xxx
xxxxxx	xxx	Yes/No	DD-MMM-YYYY/HH:MM	xxx	xxx	xxx	xxx
xxxxxx	xxx	Yes/No	DD-MMM-YYYY/HH:MM	xxx	xxx	xxx	xxx
xxxxxx	xxx	Yes/No	DD-MMM-YYYY/HH:MM	xxx	xxx	xxx	xxx
xxxxxx	xxx	Yes/No	DD-MMM-YYYY/HH:MM	xxx	xxx	xxx	xxx

Listing 16.3.5.3 Listing of Patient Urine Routine and Microscopy Parameters

Unique Patient ID	Visit	Sample Collected	Date and Time of sample collection	Lab Parameter	Result	Unit	Interpretation
xxxxxx	xxx	Yes/No	DD-MMM-YYYY/HH:MM	xxx	xxx	xxx	xxx
xxxxxx	xxx	Yes/No	DD-MMM-YYYY/HH:MM	xxx	xxx	xxx	xxx
xxxxxx	xxx	Yes/No	DD-MMM-YYYY/HH:MM	xxx	xxx	xxx	xxx
xxxxxx	xxx	Yes/No	DD-MMM-YYYY/HH:MM	xxx	xxx	xxx	xxx
xxxxxx	xxx	Yes/No	DD-MMM-YYYY/HH:MM	xxx	xxx	xxx	xxx

Listing 16.3.5.4 Listing of Patient Thyroid Function Tests

Unique Patient ID	Visit	Sample Collected	Date and Time of sample collection	Lab Parameter	Result	Unit	Interpretation
xxxxxx	xxx	Yes/No	DD-MMM-YYYY/HH:MM	xxx	Xxx	xxx	xxx
xxxxxx	xxx	Yes/No	DD-MMM-YYYY/HH:MM	xxx	Xxx	xxx	xxx
xxxxxx	xxx	Yes/No	DD-MMM-YYYY/HH:MM	xxx	Xxx	xxx	xxx
xxxxxx	xxx	Yes/No	DD-MMM-YYYY/HH:MM	xxx	Xxx	xxx	xxx
xxxxxx	xxx	Yes/No	DD-MMM-YYYY/HH:MM	xxx	Xxx	xxx	xxx