Statistical Analysis Plan

Study Title

A prospective, multicenter, phase -IV study to assess the safety of fixed dose combination of dapagliflozin and saxagliptin in Indian Type 2 Diabetes Mellitus (T2D) patients

Protocol/ Study Number	:	D1683C00013
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Document Version	:	1.0
Document Date	:	29-Jun-2022
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Not Applicable

LIST OF ABBREVIATION

Abbreviation	Term
AE	Adverse Event
ALP	Alkaline phosphatase
AST	Aspartate aminotransferase
BMI	Body Mass Index
CABG/PTCA	coronary artery bypass grafting/percutaneous transluminal coronary angioplasty
CK	Creatine kinase
CRF	Case Report Form (electronic/paper)
DAE	Discontinuation of Investigational Product due to Adverse Event
DKA	Diabetic ketoacidosis
EC	Ethics Committee, synonymous to Institutional Review Board (IRB) and Independent Ethics Committee (IEC)
ECG	Electrocardiogram
eGFR	Estimated Glomerular Filtration Rate
ESRD	End Stage Renal Disease
FBG	Fasting Blood Glucose
FDC	Fixed Dose Combination
FPG	Fasting Plasma Glucose
GCP	Good Clinical Practice
Hb	Hemoglobin
HbA1c	Glycated haemoglobin
ICH	International Council on Harmonisation
International Coordinating investigator	If a study is conducted in several countries the International Coordinating Investigator is the Investigator coordinating the investigators and/or activities internationally
IP	Investigational Product
IVRS	Interactive Voice Response System
IWRS	Interactive Web Response System
LIMS	Laboratory Information Management System
LSLV	Last Subject Last Visit
NYHA	New York Heart Association
OAE	Other Significant Adverse Event
PI	Principal Investigator
PPG	Post prandial Glucose
SAE	Serious Adverse Event
SBP	Systolic Blood Pressure
SGLT	Sodium Glucose Co transporter
SU	Sulphonylurea
T2DM	Type 2 Diabetes Mellitus
TIA	Transient Ischemic Attack
UPT	Urine Pregnancy Test
UTI	Urinary Tract Infection

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 D1683C00013 study. This document is based on protocol V 3.0, 23 Sep 2020. The statistical planning and conduct of analysis of the data from this study will follow the principles defined in relevant International Council on Harmonisation (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 describe the adverse events profile of dapagliflozin + saxagliptin fixed dose combinations in Indian T2DM patients.

2.1.2 Secondary Objective

- To describe the efficacy of dapagliflozin + saxagliptin fixed dose combination in Indian T2DM patient

2.2 Study Description

2.2.1 Study Design

This is a prospective, multicenter, phase -IV study to assess the safety of fixed dose combination of dapagliflozin and saxagliptin in Indian Type 2 Diabetes Mellitus (T2D) patients.

Informed consent will be obtained from all the screened Patients prior to enrollment in the study. This study will include patients with T2DM.

This study is planned as prospective, multicentre, Phase-IV study on 200 patients in single arm open label study. CCI

[redacted]

This is a 24-week open label prospective study. After eligibility check as per inclusion and exclusion criteria, patients will be recruited in the study and procedures as mentioned in below Section 2.2.5 will be performed at various scheduled visits.

2.2.2 Inclusion Criteria

For inclusion in the study subjects should fulfil the following criteria:

1. Provision of signed and dated, written informed consent prior to any study specific procedures according to local Indian procedure.

2. Male and female patients aged > 18 and above
3. Documented history of type 2 diabetes mellitus with HbA1c level >7.0% and ≤ 10% at screening visit
4. Patients who are on a stable dose of antidiabetic drugs (including on Metformin dose between 1000-2000mg) in the past 3 months
5. Female subjects must be 1 year post-menopausal, surgically sterile, or using an acceptable method of contraception (an acceptable method of contraception is defined as a barrier method in conjunction with a spermicide) for the duration of the study (from the time they sign consent) to prevent pregnancy. In addition, oral contraceptives, approved contraceptive implant, long-term injectable contraception, intrauterine device, or tubal ligation are allowed. Oral contraception alone is not acceptable; additional barrier methods in conjunction with spermicide must be used.

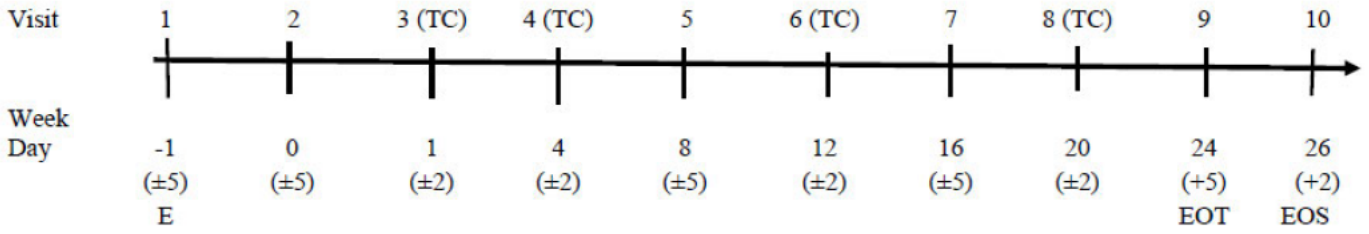
2.2.3 Exclusion Criteria

1. Known allergies or contraindication to the contents of the IP, dapagliflozin or saxagliptin tablets.
2. Active participation in another clinical study with IP and/or investigational device
3. For women only - currently pregnant (confirmed with positive pregnancy test) or breastfeeding.
4. Type 1 diabetes mellitus.
5. Treatment with a SGLT2 inhibitor, GLP-1 agonist or DPP4 inhibitors at Visit 1 or 2
6. Patients with moderate to severe renal impairment (eGFR persistently <45 mL/min/1.73m^2 by CKD-EPI formula, or end-stage renal disease (ESRD) or 'Unstable or rapidly progressing renal disease
7. Patients with severe hepatic impairment (Child-Pugh class C)
8. History of pancreatitis or pancreatic surgery
9. Patients with a history of any malignancy
10. Patients with any of the following CV/Vascular Diseases within 3 months prior to signing the consent at enrolment, as assessed by the investigator:
    - Myocardial infarction.
    - Cardiac surgery or revascularization (CABG/PTCA).
    - Unstable angina.
    - Transient ischemic attack (TIA) or significant cerebrovascular disease.
    - Unstable or previously undiagnosed arrhythmia.
11. History of heart failure
12. Severe uncontrolled hypertension defined as systolic blood pressure ≥180 mm Hg and/or diastolic blood pressure ≥110 mm Hg at any visit up to randomisation

13. History of diabetic ketoacidosis
14. Any acute/chronic systemic infections
15. Recurrent urogenital infections
16. Patients at risk for volume depletion as judged by the investigator
17. Any condition which, in the judgment of the Investigator, may render the patient unable to complete the study or which may pose a significant risk to the patient or patient suspected or with confirmed poor protocol or medication compliance

2.2.4 Study Flow chart

Dapagliflozin 10|mg and Saxagliptin 5 mg Fixed Dose Combination



E = Enrollment, TC=Telephone Contact, EOT: End Of Treatment, EoS= End of Study

2.2.5 Study Plan

Assessments	Visit 1 Enrolment* (-1 wk)	Visit2 (0wk)	Visit 3# (1wk)	Visit 4# (4wk)	Visit 5# (8wk)	Visit 6# (12wk)	Visit 7# (16wk)	Visit 8# (20wk)	Visit 9# (24wk)	Visit10# (26wk)
Window period (Days)	(±5)	(±5)	(±2)	(±2)	(±5)	(±2)	(±5)	(±2)	(±5)	(±2)
Informed Consent	X									
Physical Exam	X	X			X		X		X	X
Vital Signs	X	X			X		X		X	X
Eligibility Check	X	X								
HbA1c	X	X			X		X		X	X
Fasting Plasma Glucose (FPG)***		X			X		X		X	X
Weight & Height		X			X		X		X	X
Waist Circumference		X			X		X		X	X

BMI (Body Mass Index)		X			X		X		X	X
Blood Pressure		X			X		X		X	X
Safety labs	X	X			X		X		X	X
ECG		X					X		X	X
AE Assessment		X	X	X	X	X	X	X	X	X
Urinalysis	X	X			X		X		X	X
UPT (WOCBP)	X	X			X		X		X	X
IP dispensation		X			X					
IP accountability		X	X	X	X	X	X		X	X

*Enrolment and Visit 2 can coincide to enter patient into the study, #telephonic visit

** Subjects must be in a fasting state at least 8 hours prior to study visit.

2.3 Randomization

Not Applicable

2.4 Blinding and Un-Blinding

Not Applicable

2.5 Interim Analysis

Not Applicable

3. Population Analysis Set

3.1 Safety population

The safety analysis population will include all patients who sign the ICF and receive at least one dose of study medication.

The safety analysis population is also applicable to the efficacy analysis, and any efficacy measurements collected before the study medication discontinuation will be included. Last on treatment observation will be carried forward to impute the missing data at week 24.

4. Sample Size and Power Calculations

This is an India regulatory requirement study. Objective is to establish that FDC of Dapagliflozin 10mg / Saxagliptin 5 mg is a safe treatment option in Indian T2DM patients. This study is planned as prospective study on 200 patients in single arm open label study. CCI [redacted]

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 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.

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 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 Population who consented to participate in the study. The following summaries will be included in the disposition table: total number of Patients screened in the study, number of Patients who failed screening, number of Patient enrolled, 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 End Treatment

Patient End Treatment table will be based on all Safety Population. The following summaries will be included in the End Treatment table: total number and percentage of Patient who Completed the Treatment and number and percentage of Patient who discontinued from the Treatment with Most appropriate reason for withdrawal/discontinuation of study

5.5 Demographic Characteristics

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

Descriptive summaries will be provided for the demographic and baseline characteristics. Demographic characteristics and baseline characteristics such as age, Gender and Race, etc. will be summarized and tabulated for Safety Population.

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 counts and percentages.

6. Study Analysis Strategy

6.1 Study Endpoints

6.1.1 Primary Endpoint

- Adverse Events (AEs) including Serious adverse events (SAEs), AEs leading to discontinuation (DAE) and adverse events of special interest (volume depletion, renal events, major hypoglycaemic events, fractures, urinary/genital tract infections, diabetic ketoacidosis, amputations and hospitalization for heart failure)
- Safety laboratory values
- Electrocardiogram (ECG)
- Vital Signs (pulse and BP)
- Physical examination

6.1.2 Secondary Endpoint

- HbA1c change at week 24 compared to baseline
- Weight change at week 24 compared to baseline
- Systolic Blood Pressure (SBP) change at week 24 compared to baseline
- FPG change at week 24 compared to baseline

6.2 Study Hypothesis

Not Applicable

6.3 Statstical Methods for Study Analsysis

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 Population.

Primary Endpoint evaluations will include adverse event monitoring, Safety Laboratory parameter, Electrocardiogram, VitalSigns and physical examinations.

Adverse Events (AEs) including Serious adverse events (SAEs), AEs leading to discontinuation (DAE) and adverse events of special interest (volume depletion, renal events, major hypoglycaemic events, fractures, urinary/genital tract

infections, diabetic ketoacidosis, amputations and hospitalization for heart failure) will be summarized using Frequency and percentages.

Safety laboratory Parameter data will be collected as per visit schedule. Observed values will be summarized descriptively (n, mean, median, standard deviation, minimum, and maximum values). A listing will be provided which contains data for each laboratory parameter.

Electrocardiogram parameters data will be collected as per visit schedule. Observed values will be summarized descriptively (n, mean, median, standard deviation, minimum, and maximum values). A listing will be provided which contains data for each Electrocardiogram parameter.

Vital Signs will be summarized based on the Safety population. Descriptive summaries will be provided for the Vital Signs. All the 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.

Physical Examination will be summarized based on the Safety populations. Descriptive summaries will be provided for the Physical Examination. All the categorical variables will be summarized as frequency and percentages.

6.3.2 Secondary Endpoint Analysis

The Secondary analysis for Secodary endpoints will be based on Safety Population.

The safety analysis population is also applicable to the Secondary Endpoint analysis, and any Secondary Endpoint efficacy measurements collected before the study medication discontinuation will be included. Last on treatment observation will be carried forward to impute the missing data at week 24.

The Secondary endpoints (HbA1c, Weight, Blood Pressure and FPG) in this study is to evaluate the change from baseline to Post-baseline will be analysed using Paired t – test / Wilcoxon signed-rank test at 5% level of significance.

Change from baseline will be determined as:

Change from Baseline = (Post-baseline – Baseline)

Percent Change Change from Baseline = ([Post-baseline – Baseline] / Baseline) X 100

7. References

1. ICH E3 Guideline_International Council for Harmonisation
2. ICH E9; STATISTICAL PRINCIPLES FOR CLINICAL TRIALS

8. Mock Tables

Table 14.1.1.1. Patient Disposition in the Study (Enrolled Population)

	N = xx
	n (%)
Patients Screened	xx
Screen Failures	xx
Patient Enrolled	xx
Patients Completed the study	xx (xx.xx)
Patients Discontinued the study	xx (xx.xx)
Reason for Discontinuation	
Withdrawal of Informed Consent	xx (xx.xx)
Discontinuation of the study	xx (xx.xx)
Other	xx (xx.xx)
Other 1	xx (xx.xx)
Other 2	xx (xx.xx)

- The Capital "N" in the column header represents the total number of Enrolled Population.
- The small "n" in summary statistics represents the total number of Patients.
- Percentages in the "Patient completed the study" and "Patients Discontinued the study" rows are based on the total number of Enrolled Patients.
- Percentages in the "Reasons for Discontinuation" rows are based on the number of Patients Discontinued study.
- Note: Screened Patients are those who signed the informed consent
- Source :Listing 16.2.1.1 and Listing 16.2.1.3

Table 14.1.1.2. Summary of End Treatment (Safety Population)

	N = xx
	n (%)
Treatment with study drug discontinued prematurely	
Yes	xx (xx.xx)
No	xx (xx.xx)
Reason for withdrawal/discontinuation of Study	
Voluntary discontinuation by the subject	xx (xx.xx)
Risk to subjects	xx (xx.xx)
Severe non-compliance to protocol	xx (xx.xx)
Incorrectly enrolled subjects	xx (xx.xx)
Adverse Event	xx (xx.xx)
Major and/or frequent hypoglycemic events	xx (xx.xx)
Diabetic Ketoacidosis	xx (xx.xx)
Acute renal insufficiency or worsened chronic renal insufficiency	xx (xx.xx)
Pregnancy	xx (xx.xx)
Lost to follow up	xx (xx.xx)

- The Capital "N" in the column header represents the total number of Safety Population.
- The small "n" in summary statistics represents the total number of Patients.
- Percentages in the “Treatment with study drug discontinued prematurely” rows are based on the total number of Safety Patients.
- Percentages in the “Reasons for Withdrwal/Discontinuation of Treatment” rows are based on the number of Patients Treatment with study drug discontinued prematurely.
- Source :Listing 16.2.1.2

Table 14.1.1.3. Summary of Analysis Population (Enrolled Population)

	N = xx
	n (%)
Safety Population	xx (xx.xx)

- The Capital "N" in the column header represents the total number of Enrolled Population.
- The small "n" in summary statistics represents the total number of Patients.
- Percentages in the “Safety Population” row is based on the total number of Enrolled Population.
- Safety Population : The Safety Population include all Patient who sign the ICF and receive at least one dose of study medication.

Table 14.1.2.1. Summary of Demographic Characteristics (Enrolled Population)

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	
Male	xx (xx.xx)
Female	xx (xx.xx)
Missing	xx (xx.xx)
Race	
Asian	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 Enrolled Population.
- The small "n" in summary statistics represents the total number of Patients.
- Percentages are based on number of Enrolled Population.
- SD = Standard Deviation, min=minimum, max=maximum
- Source: Listing 16.2.2.1

Table 14.1.2.2. Summary of Anthropometric Assessment (Safety Population)

	N = xx
Visit x	
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)
Waist circumference (cm)	
n	xx
Missing	xx
Mean (SD)	xx.x (xx.xx)
Median	xx.x
(min, max)	(xx.xx, xx.xx)
Body Mass Index (Kg/m^2)	
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 Safety Population.
- The small "n" in summary statistics represents the total number of Patients.
- SD = Standard Deviation, min=minimum, max=maximum
- Programmer Note: Visit x: Visit 2, Visit 5, Visit 7, Visit 9 and Visit 10.
- Source: Listing 16.2.2.2

Table 14.1.3. Summary of Medical and Surgical History (Safety Population)

System Organ Class /Preferred Term	N = xx n (%)
Patient with any 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)
System Organ Class 4	xx (xx.xx)
Preferred Term 1	xx (xx.xx)
Preferred Term 2	xx (xx.xx)
System Organ Class 5	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 Safety Population.
- The small "n" in summary statistics represents the total number of Patients.
- Percentages in the “Patient with any medical/Surgical history” rows are based on number of Safety Popluation.
- Percentages in the “System Organ Class” and “Preferred Term” rows are based on number of Patient with any medical history.
- Medical histories were coded using MedDRA Ver24.1
- Source :Listing 16.2.3

Table 14.1.4. Summary of Urine Pregnancy Test (Safety Population)

	N = xx
	n (%)
Visit x	
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 of Safety Population.
- The small "n" in summary statistics represents the total number of Patients.
- Percentage in the “Urine pregnancy test performed” rows are based on the number of Safety Population.
- Percentage in the “Result” rows are based on the number of Patients with Urine Pregnancy test performed.
- SD = Standard Deviation, min=minimum, max=maximum
- Visit x: Visit 1, Visit 2, Visit 5, Visit 7, Visit 9, Visit 10
- Source :Listing 16.2.4.

Table 14.1.5. Summary of IP Medication Accountability (Safety Population)

	N=xx
Visit x	
No. of Dose missed in the treatment period	
N	xx
Missing	xx
Mean (SD)	xx.x (xx.xx)
Median	xx.x
(min, max)	(xx.xx, xx.xx)
No. of Tablets lost in the treatment period	
N	xx
Missing	xx
Mean (SD)	xx.x (xx.xx)
Median	xx.x
(min, max)	(xx.xx, xx.xx)
No. of Tablets returned	
N	xx
Missing	xx
Mean (SD)	xx.x (xx.xx)
Median	xx.x
(min, max)	(xx.xx, xx.xx)
No. of Tablets to be taken in the treatment period	
N	xx
Missing	xx
Mean (SD)	xx.x (xx.xx)
Median	xx.x
(min, max)	(xx.xx, xx.xx)
No. of Tablets consumed in the treatment period	
N	xx
Missing	xx
Mean (SD)	xx.x (xx.xx)
Median	xx.x
(min, max)	(xx.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 Safety Population.
- The small "n" in summary statistics represents the total number of Patients.
- SD = Standard Deviation, min=minimum, max=maximum.
- Visit x: Visit 5, Visit 7, Visit 9 and Visit 10.
- Source :Listing 16.2.5.1 and Listing 16.2.5.2

Table 14.2.1. Analysis of change in HbA1c from baseline to Week 24 (Safety Population)

	Observed value (N = xx)	Change from Baseline (N = xx)	% Change from Baseline (N = xx)
Baseline (Visit 2)			
N	xxx		
Missing	xx		
Mean (SD)	xx.x (xx.xx)		
Median	xx.x		
(min, max)	(xx.xx, xx.xx)		
Week 24			
N	Xx	Xx	xx
Missing	Xx	Xx	Xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x
(min, max)	(xx.xx, xx.xx)	(xx.xx, xx.xx)	(xx.xx, xx.xx)
p-value		x.xxx	x.xxx

- The Capital "N" in the column header represents the total number of Patients in Safety Population.
- The small "n" in summary statistics represents the total number of Patients.
- SD = Standard deviation, min=minimum, max=maximum
- Change from Baseline= Post-Baseline - Baseline
- % Change from Baseline = (Post-Baseline - Baseline / Baseline) X 100
- p-value calculate using Paired t – test / Wilcoxon signed-rank test.
- Source : Listing 16.2.6.1

Table 14.2.2. Analysis of change in Weight from baseline to Week 24. (Safety Population)

	Observed value (N = xx)	Change from Baseline (N = xx)	% Change from Baseline (N = xx)
Baseline (Visit 2)			
N	xx		
Missing	xx		
Mean (SD)	xx.x (xx.xx)		
Median	xx.x		
(min, max)	(xx.xx, xx.xx)		
Week 24			
N	Xx	Xx	xx
Missing	Xx	Xx	Xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x
(min, max)	(xx.xx, xx.xx)	(xx.xx, xx.xx)	(xx.xx, xx.xx)
p-value		x.xxx	x.xxx

- The Capital "N" in the column header represents the total number of Patients in Safety Population.
- The small "n" in summary statistics represents the total number of Patients.
- SD = Standard deviation, min=minimum, max=maximum
- Change from Baseline= Post-Baseline - Baseline
- % Change from Baseline = (Post-Baseline - Baseline / Baseline) X 100
- p-value calculate using Paired t – test / Wilcoxon signed-rank test.
- Source : Listing 16.2.2.2

Table 14.2.3. Analysis of change in Blood Pressure from baseline to Week 24. (Safety Population)

	Observed value (N = xx)	Change from Baseline (N = xx)	% Change from Baseline (N = xx)
Systolic Blood Pressure			
Baseline (Visit 2)			
N	xx		
Missing	xx		
Mean (SD)	xx.x (xx.xx)		
Median	xx.x		
(min, max)	(xx.xx, xx.xx)		
Week 24			
N	xx	xx	xx
Missing	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x
(min, max)	(xx.xx, xx.xx)	(xx.xx, xx.xx)	(xx.xx, xx.xx)
p-value		x.xxx	x.xxx
Diastolic Blood Pressure			
Baseline (Visit 2)			
N	xx		
Missing	xx		
Mean (SD)	xx.x (xx.xx)		
Median	xx.x		
(min, max)	(xx.xx, xx.xx)		
Week 24			
N	xx	xx	xx
Missing	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x
(min, max)	(xx.xx, xx.xx)	(xx.xx, xx.xx)	(xx.xx, xx.xx)
p-value		x.xxx	x.xxx

- The Capital "N" in the column header represents the total number of Patients in Safety Population.
- The small "n" in summary statistics represents the total number of Patients.
- SD = Standard deviation, min=minimum, max=maximum
- Change from Baseline= Post-Baseline - Baseline
- % Change from Baseline = (Post-Baseline - Baseline / Baseline) X 100
- p-value calculate using Paired t – test / Wilcoxon signed-rank test.
- Source : Listing 16.3.5

Table 14.2.4. Analysis of change in Fasting Plasma Glucose from baseline to Week 24. (Safety Population)

	Observed value (N = xx)	Change from Baseline (N = xx)	% Change from Baseline (N = xx)
Baseline (Visit 2)			
N	xx		
Missing	xx		
Mean (SD)	xx.x (xx.xx)		
Median	xx.x		
(min, max)	(xx.xx, xx.xx)		
Week 24			
N	Xx	Xx	xx
Missing	Xx	Xx	Xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x
(min, max)	(xx.xx, xx.xx)	(xx.xx, xx.xx)	(xx.xx, xx.xx)
p-value		x.xxx	x.xxx

- The Capital "N" in the column header represents the total number of Patients in Safety Population.
- The small "n" in summary statistics represents the total number of Patients.
- SD = Standard deviation, min=minimum, max=maximum
- Change from Baseline= Post-Baseline - Baseline
- % Change from Baseline = (Post-Baseline - Baseline / Baseline) X 100
- p-value calculate using paired t – test.
- Source : Listing 16.2.6.1

Table 14.2.5. Summary of HbA1c and Fasting Plasma Glucose (Safety Population)

	N=xx
Visit 1	
HbA1c (%)	
N	xx
Missing	xx
Mean (SD)	xx.x (xx.xx)
Median	xx.x
(min, max)	(xx.xx, xx.xx)
Duration of Type 2 Diabetes Mellitus (in months)	
N	xx
Missing	xx
Mean (SD)	xx.x (xx.xx)
Median	xx.x
(min, max)	(xx.xx, xx.xx)
Visit x	
HbA1c and Fasting Plasma Glucose assessed	
Yes	xx (xx.xx)
No	xx (xx.xx)
HbA1c (%)	
N	xx
Missing	xx
Mean (SD)	xx.x (xx.xx)
Median	xx.x
(min, max)	(xx.xx, xx.xx)
Fasting Plasma Glucose (mg/dL)	
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 Safety Population.
- The small "n" in summary statistics represents the total number of Patients.
- Percentage in the “HbA1c and Fasting Plasma Glucose Assessed” rows are based on the number of Safety Population.
- SD = Standard Deviation, min=minimum, max=maximum
- Visit x: Visit 2, Visit 5, Visit 7, Visit 9 and Visit 10
- Source :Listing 16.2.6.1

Table 14.3.5. Summary of Hypoglycemic Event (Safety Population).

	N = xx n (%)
Patient Experience any hypoglycemic event	
Yes	xx (xx.xx)
No	xx (xx.xx)
Event occur Time	
Sleeping Time	xx (xx.xx)
Day Time	xx (xx.xx)
Other Time	xx (xx.xx)
Symptoms are present	
Yes	xx (xx.xx)
No	xx (xx.xx)
Symptoms are present, If Yes	
An irregular heart rhythm	xx (xx.xx)
Fatigue	xx (xx.xx)
Pale skin	xx (xx.xx)
Shakiness	xx (xx.xx)
Anxiety	xx (xx.xx)
Sweating	xx (xx.xx)
Hunger	xx (xx.xx)
Irritability	xx (xx.xx)
Tingling sensation around the mouth	xx (xx.xx)
Crying out during sleep	xx (xx.xx)
Other	xx (xx.xx)
Possible contributing factors of the event	
Yes	xx (xx.xx)
No	xx (xx.xx)
Possible contributing factors of the event, If Yes	
Alcohol consumption	xx (xx.xx)
Concurrent illness	xx (xx.xx)
Overdose of IP/Deviation from dosin	xx (xx.xx)
Physical Activity	xx (xx.xx)
Other	xx (xx.xx)
Fingerstick value obtained at the time of event	
Yes	xx (xx.xx)
No	xx (xx.xx)
Plasma glucose (mg/dL)	
n	Xx
Missing	Xx
Mean (SD)	xx.x (xx.xx)
Median	xx.x
(min, max)	(xx.xx, xx.xx)
Glucose (mg/dL)	
n	Xx
Missing	Xx
Mean (SD)	xx.x (xx.xx)
Median	xx.x
(min, max)	(xx.xx, xx.xx)
Treatment intervention needed for recovery	
Yes	xx (xx.xx)

No	xx (xx.xx)
Episode treated	
Drink/Food	xx (xx.xx)
Glucose Injection	xx (xx.xx)
Other	xx (xx.xx)
Indicate assistance needed	
None – Subject treated self	xx (xx.xx)
Patient was capable of treating self, but received assistance	xx (xx.xx)
Patient was not capable of treating self and received assistance	xx (xx.xx)
Patient recover post treatment	
Yes	xx (xx.xx)
No	xx (xx.xx)

- The Capital "N" in the column header represents the total number of Safety Population.
- The small "n" in summary statistics represents the total number of Patients.
- Percentages in the “Patient Experience any hypoglycemic event” rows are based on the number of Safety Population.
- Percentages in the “Event occur Time, Symptoms are present, Possible contributing factors of the event, Fingerstick value obtained at the time of event, Treatment intervention needed for recovery, Episode treated, Indicate assistance needed, Patient recover post treatment” rows are based on Patient Experience any hypoglycemic event.
- Percentages in the “Symptoms are present, If Yes” rows are based on Patient Symptoms are present.
- Percentages in the “Possible contributing factors of the event, If Yes” rows are based on Patient Possible contributing factors of the event.
- SD = Standard Deviation, min=minimum, max=maximum
- Source :Listing 16.2.7.1 and Listing 16.2.7.2

Table 14.3.1. Summary of Adverse Event (Safety Population)

	N = xx n (%)
Patient experience any Adverse Event	
Yes	xx (xx.xx)
No	xx (xx.xx)
Relationship	
Certain	xx (xx.xx)
Probable/Likely	xx (xx.xx)
Possible	xx (xx.xx)
Unlikely	xx (xx.xx)
Not related	xx (xx.xx)
Action taken	
None	xx (xx.xx)
Change in the study drug administration	xx (xx.xx)
Drug Withdrawn	xx (xx.xx)
Drug interrupted	xx (xx.xx)
Dose reduced	xx (xx.xx)
Dose increased	xx (xx.xx)
Drug treatment required	xx (xx.xx)
Non-drug treatment required	xx (xx.xx)
Hospitalization/prolonged hospitalization	xx (xx.xx)
Diagnostic or clinical test(s) conducted	xx (xx.xx)
Patient discontinued from the study	xx (xx.xx)
Severity	
Mild	xx (xx.xx)
Moderate	xx (xx.xx)
Severe	xx (xx.xx)
Outcome	
Recovered without sequelae	xx (xx.xx)
Recovered with sequelae	xx (xx.xx)
Not recovered/ Not resolved	xx (xx.xx)
Recovering/ resolving	xx (xx.xx)
Unknown	xx (xx.xx)
Fatal	xx (xx.xx)
Treatment Taken	
Yes	xx (xx.xx)
No	xx (xx.xx)
Expectedness	
Expected	xx (xx.xx)
UnExpected	xx (xx.xx)
SAE	
Yes	xx (xx.xx)
No	xx (xx.xx)
SAE Criteria	
Result in Death	xx (xx.xx)
immediately life-threatening	xx (xx.xx)
New in-patient hospitalisation	xx (xx.xx)
Prolonged in-patient hospitalisation	xx (xx.xx)
Persistent or significant disability/incapacity	xx (xx.xx)

Congenital anomaly	xx (xx.xx)
Any Other	xx (xx.xx)

- The Capital "N" in the column header represents the total number of Safety Population.
- The small "n" in summary statistics represents the total number of Patients.
- Percentages in the “Patient experience any Adverse Event” rows are based on the number of safety Population.
- Percentages in the “Relationship, Action taken, Severity, Outcome, Treatment Taken, Expectedness and SAE” rows are based on the number of Patient experience any Adverse Event.
- Percentage in the “SAE Criteria” rows are based on the number of Patient any SAE.
- Source :Listing 16.3.1.1

Table 14.3.2. Summary of Adverse Event of special interest (Safety Population)

	N = xx
	n (%)
Hypoglycemic Events	xx (xx.xx)
Urinary Tract Infection	xx (xx.xx)
Gentital Tract Infection	xx (xx.xx)
Volume depletion	xx (xx.xx)
Diabetic Ketoacidosis	xx (xx.xx)
Renal Events	xx (xx.xx)
Hospitalization for Heart Failure	xx (xx.xx)

- The Capital "N" in the column header represents the total number of Safety Population.
- The small "n" in summary statistics represents the total number of Patients.
- Percentages rows are based on the number of safety Population.
- Source :Listing 16.3.7

Table 14.3.3. Summary of Haematology Parameter (Safety Population)

	N = xx
Visit x	
Blood Sample Collected	
Yes	xx (xx.xx)
No	xx (xx.xx)
Haematology Parameter x	
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 Safety Population.
- The small "n" in summary statistics represents the total number of Patients.
- SD = Standard Deviation, min=minimum, max=maximum;
- Percentages in the “Blood Sample Collected” rows are based on the number of Safety Population.
- Programmer Note: Haematology Parameter x: Hematocrit (%), Leukocyte count (/µL), Neutrophils (%), Basophils (%), Lymphocytes (%), Eosinophils (%), Monocytes (%), Platelet count (/µL), Haemoglobin (g/dL)
- Visit x: Visit 1, Visit 2, Visit 5, Visit 7, Visit 9 and Visit 10
- Source :Listing 16.3.3.1

Table 14.3.4. Summary of Clinical Chemistry Parameter (Safety Population)

	N = xx
Visit x	
Blood Sample Collected	
Yes	xx (xx.xx)
No	xx (xx.xx)
Clinical chemistry Parameter x	
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 safety population.
- The small "n" in summary statistics represents the total number of Patients.
- SD = Standard Deviation, min=minimum, max=maximum;
- Percentages in the "Blood Sample Collected" rows are based on the number of Safety Population.
- Programmer Note: Clinical chemistry Parameter x: Creatinine (mg/dL), Total Bilirubin (mg/dL), Alkaline phosphatise (U/L), Aspartate transaminase (U/L), Alanine transaminase (U/L), Albumin (g/dL), Potassium (mEq/L), Total Calcium (mg/dL), Sodium (mg/dL) , Sodium (mmol/L), Sodium (mEq/L) and Creatine kinase (U/L)
- Visit x: Visit 1, Visit 2, Visit 5, Visit 7, Visit 9 and Visit 10
- Source : Listing 16.3.3.2

Table 14.3.5. Summary of Urinalysis (Safety Population)

	N=xx
	n (%)
Visit x	
Sample collected	
Yes	xx (xx.xx)
No	xx (xx.xx)
Blood	
Normal	xx (xx.xx)
Abnormal NCS	xx (xx.xx)
Abnormal CS	xx (xx.xx)
Protein	
Normal	xx (xx.xx)
Abnormal NCS	xx (xx.xx)
Abnormal CS	xx (xx.xx)
Glucose	
Normal	xx (xx.xx)
Abnormal NCS	xx (xx.xx)
Abnormal CS	xx (xx.xx)

- The Capital "N" in the column header represents the total number of Safety Population.
- The small "n" in summary statistics represents the total number of Patients.
- Percentages in the "Sample Collected" rows are based on the number of Safety Population.
- Percentages in the "Blood, Protein, Glucose" rows are based on the number of Patient sample collected.
- Visit x: Visit 1, Visit 2, Visit 5, Visit 7, Visit 9 and Visit 10.
- Source : Listing 16.3.3.3

Table 14.3.6. Summary of Electrocardiogram (Safety Population)

	(N = xx)
Visit x	
ECG Performed	
Yes	xx (xx.xx)
No	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 of Safety Population.
- The small "n" in summary statistics represents the total number of Patients.
- SD = Standard Deviation, min=minimum, max=maximum.
- Visit x: Visit 2, Visit 7, Visit 9 and Visit 10
- Source :Listing 16.3.4

Table 14.3.7. Summary of Vital Signs (Safety Population)

	N = xx
Visit x	
Vital Signs Collected	
Yes	xx (xx.xx)
No	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)
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)
Respiratory Rate (breaths/min)	
N	Xx
Missing	Xx
Mean (SD)	xx.x (xx.xx)
Median	xx.x
(min, max)	(xx.xx, xx.xx)
Body Temperature (^{0}F)	
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 Safety Population.
- The small "n" in summary statistics represents the total number of Patients.
- Percentage in the “Vital Signs collected” rows are based on the number of Safety Population.
- SD = Standard Deviation, min=minimum, max=maximum;
- Visit x: Visit 1, Visit 2, Visit 5, Visit 7, Visit 9 and Visit 10
- Source : Listing 16.3.5

Table 14.3.8. Summary of Physical examination

	N = xx n (%)
Visit x	
Physical examination performed	
Yes	xx (xx.xx)
No	xx (xx.xx)
System x	
Normal	xx (xx.xx)
Abnormal NCS	xx (xx.xx)
Abnormal CS	xx (xx.xx)

- The Capital "N" in the column header represents the total number Safety Population.
- The small "n" in summary statistics represents the total number of Patients.
- Percentages in the “Physical Examination performed” rows are based on Total number of Patient Safety Population.
- Percentages in the “System x” rows are based on number of Patient Physical Examination performed.
- Programmer Note: Generate summaries for the following System x :General Appearance, Cardiovascular System, Lungs, Abdomen, Extremities, Head Eye Ear Nose Throat (HEENT), Neurological System, Dermatological System, Genito-urinary System and Other.
- NCS= Non-clinically significant
- CS= clinically significant
- Programme Note: Visit 1, Visit 2, Visit 5, Visit 7, Visit 9 and Visit 10
- Source :Listing 16.3.6

Listing 16.2.1.1. Listing of Patients Informed Consent Details

Patient Number	Written Informed consent obtained	Date of Written Informed Consent	Time of Written Informed Consent
xx-xxx	Yes/No	DD-MMM-YYYY	HH:MM
xx-xxx	Yes/No	DD-MMM-YYYY	HH:MM
xx-xxx	Yes/No	DD-MMM-YYYY	HH:MM
xx-xxx	Yes/No	DD-MMM-YYYY	HH:MM
xx-xxx	Yes/No	DD-MMM-YYYY	HH:MM

Listing 16.2.1.2. Listing of Patients End of Treatment

Patient Number	Visit	Treatment with study Drug Discontinued prematurely	Date of Last Dose taken	Most appropriate reason for withdrawal/Discontinued of Study	Date of Last contact
xx-xxx	xxxx	Yes/No	DD-MMM-YYYY	xxxx	DD-MMM-YYYY
xx-xxx	xxxx	Yes/No	DD-MMM-YYYY	xxxx	DD-MMM-YYYY
xx-xxx	xxxx	Yes/No	DD-MMM-YYYY	xxxx	DD-MMM-YYYY
xx-xxx	xxxx	Yes/No	DD-MMM-YYYY	xxxx	DD-MMM-YYYY
xx-xxx	xxxx	Yes/No	DD-MMM-YYYY	xxxx	DD-MMM-YYYY

Listing 16.2.1.3. Listing of Patients Study Completion

Patient Number	Visit	Patient complete the study	Date of Completion/ Discontinuation	Primary reason for withdrawal	Other, Specify
xx-xxx	xxxx	Yes/No	DD-MMM-YYYY	xxxx	xxxx
xx-xxx	xxxx	Yes/No	DD-MMM-YYYY	xxxx	xxxx
xx-xxx	xxxx	Yes/No	DD-MMM-YYYY	xxxx	xxxx
xx-xxx	xxxx	Yes/No	DD-MMM-YYYY	xxxx	xxxx
xx-xxx	xxxx	Yes/No	DD-MMM-YYYY	xxxx	xxxx

Listing 16.2.1.4. Listing of Analysis Population

Patient Number	Enrolled Population	Safety Population
xx-xxx	Yes/No	Yes/No
xx-xxx	Yes/No	Yes/No
xx-xxx	Yes/No	Yes/No
xx-xxx	Yes/No	Yes/No
xx-xxx	Yes/No	Yes/No

Listing 16.2.2.1. Listing of Patients Demographics

Patient Number	Date of Birth	Age (Year)	Gender	Race	Other, Specify
xx-xxx	DD-MMM-YYYY	xx	Male/Female	Race/Other	xxxx
xx-xxx	DD-MMM-YYYY	xx	Male/Female	Race/Other	xxxx
xx-xxx	DD-MMM-YYYY	xx	Male/Female	Race/Other	xxxx
xx-xxx	DD-MMM-YYYY	xx	Male/Female	Race/Other	xxxx
xx-xxx	DD-MMM-YYYY	xx	Male/Female	Race/Other	xxxx

Listing 16.2.2.2. Listing of Patients Anthropometric Assessment

Patient Number	Visit	Height (cm)	Weight (Kg)	Waist Circumference (cm)	Body Mass Index (Kg/m2)
xx-xxx	xxxx	xxx	xxx	xxx	xxx
xx-xxx	xxxx	xxx	xxx	xxx	xxx
xx-xxx	xxxx	xxx	xxx	xxx	xxx
xx-xxx	xxxx	xxx	xxx	xxx	xxx
xx-xxx	xxxx	xxx	xxx	xxx	xxx

Listing 16.2.3. Listing of Patients Medical History

Patient Number	Patient have any Medical/Surgical history	Seq. No	Medical/Surgical Description	Preferred Term	System Organ Class	Start Date	Stop Date	Ongoing	Receiving Treatment
xx-xxx	Yes/No	xx	xxxx	xxxx	xxxx	DD-MMM-YYYY	DD-MMM-YYYY	xxxx	Yes/No
xx-xxx	Yes/No	xx	xxxx	xxxx	xxxx	DD-MMM-YYYY	DD-MMM-YYYY	xxxx	Yes/No
xx-xxx	Yes/No	xx	xxxx	xxxx	xxxx	DD-MMM-YYYY	DD-MMM-YYYY	xxxx	Yes/No
xx-xxx	Yes/No	xx	xxxx	xxxx	xxxx	DD-MMM-YYYY	DD-MMM-YYYY	xxxx	Yes/No
xx-xxx	Yes/No	xx	xxxx	xxxx	xxxx	DD-MMM-YYYY	DD-MMM-YYYY	xxxx	Yes/No

Listing 16.2.4. Listing of Patients Urine Pregnancy test (Women of child bearing potential)

Patient Number	Visit	Urine Pregnancy test performed	If No, Specify Reason	Date and Time of Urine Sample	Result
xx-xxx	xxxx	Yes/No/NA	xxxx	DD-MMM-YYYY/HH:MM	Positive/Negative
xx-xxx	xxxx	Yes/No/NA	xxxx	DD-MMM-YYYY/HH:MM	Positive/Negative
xx-xxx	xxxx	Yes/No/NA	xxxx	DD-MMM-YYYY/HH:MM	Positive/Negative
xx-xxx	xxxx	Yes/No/NA	xxxx	DD-MMM-YYYY/HH:MM	Positive/Negative
xx-xxx	xxxx	Yes/No/NA	xxxx	DD-MMM-YYYY/HH:MM	Positive/Negative

Listing 16.2.5.1. Listing of Patients IP Dispensing

Patient Number	Visit	Study Drug dispensed	If No, Specify Reason	Number of Tables dispensed	Kit Number 1	Kit Number 2	Kit Number 3
xx-xxx	xxxx	Yes/No/NA	xxxx	xxxx	xxxx	xxxx/NA	xxxx/NA
xx-xxx	xxxx	Yes/No/NA	xxxx	xxxx	xxxx	xxxx/NA	xxxx/NA
xx-xxx	xxxx	Yes/No/NA	xxxx	xxxx	xxxx	xxxx/NA	xxxx/NA
xx-xxx	xxxx	Yes/No/NA	xxxx	xxxx	xxxx	xxxx/NA	xxxx/NA
xx-xxx	xxxx	Yes/No/NA	xxxx	xxxx	xxxx	xxxx/NA	xxxx/NA

Listing 16.2.5.2. Listing of Patients IP Medication Accountability

Patient Number	Visit	No. of Dose missed in the treatment Period	No. of Tablets lost in the treatment period	No. of Tablets returned	No. of Tablets to be taken in the treatment period	No. of Tablets consumed in the treatment period	Compliance (%)
xx-xxx	xxxx	xx	xx	xx	xx	xx	xxx
xx-xxx	xxxx	xx	xx	xx	xx	xx	xxx
xx-xxx	xxxx	xx	xx	xx	xx	xx	xxx
xx-xxx	xxxx	xx	xx	xx	xx	xx	xxx
xx-xxx	xxxx	xx	xx	xx	xx	xx	xxx

Listing 16.2.6.1. Listing of Patients HbA1c and Fasting Plasma Glucose

Patient Number	Visit	HbA1c and Fasting Plasma Glucose assessed	Date of HbA1c Assessment	HbA1c (%)	Duration of Type 2 Diabetes Mellitus (in months)	Fasting Plasma Glucose (mg/dL)
xx-xxx	xxxx	Yes/No	DD-MMM-YYYY	xxxx	xxx	xxx
xx-xxx	xxxx	Yes/No	DD-MMM-YYYY	xxxx	xxx	xxx
xx-xxx	xxxx	Yes/No	DD-MMM-YYYY	xxxx	xxx	xxx
xx-xxx	xxxx	Yes/No	DD-MMM-YYYY	xxxx	xxx	Xxx
xx-xxx	xxxx	Yes/No	DD-MMM-YYYY	xxxx	xxx	xxx

Listing 16.2.6.2. Listing of Patients Fasting Plasma Glucose

Patient Number	Visit	Date and Time of self-monitoring	Patient fasting for 8 hours	Fasting Plasma glucose (mg/dL)	Repeated Fasting Plasma Glucose (mg/dL)	Patient scheduled for Laboratory FPG within a week	Laboratory FPG Value
xx-xxx	xxxx	DD-MMM-YYYY/HH:MM	Yes/No	xxx	xxx	yes/no	xxx
xx-xxx	xxxx	DD-MMM-YYYY/HH:MM	Yes/No	xxx	xxx	yes/no	xxx
xx-xxx	xxxx	DD-MMM-YYYY/HH:MM	Yes/No	xxx	xxx	yes/no	xxx
xx-xxx	xxxx	DD-MMM-YYYY/HH:MM	Yes/No	xxx	xxx	yes/no	xxx
xx-xxx	xxxx	DD-MMM-YYYY/HH:MM	Yes/No	xxx	xxx	yes/no	xxx

Listing 16.2.7.1. Listing of Patients Hypoglycaemic Event (Part I)

Patient Number	Visit	Patient experience any hypoglycaemic event	Start Date/Stop Date	Event occur Time	Symptoms Present	If Yes	Any Possible Contributing factors of the Event	If Yes	Fingerstick value obtained at the time of event	Plasma glucose (mg/dL)	Glucose Value
xx-xxx	xxxx	Yes/No	DD-MMM-YYYY/ DD-MMM-YYYY	Sleeping Time/ Day Time/Other	Yes/No	xxxx	Yes/No	xxxx	Yes/No	Xxx	Xxx
xx-xxx	xxxx	Yes/No	DD-MMM-YYYY/ DD-MMM-YYYY	Sleeping Time/ Day Time/Other	Yes/No	xxxx	Yes/No	xxxx	Yes/No	Xxx	Xxx
xx-xxx	xxxx	Yes/No	DD-MMM-YYYY/ DD-MMM-YYYY	Sleeping Time/ Day Time/Other	Yes/No	xxxx	Yes/No	xxxx	Yes/No	Xxx	Xxx
xx-xxx	xxxx	Yes/No	DD-MMM-YYYY/ DD-MMM-YYYY	Sleeping Time/ Day Time/Other	Yes/No	xxxx	Yes/No	xxxx	Yes/No	xxx	xxx
xx-xxx	xxxx	Yes/No	DD-MMM-YYYY/ DD-MMM-YYYY	Sleeping Time/ Day Time/Other	Yes/No	xxxx	Yes/No	xxxx	Yes/No	xxx	xxx

Listing 16.2.7.2. Listing of Patients Hypoglycaemic Event (Part II)

Patient Number	Visit	Treatment intervention needed for recovery	How was the Episode treated	Indicate assistance needed	Patient recover post treatment	Time of last IP administration	Time of last meal	Meal content
xx-xxx	xxxx	Yes/No	(Drink/Food)/ (Glucose Injection)/Other	xxxx	Yes/No	HH:MM	HH:MM	xxxx
xx-xxx	xxxx	Yes/No	(Drink/Food)/ (Glucose Injection)/Other	xxxx	Yes/No	HH:MM	HH:MM	xxxx
xx-xxx	xxxx	Yes/No	(Drink/Food)/ (Glucose Injection)/Other	xxxx	Yes/No	HH:MM	HH:MM	xxxx
xx-xxx	xxxx	Yes/No	(Drink/Food)/ (Glucose Injection)/Other	xxxx	Yes/No	HH:MM	HH:MM	xxxx
xx-xxx	xxxx	Yes/No	(Drink/Food)/ (Glucose Injection)/Other	xxxx	Yes/No	HH:MM	HH:MM	xxxx

Listing 16.3.1.1. Listing of Patients Adverse Event Assessment

Patient Number	Visit	Patient Experience any Adverse Event Since last visit
xx-xxx	xxxx	Yes/No
xx-xxx	xxxx	Yes/No
xx-xxx	xxxx	Yes/No
xx-xxx	xxxx	Yes/No
xx-xxx	xxxx	Yes/No

Listing 16.3.1.2. Listing of Patients Adverse Event

Patient Number	Patient Experience Any Adverse Event	Seq. No	Event Description	Start Date/ End Date	Ongoing	Relationship	Action taken	Severity	Outcome	Treatment taken	Expectedness	SAE
xx-xxx	Yes/No	xx	xxx	DD-MMM-YYYY/ DD-MMM-YYYY	xxx	xxx	xxx	xxx	xxx	Yes/No	Expected/ Unexpected	Yes/No
xx-xxx	Yes/No	xx	xxx	DD-MMM-YYYY/ DD-MMM-YYYY	xxx	xxx	xxx	xxx	xxx	Yes/No	Expected/ Unexpected	Yes/No
xx-xxx	Yes/No	xx	xxx	DD-MMM-YYYY/ DD-MMM-YYYY	xxx	xxx	xxx	xxx	xxx	Yes/No	Expected/ Unexpected	Yes/No
xx-xxx	Yes/No	xx	xxx	DD-MMM-YYYY/ DD-MMM-YYYY	xxx	xxx	xxx	xxx	xxx	Yes/No	Expected/ Unexpected	Yes/No
xx-xxx	Yes/No	xx	xxx	DD-MMM-YYYY/ DD-MMM-YYYY	xxx	xxx	xxx	xxx	xxx	Yes/No	Expected/ Unexpected	Yes/No

Listing 16.3.2. Listing of Patients Serious Adverse Event

Patient Number	Age	Gender	SAE Term	Date of AE met criteria for SAE	Date Investigator became aware of serious AE	Patient hospitalised due to SAE	Date of Hospitalisation	Date of Discharge	Seriousness Criteria	Date of Event Onset	Outcome
xx-xxx	xx	Male/Female	xxxx	DD-MMM-YYYY	DD-MMM-YYYY	Yes/No	DD-MMM-YYYY	DD-MMM-YYYY	xxxx	DD-MMM-YYYY	xxxx
xx-xxx	xx	Male/Female	xxxx	DD-MMM-YYYY	DD-MMM-YYYY	Yes/No	DD-MMM-YYYY	DD-MMM-YYYY	xxxx	DD-MMM-YYYY	xxxx
xx-xxx	xx	Male/Female	xxxx	DD-MMM-YYYY	DD-MMM-YYYY	Yes/No	DD-MMM-YYYY	DD-MMM-YYYY	xxxx	DD-MMM-YYYY	xxxx
xx-xxx	xx	Male/Female	xxxx	DD-MMM-YYYY	DD-MMM-YYYY	Yes/No	DD-MMM-YYYY	DD-MMM-YYYY	xxxx	DD-MMM-YYYY	xxxx
xx-xxx	xx	Male/Female	xxxx	DD-MMM-YYYY	DD-MMM-YYYY	Yes/No	DD-MMM-YYYY	DD-MMM-YYYY	xxxx	DD-MMM-YYYY	xxxx

Listing 16.3.3.1 Listing of Patients Haematology (WHOLE BLOOD)

Patient Number	Visit	Blood Sample Collected	If No, Specify Reason	Date and Time of blood Sample	Parameters	Result	Unit	Normal/Abnormal NCS	If Abnormal CS, describe the abnormality#
xx-xxx	xxxx	Yes/No	xxxx	DD-MMM-YYYY/HH:MM	xxxx	xxxx	xxxx	Normal/Abnormal NCS	xxxx
xx-xxx	xxxx	Yes/No	xxxx	DD-MMM-YYYY/HH:MM	xxxx	xxxx	xxxx	Normal/Abnormal NCS	xxxx
xx-xxx	xxxx	Yes/No	xxxx	DD-MMM-YYYY/HH:MM	xxxx	xxxx	xxxx	Normal/Abnormal NCS	xxxx
xx-xxx	xxxx	Yes/No	xxxx	DD-MMM-YYYY/HH:MM	xxxx	xxxx	xxxx	Normal/Abnormal NCS	xxxx
xx-xxx	xxxx	Yes/No	xxxx	DD-MMM-YYYY/HH:MM	xxxx	xxxx	xxxx	Normal/Abnormal NCS	xxxx

Listing 16.3.3.2. Listing of Patients Clinical chemistry (Plasma / Serum)

Patient Number	Visit	Blood Sample Collected	If No, Specify Reason	Date and Time of blood Sample	Parameters	Result	Unit	Normal/Abnormal NCS	If Abnormal CS, describe the abnormality#
xx-xxx	xxxx	Yes/No	xxxx	DD-MMM-YYYY/HH:MM	xxxx	xxxx	xxxx	Normal/Abnormal NCS	xxxx
xx-xxx	xxxx	Yes/No	xxxx	DD-MMM-YYYY/HH:MM	xxxx	xxxx	xxxx	Normal/Abnormal NCS	xxxx
xx-xxx	xxxx	Yes/No	xxxx	DD-MMM-YYYY/HH:MM	xxxx	xxxx	xxxx	Normal/Abnormal NCS	xxxx
xx-xxx	xxxx	Yes/No	xxxx	DD-MMM-YYYY/HH:MM	xxxx	xxxx	xxxx	Normal/Abnormal NCS	xxxx
xx-xxx	xxxx	Yes/No	xxxx	DD-MMM-YYYY/HH:MM	xxxx	xxxx	xxxx	Normal/Abnormal NCS	xxxx

Listing 16.3.3.3. Listing of Patients Urinalysis (Dipstick)

Patient Number	Visit	Urine Sample Collected	If No, Specify Reason	Date and Time of Urine Sample	Parameters	Result	Unit	Normal/Abnormal NCS	If Abnormal CS, describe the abnormality#
xx-xxx	xxxx	Yes/No	xxxx	DD-MMM-YYYY/HH:MM	xxxx	xxxx	xxxx	Normal/Abnormal NCS	xxxx
xx-xxx	xxxx	Yes/No	xxxx	DD-MMM-YYYY/HH:MM	xxxx	xxxx	xxxx	Normal/Abnormal NCS	xxxx
xx-xxx	xxxx	Yes/No	xxxx	DD-MMM-YYYY/HH:MM	xxxx	xxxx	xxxx	Normal/Abnormal NCS	xxxx
xx-xxx	xxxx	Yes/No	xxxx	DD-MMM-YYYY/HH:MM	xxxx	xxxx	xxxx	Normal/Abnormal NCS	xxxx
xx-xxx	xxxx	Yes/No	xxxx	DD-MMM-YYYY/HH:MM	xxxx	xxxx	xxxx	Normal/Abnormal NCS	xxxx

Listing 16.3.4. Listing of Patients Electrocardiogram (ECG)

Patient Number	Visit	ECG Performed	If No, Specify Reason	Date and Time of ECG	Parameter	Result	Unit	Normal/Abnormal NCS	If Abnormal CS, describe the abnormality#
xx-xxx	xxxx	Yes/No	xxxx	DD-MMM-YYYY/HH:MM	xxxx	xxxx	xxxx	Normal/Abnormal NCS	xxxx
xx-xxx	xxxx	Yes/No	xxxx	DD-MMM-YYYY/HH:MM	xxxx	xxxx	xxxx	Normal/Abnormal NCS	xxxx
xx-xxx	xxxx	Yes/No	xxxx	DD-MMM-YYYY/HH:MM	xxxx	xxxx	xxxx	Normal/Abnormal NCS	xxxx
xx-xxx	xxxx	Yes/No	xxxx	DD-MMM-YYYY/HH:MM	xxxx	xxxx	xxxx	Normal/Abnormal NCS	xxxx
xx-xxx	xxxx	Yes/No	xxxx	DD-MMM-YYYY/HH:MM	xxxx	xxxx	xxxx	Normal/Abnormal NCS	xxxx

Listing 16.3.5. Listing of Patients Vital Signs

Patient Number	Visit	Vital Signs Collected	If No, Specify Reason	Date of Vital Signs	Parameter	Result	Normal/Abnormal NCS	If Abnormal CS, describe the abnormality#
xx-xxx	xxxx	Yes/No	xxxx	DD-MMM-YYYY	xxxx	xxxx	Normal/Abnormal NCS	xxxx
xx-xxx	xxxx	Yes/No	xxxx	DD-MMM-YYYY	xxxx	xxxx	Normal/Abnormal NCS	xxxx
xx-xxx	xxxx	Yes/No	xxxx	DD-MMM-YYYY	xxxx	xxxx	Normal/Abnormal NCS	xxxx
xx-xxx	xxxx	Yes/No	xxxx	DD-MMM-YYYY	xxxx	xxxx	Normal/Abnormal NCS	xxxx
xx-xxx	xxxx	Yes/No	xxxx	DD-MMM-YYYY	xxxx	xxxx	Normal/Abnormal NCS	xxxx

Listing 16.3.6. Listing of Patients Physical Examination

Patient Number	Visit	Physical Examination Performed	If No, Specify Reason	Date of Physical Examination	Seq. No.	System	Normal/Abnormal NCS	If Abnormal CS, describe the abnormality#
xx-xxx	xxxx	Yes/No	xxxx	DD-MMM-YYYY	xx	xxxx	Normal/Abnormal NCS	xxxx
xx-xxx	xxxx	Yes/No	xxxx	DD-MMM-YYYY	xx	xxxx	Normal/Abnormal NCS	xxxx
xx-xxx	xxxx	Yes/No	xxxx	DD-MMM-YYYY	xx	xxxx	Normal/Abnormal NCS	xxxx
xx-xxx	xxxx	Yes/No	xxxx	DD-MMM-YYYY	xx	xxxx	Normal/Abnormal NCS	xxxx
xx-xxx	xxxx	Yes/No	xxxx	DD-MMM-YYYY	xx	xxxx	Normal/Abnormal NCS	xxxx

Listing 16.3.7. Listing of Patients Other Assessment

Patient Number	Visit	Hypoglycemic Events	Urinary Tract Infection	Gental Tract Infection	Volume depletion	Diabetic Ketoacidosis	Renal Events	Hospitalization for Heart Failure
xx-xxx	xxxx	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No
xx-xxx	xxxx	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No
xx-xxx	xxxx	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No
xx-xxx	xxxx	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No
xx-xxx	xxxx	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No

Listing 16.3.8.1. Listing of Patients Urinary Tract Infection

Patient Number	Visit	Urine Sample obatianed for culture	Date and Time of Sample Collection	Patient confirmed with Urinnary tract Infection	Cystitis	Urinary Tract Infection	Pyelonephritis	Prostatitis	Other
xx-xxx	xxxx	Yes/No	DD-MMM-YYYY/HH:MM	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No
xx-xxx	xxxx	Yes/No	DD-MMM-YYYY/HH:MM	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No
xx-xxx	xxxx	Yes/No	DD-MMM-YYYY/HH:MM	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No
xx-xxx	xxxx	Yes/No	DD-MMM-YYYY/HH:MM	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No
xx-xxx	xxxx	Yes/No	DD-MMM-YYYY/HH:MM	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No

Listing 16.3.8.2. Listing of Patients Genital Tract Infection

Patient Number	Visit	Urine Sample obatianed for genital swab	If No, specify reason	Date and Time of Sample Collection	Patient confirmed with Gential tract Infection	Vaginitis	Vulvoviginitis	Vulvitis	Balantis
xx-xxx	xxxx	Yes/No	xxxx	DD-MMM-YYYY/HH:MM	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No
xx-xxx	xxxx	Yes/No	xxxx	DD-MMM-YYYY/HH:MM	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No
xx-xxx	xxxx	Yes/No	xxxx	DD-MMM-YYYY/HH:MM	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No
xx-xxx	xxxx	Yes/No	xxxx	DD-MMM-YYYY/HH:MM	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No
xx-xxx	xxxx	Yes/No	xxxx	DD-MMM-YYYY/HH:MM	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No

Listing 16.3.8.3. Listing of Patients Volume Depletion

Patient Number	Visit	Patient at high risk of Volume Depletion	Dehydrtion	Hypovolemia	Hypptensio
xx-xxx	xxxx	Yes/No	Yes/No	Yes/No	Yes/No
xx-xxx	xxxx	Yes/No	Yes/No	Yes/No	Yes/No
xx-xxx	xxxx	Yes/No	Yes/No	Yes/No	Yes/No
xx-xxx	xxxx	Yes/No	Yes/No	Yes/No	Yes/No
xx-xxx	xxxx	Yes/No	Yes/No	Yes/No	Yes/No

Listing 16.3.8.4. Listing of Patients Diabetic Ketoacidosis

Patient Number	Visit	Patient conformed with DKA	Date of DKA Conformation	Medication Taken for the Events	Action Taken with Investigation Product
xx-xxx	xxxx	Yes/No	DD-MMM-YYYY	Yes/No	Discontinued/ Temporary Stopped
xx-xxx	xxxx	Yes/No	DD-MMM-YYYY	Yes/No	Discontinued/ Temporary Stopped
xx-xxx	xxxx	Yes/No	DD-MMM-YYYY	Yes/No	Discontinued/ Temporary Stopped
xx-xxx	xxxx	Yes/No	DD-MMM-YYYY	Yes/No	Discontinued/ Temporary Stopped
xx-xxx	xxxx	Yes/No	DD-MMM-YYYY	Yes/No	Discontinued/ Temporary Stopped

Listing 16.3.8.5. Listing of Patients Renal Events

Patient Number	Visit	Renal Event Occurred	Doubling of serum creatinine	Dialysis	Renal transpiantion
xx-xxx	xxxx	Yes/No	Yes/No	Yes/No	Yes/No
xx-xxx	xxxx	Yes/No	Yes/No	Yes/No	Yes/No
xx-xxx	xxxx	Yes/No	Yes/No	Yes/No	Yes/No
xx-xxx	xxxx	Yes/No	Yes/No	Yes/No	Yes/No
xx-xxx	xxxx	Yes/No	Yes/No	Yes/No	Yes/No

Listing 16.3.8.6. Listing of Patients Hospitalization for Heart Failure

Patient Number	Visit	Patient admitted to the hospital with Primary diagnosis of Heart Failure	Patient hospitalized for nore than 24 hours
xx-xxx	xxxx	Yes/No	Yes/No
xx-xxx	xxxx	Yes/No	Yes/No
xx-xxx	xxxx	Yes/No	Yes/No
xx-xxx	xxxx	Yes/No	Yes/No
xx-xxx	xxxx	Yes/No	Yes/No

Listing 16.3.9.1. Listing of Patients Concomitant Medications

Patient Number	Visit	Patient Take any other concomitant medication during Visit	Patient Take any other concomitant medication since last visit
xx-xxx	xxxx	Yes/No	Yes/No
xx-xxx	xxxx	Yes/No	Yes/No
xx-xxx	xxxx	Yes/No	Yes/No
xx-xxx	xxxx	Yes/No	Yes/No
xx-xxx	xxxx	Yes/No	Yes/No

Listing 16.3.9.2. Listing of Patients Concomitant Medication

Patient Number	Patient Receive Any Concomitant Medication	Seq. No	Medication name	Start Date / Stop date	Ongoing	Indication	Dose Form	Dose	unit	Route	Frequency
xx-xxx	Yes/No	xx	xxx	DD-MMM-YYYY/ DD-MMM-YYYY	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx
xx-xxx	Yes/No	xx	xxx	DD-MMM-YYYY/ DD-MMM-YYYY	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx
xx-xxx	Yes/No	xx	xxx	DD-MMM-YYYY/ DD-MMM-YYYY	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx
xx-xxx	Yes/No	xx	xxx	DD-MMM-YYYY/ DD-MMM-YYYY	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx
xx-xxx	Yes/No	xx	xxx	DD-MMM-YYYY/ DD-MMM-YYYY	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx