CLINICAL TRIAL CONSULTANTS AB

CONFIDENTIAL

Statistical Analysis Plan (SAP)

Sponsor:	Blue Earth Diagnostics Ltd.
Study code:	BED-PSMA-101
CTC project no:	213-22-2018
Study title:	A phase I, open-label study to assess safety, biodistribution, and internal radiation dosimetry of ^{18}F-rhPSMA-7.3 injection in healthy volunteers, and to assess safety and investigate the imaging characteristics in subjects with prostate cancer.
SAP version and date:	30OCT2019 – Final v 1.0

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1 VERSION HISTORY

This Statistical Analysis Plan (SAP) for study BED-PSMA-101 is based on the protocol dated 22FEB2019.

Table 1 SAP Version History Summary

SAP version	Approval Date	Changes	Rationale
1		NA	Original version

2 INTRODUCTION

This Statistical Analysis Plan (SAP) gives details regarding the statistical analyses and data presentation outlined in the final Clinical study protocol (CSP) for the study BED-PSMA-101. Any changes from the final CSP are given in Section 0.

3 CLINICAL STUDY DETAILS

3.1 Clinical Study Objectives and Endpoints

Objects	Estimands/Endpoints
Primary	
• **To assess the safety of a single administration of ^{18}F-rhPSMA-7.3 in healthy subjects and subjects with PCa.**	• Safety is the primary endpoint of the study and it will be assessed from data on the occurrence of one or more treatment-emergent AEs from the time of i.v. administration of ^{18}F-rhPSMA-7.3 throughout the study period, and changes in serum biochemistry, haematology, coagulation, urinalysis, vital signs, ECG, injection site status, and physical examination findings.
Secondary	
• **To determine the biodistribution of ^{18}F following intravenous (i.v.) administration of ^{18}F-rhPSMA-7.3 and hence calculate the internal radiation dosimetry and the effective dose (ED) in healthy volunteers.** • **To explore the optimization of PET imaging with ^{18}F-rhPSMA-7.3 injection in visualizing tumours in subjects with biopsy-proven PCa.** • **To preform kinetic modelling on the distribution of ^{18}F-rhPSMA-7.3 in subjects with PCa.** • **To use the kinetic modelling data to optimize protocol for future studies in subjects with PCa.** • **To determine the *in vivo* Stability of ^{18}F-rhPSMA-7.3 injection by determining proportion of radioactive parent compound present over time.**	• Dosimetry estimates and cumulated radioactivity exposure by source region and the entire body including analysis of radioactivity in whole blood, plasma and excreted urine in healthy volunteers. • Uptake of ^{18}Fr-h-PSMA-7.3 visualised by PET imaging compared to histopathology in subjects with PCa, if histopathology information is available. • Use of kinetic modelling data to investigate distribution of ^{18}Frh-PSMA-7.3 in subjects with PCa. • Use of kinetic modelling data to optimise the imaging protocol for future studies in subjects with PCA, by estimating *in vivo* ^{18}F radioactivity in PCa lesions • Analysis of % of radioactive parent compound present in plasma over time in healthy volunteers and subjects with PCa. Relative proportions of radioactive tracer metabolites will be monitored, as well, if detected in significant amounts in the radio-HPLC analysis.
Tertiary/Exploratory	

3.2 Clinical Study Design

This is a phase 1, open-label, single administration, healthy volunteer and patient study of a PET imaging agent performed at a single centre. The use of placebo, randomisation or blinding are not applicable in this study. Altogether 15 evaluable subjects are planned to participate in the trial: 6 healthy volunteer subjects (3 males and 3 females) and 9 patients with PCa (3 in each patient cohort). Additional subjects may be enrolled in order to end up with evaluable PET imaging data from 6 healthy volunteer subjects and 9 patients with PCa. Each subject will receive a single i.v. administration of ^{18}F-rhPSMA-7.3.

3.3 Statistical Hypotheses

No formal statistical hypotheses are stated. This study is exploratory in nature.

3.4 Number of Subjects

Fifteen (15) evaluable subjects will be included in the study: 6 healthy volunteer subjects (3 males, 3 females); 3 patients with high risk PCa, 3 patients with hormone sensitive metastatic PCa, and 3 patients with castration-resistant metastatic PCa. If an included subject's results are non–evaluable (see section 3.5 – Evaluability criteria), an additional subject may be included in the study to substitute for this.

3.5 Evaluability criteria

Healthy Volunteer Evaluability Criteria:

The following criteria will be applied for evaluable healthy volunteers:

• Completion of scanning sessions I, II and III and collection of venous blood and urine analysis (as described in the Study Imaging Manual) to be able to undertake a calculation of the subject's internal radiation dosimetry.

Patient Evaluability Criteria:

The following criteria will be applied and if the patient is not evaluable for efficacy, an additional subject may be included in the study to substitute for the non-evaluable subject:

• Completion of scanning sessions I and II and collection of venous blood and urine analysis (as described in the Study Imaging Manual) to be able to perform kinetic modelling.

• At least one positive lesion on the ^{18}F-rhPSMA-7.3 scan.

• Cohort A only: Radical prostatectomy performed within 30 days of the ^{18}F-rhPSMA-7.3 scan. In case of a delay of the planned surgery by up to 2 days beyond this 30-day window, a subject may still be considered evaluable.

3.6 Methods of Assigning Subject to IMP

The total duration of subject participation will be up to 52 days for each subject. The study consists of a screening period (up to 21 days), an IMP administration/PET imaging visit, a 24-hour post scan visit and a 30-day telephone contact. In case surgical prostatectomy is for some reason delayed in Cohort A patients scheduled for surgery, the participation of such subjects may be extended by up to two days to cover the surgery.

Subjects who sign the informed consent form (ICF) will enter the screening period of the study. A screening visit will take place within 21 days prior to the IMP administration/PET scan visit.

After the screening period, each subject will receive a single administration of IMP. The healthy volunteers will have 3 CT attenuation-correction scans, each followed by multiple whole-body (WB) PET acquisitions.

The subjects with PCa will have two CT attenuation-correction scans and dynamic PET imaging of the pelvic region (Cohort A) or the area with one or more metastases defined as representative target lesions (Cohorts B and C) for 45 min, followed by a 15 min break, and then multiple base of skull to mid-thigh PET acquisitions of up to 118 min p.i. The investigator will determine what the representative target lesions are in order to ensure that in the Cohort B and C patients all types of metastases, i.e. lymph node metastases, bone metastases, and soft tissue metastases, are represented on the dynamic images.

All subjects will attend a safety follow-up visit 24 hours (+/- 6 hours) after IMP administration and will be contacted by telephone 30 days (+/- 2 days; this may be extended further in Cohort A patients if the prostatectomy is delayed) after IMP administration to determine whether any AEs have occurred. Additional study visits will be arranged as needed for AE management. Any AEs will be followed up until resolution or stabilisation.

3.7 Blinding

This is an open-label study; therefore, no blinding is needed in this study.

4 STATISTICAL AND ANALYTICAL PLANS

4.1 Sample Size Determination

Sufficient numbers of evaluable subjects have been planned to be included in the study in order to fulfil the study objectives, at the same time limiting the groups of healthy volunteer and patient volunteer subjects to the smallest informative numbers.

Altogether 15 evaluable subjects will be included in the study: 6 evaluable healthy volunteer subjects (3 males, 3 females), 3 evaluable subjects with high risk PCa (Cohort A), 3 evaluable subjects with hormone sensitive metastatic PCa (Cohort B), and 3 evaluable subjects with castration resistant metastatic disease (Cohort C).

4.2 Definition of Analysis Sets

4.2.1 Safety Analysis Set

The safety analysis set (SAF) will include all subjects who received any administration of the IMP.

4.2.2 Evaluable Analysis Set

Evaluable analysis set (EAS) will include all subjects who met all inclusion and exclusion criteria, received IMP, underwent PET/CT scans and met the scan evaluability criteria set.

4.2.3 Use of analysis set

The SAF will be used for safety evaluation. EAS will be used for the efficacy (i.e. secondary objectives) evaluations.

4.3 Definition of Baseline

Baseline measurement is defined as the latest measurement prior to first dose of IMP at visit 2.

4.4 Summary Statistics

In general, all data collected will be presented with summary statistics and given in patient data listings. Summary statistics will include at least number of patients, mean, standard deviation, median, minimum and maximum for continuous data and frequency and percentage for categorical data. Table with summary statistics will be divided by treatment group, and assessment timepoint where applicable. Patient data listings will be sorted by treatment group, subject and timing of assessments.

The following treatment groups will be used for summary tables:

- Healthy Volunteers

- Patient Cohort A
- Patient Cohort B
- Patient Cohort C
- All Patient Cohorts (ie Cohorts A+B+C)
- All Cohorts (ie Healthy Volunteers + all patients)

4.5 Significance Level

Not applicable.

4.6 Multiple Comparisons/Multiplicity

No adjustment for multiple comparison/multiplicity will be performed, all significant statistical findings, must be reviewed for medical relevance.

4.7 Handling of Drop-outs, Missing Data and Outliers

Outliers will be included in summary tables and listings, and will not be handled separately in any analyses. No imputation of data will be performed.

4.8 Adjustment for Covariates

No adjustment for covariates will be performed.

4.9 Multicentre Studies

No multicentre studies will be performed.

4.10 Examination of Subgroups

No examination of subgroups will be performed.

4.11 Blind Review

Not applicable.

5 SUBJECTS

5.1 Subject Disposition

The number of subjects that entered the study, withdrawn subjects, completed subjects and the number of subjects at each visit will be summarised by treatment.

5.2 Baseline Characteristics and Demographics

The following baseline characteristics will be summarised by treatment:

- Age
- Sex
- Ethnicity
- Race
- Use of nicotine
- Weight
- Height
- BMI

5.3 Protocol Deviations

A Protocol Deviation Log will be maintained for all protocol deviations, and the significance of each deviations will be assessed before database lock. All protocol deviations will be listed.

6 TREATMENT INFORMATION AND EXTENT OF EXPOSURE

6.1 Active Treatment

The number of subjects who have been administered the IMP, the volume of undiluted IMP and the total administered activity will be summarised.

6.2 Prior and Concomitant Medications

Prior and concomitant medication data will be listed, and summarised by ATC name (Level 4 and Level 5, or the closest level). Prior and concomitant medications will be coded according to the World Health Organization (WHO) Anatomic Therapeutic Chemical (ATC) classification system.

7 STATISTICAL METHODOLOGY

All parameters will be presented by treatment and assessment timepoint using summary statistics. Additional statistical analyses are specified below.

7.1 Primary Endpoint(s) Analysis

7.1.1 Definition of endpoint(s)

7.1.1.1 Adverse events

All AEs will be summarised according to time of appearance (screening period and post-administration (=TEAE) AEs separately), following classification of the verbatim terms according to the Medical Dictionary for Regulatory Activities (MedDRA) dictionary. The number and percentage of subjects for all classified events will be presented according to System organ class (SOC) and Preferred term (PT) by subject group and overall.

Separate summaries will be presented for all AEs by subject and also for all AEs according to Seriousness, Severity and Relationship. For severity, if the subject has the same AE more than once but with different severities, the worst severity will be used for the summary. For relationship, if a subject has the same AE but if it is IMP-related at least once, then the AE will be considered as IMP-related in the summary.

If applicable, the following summaries by SOC and PT will also be produced.:

- Number of subjects with fatal AEs
- Number of subjects with AEs leading to study withdrawal
- The table will be sorted by alphabetic order.

The number and percentage of subjects with Injection site reaction during or within 4 h after IMP dosing will also be summarised, if applicable.

7.1.1.1 Vital signs

For blood pressure and pulse rate, descriptive statistics of actual values and of change from baseline will be used to summarise by treatment group and assessment timepoint. Baseline is defined as the value taken at visit 2, -5min to 0min, or this value is not available, then visit 2, -120min to -5min.

7.1.1.2 ECG resting 12-lead

ECG variables will be summarised according to actual values and change from baseline using summary statistics and will be presented by treatment group and assessment timepoint. Baseline is defined as the value taken at visit 2, -5 min to 0 min, or this value is not available, then visit 2, -120 min to -5 min.

7.1.1.3 Safety laboratory analyses

All haematology, clinical chemistry and coagulation laboratory tests will be summarised using descriptive statistics for actual values and change from baseline and presented by treatment group and assessment timepoint. Baseline is defined as the value taken at visit 2,

-5min to 0min, or this value is not available, then visit 2, -120min to -5min. All listings for safety laboratory will be sorted by laboratory parameter and then subject ID.

7.1.1.4 Physical examinations

Physical examination results will be categorically summarised as the number and percentage of subjects according to body system, treatment group and assessment timepoint.

7.2 Main analytical approach

Summary statistics will include number of patients, mean, standard deviations, median, minimum and maximum for continuous data (mean and median will be presented to 1 additional decimal place relative to the collected data, and standard deviation will be presented to 2 additional decimal places related to the collected data) and frequency and percentage for categorical data.

7.3 Sensitivity analysis

No sensitivity analysis will be performed.

7.4 Supplementary analyses

No supplementary analysis will be performed.

7.5 Presentation

7.5.1.1 Adverse Events

See tables and listings in Statistical Output Layout, section 13.

7.5.1.2 Vital signs

See tables and listings in Statistical Output Layout, section 13.

7.5.1.3 ECG resting 12-lead

See tables and listings in Statistical Output Layout, section 13.

7.5.1.4 Safety laboratory analyses

See tables and listings in Statistical Output Layout, section 13.

7.5.1.5 Physical examinations

See tables and listings in Statistical Output Layout, section 13.

7.6 Secondary Endpoint(s) Analysis

7.6.1 Definition of endpoint(s)

The biodistribution and dosimetry analyses in the Healthy Volunteers, and the kinetic modelling in the Patients, are described in the "BED-PSMA-101 Imaging Data Management Plan" written by Turku PET Centre. These analyses will be performed by Turku PET Centre in a separate report.

7.6.2 Main analytical approach

Not applicable.

7.6.3 Sensitivity analysis

No sensitivity analysis will be performed.

7.6.4 Supplementary analyses

No supplementary analysis will be performed.

7.6.5 Presentation

Not applicable.

7.7 Tertiary/Exploratory Endpoint(s) Analysis

No tertiary/exploratory endpoints analysis will be performed.

7.8 Discontinuation

Patients who discontinue from IMP treatment will be tabulated. The reason for discontinuation will be given. For discontinuation due to AE, the AEs will be given.

7.9 Other Analyses

No other analysis will be performed.

7.10 Interim Analysis

No interim analysis will be performed.

8 CHANGES FROM THE CSP

The following have been changed or added regarding to the CSP:

- FAS and PPS population have been taken away from the study. Decision from the sponsor, a protocol amendment will be written by sponsor.
- Categorically classified (Normal/Abnormal) results have been taken away from the sections 7.1.1.1 Vital signs and 7.1.1.2 ECG resting 12-lead. Decision from the sponsor.

9 STATISTICAL DELIVERABLES

The following documents will be delivered:

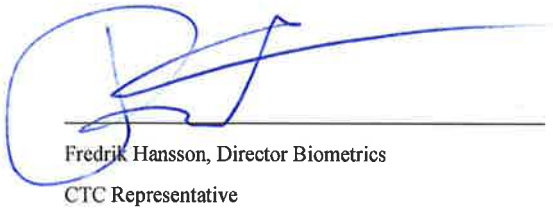
- SAP
- Statistical analyses and summary tables

10 SOFTWARE

All statistical analyses will be performed using SAS Version 9.4 (SAS institute, Cary, NC).

11 APPROVAL

Issued by:



Fredrik Hansson, Director Biometrics
CTC Representative

11 NOV 2019
Date (dd-Mmm-yyyy)

Approved by:

ALBERT CHAN
Sponsor Representative

05-NOV-2019
Date (dd-Mmm-yyyy)

12 SUPPORTIVE DOCUMENTATION

12.1 Appendix 1 – List of Abbreviations

Abbreviation of term	Explanation
ADL	Activities of daily living
ADR	Adverse drug reaction
AE	Adverse event
ATC	Anatomical-Therapeutic-Chemical
AUC	Area under the concentration by time curve
BMI	Body mass index
BP	Blood pressure
CA	Competent authority
CF	Clean File
C_{max}	Maximum observed concentration
CRF	Case Report Form
CSP	Clinical study protocol
CT	Computed tomography
DM	Data management
EC	Ethics committee
ECG	Electrocardiography
ECOG	Eastern Cooperative Oncology Group
(e)CRF	(electronic) Case report form
ED	Effective dose
^{18}F	Isotope of fluorine
FAS	Full Analysis Set
FSH	Follicle Stimulating Hormone
GCP	Good Clinical Practise
GDPR	General Data Protection Regulation
GLP	Good Laboratory Practise
GMP	Good Manufacturing Practise
HBsAg	Hepatitis B virus surface antigens
HCVAg	Hepatitis C virus antibodies

HIVAgAb	Human immunodeficiency virus antibodies
HR	Heart rate
IC	Informed consent
ICF	Informed consent form
ISF	Investigator's study file
IMP	Investigational medicinal product
i.v.	Intravenous
MBq	Mega Becquerel
MCV	Mean Corpuscular Volume
MCH	Mean Corpuscular Haemoglobin
MedDRA	Medical Dictionary for Regulatory Activities
mpMRI	Multi-parametric MRI
mSv	MilliSievert
OTC	Over-the-counter
p.i.	Post injection
PCa	Prostate cancer
PET	Positron Emission Tomography
PPS	Per Protocol Set
PSA	Prostate specific antigen
PSMA	Prostate specific membrane antigen
PT	Preferred term
RECIST	Response Evaluation Criteria in Solid Tumours
SAE	Serious adverse event
SAP	Statistical Analysis Plan
SAS	Statistical Analysis System
SAF	Safety Analysis Set
SD	Standard Deviation
SOC	System Organ Class
SOP	Standard operating procedure
SUSAR	Suspected unexpected serious adverse reaction
SUV	Standardized Uptake Value
SUVR	Standardized Uptake Value Ratio

$t_{½}$	Elimination half-life
TMF	Trial Master File
TPC	Turku PET Centre
TRUS	Transrectal ultrasound

12.2 Appendix 2 – Changes to Protocol-Planned Analyses

13 STATISTICAL OUTPUTS LAYOUT

13.1 Tables

All tables will be grouped by: Healthy Volunteers, Cohort A, Cohort B, Cohort C, Cohort A+B+C and All Subjects.

Subject disposition

TABLE 14.1.1.1 SUBJECT DISPOSITION (ALL SUBJECTS)

	Treatment A	Treatment B	Total
Screened subjects	xx	xx	xx
Subjects that entered the study	xx	xx	xx
Withdrawn subjects	xx	xx	xx
Completed subjects	xx	xx	xx
Included in SAF	xx	xx	xx
Included in EAS	xx	xx	xx
Subjects at Visit 1 (Screening)	xx	xx	xx
Subjects at Visit 2	xx	xx	xx
Subjects at Visit 3	xx	xx	xx
Subjects at Visit 4	xx	xx	xx

Demographic information

TABLE 14.1.2.1 BASELINE CHARACTERISTICS AND DEMOGRAPHICS (EAS)

		Treatment A (N=xx)	Treatment B (N=xx)	Total (N=xx)
Age (years)	n	xx	xx	xx
	Mean (SD)	xx.x (x.xx)	xx.x (x.xx)	xx.x (x.xx)
	Median (Min, Max)	xx.x (x, xx)	xx.x (x, xx)	xx.x (x, xx)
Age Group (years)	<65	xx(xx%)	xx(xx%)	xx(xx%)
	65-<75	xx(xx%)	xx(xx%)	xx(xx%)
	>=75	xx(xx%)	xx(xx%)	xx(xx%)
Sex	Female	xx(xx%)	xx(xx%)	xx(xx%)
	Male	xx(xx%)	xx(xx%)	xx(xx%)
Ethnicity	Hispanic or Latino	xx(xx%)	xx(xx%)	xx(xx%)
	Non-Hispanic or Latino	xx(xx%)	xx(xx%)	xx(xx%)
	Not reported	xx(xx%)	xx(xx%)	xx(xx%)
Race	XXX	xx(xx%)	xx(xx%)	xx(xx%)
	XXX	xx(xx%)	xx(xx%))	xx(xx%))
	XXX	xx(xx%)	xx(xx%)	xx(xx%)
	Not reported	xx(xx%)	xx(xx%)	xx(xx%)
Weight (kg)	n	xx	xx	xx
	Mean (SD)	xx.xx (x.xxx)	xx.xx (x.xxx)	xx.xx (x.xxx)
	Median (Min, Max)	xx.xx (x.x,.xx.x)	xx.xx (x.x,.xx.x)	xx.x (x.x,.xx.x)
Height (cm)	n	xx	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)	xx.x (x.x)
	Median (Min, Max)	xx.x (x, xx)	xx.x (x, xx)	xx.x (x, xx)
Body Mass Index (kg/m^2)	n	xx	xx	xx
	Mean (SD)	xx.xx (x.xxx)	xx.xx (x.xxx)	xx.xx (x.xxx)
	Median (Min, Max)	xx.xx (x.xx, xx.x)	xx.x (x.xx, xx.x)	xx.x (x.xx, xx.x)

TABLE 14.1.2.2 BASELINE CHARACTERISTICS AND DEMOGRAPHICS (SAF)

		Treatment A (N=xx)	Treatment B (N=xx)	Total (N=xx)
Age (years)	n	xx	xx	xx
	Mean (SD)	xx.x (x.xx)	xx.x (x.xx)	xx.x (x.xx)
	Median (Min, Max)	xx.x (x, xx)	xx.x (x, xx)	xx.x (x, xx)
Age Group (years)	<65	xx(xx%)	xx(xx%)	xx(xx%)
	65-<75	xx(xx%)	xx(xx%)	xx(xx%)
	>=75	xx(xx%)	xx(xx%)	xx(xx%)
Sex	Female	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)
	Male	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)
Ethnicity	Hispanic or Latino	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)
	Non-Hispanic or Latino	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)
	Not reported	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)
Race	XXX	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)
	XXX	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)
	XXX	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)
	Not reported	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)
Weight (kg)	n	xx	xx	xx
	Mean (SD)	xx.xx (x.xxx)	xx.xx (x.xxx)	xx.xx (x.xxx)
	Median (Min, Max)	xx.xx (x.x,.xx.x)	xx.xx (x.x,.xx.x)	xx.x (x.x,.xx.x)
Height (cm)	N	xx	xx	xx
	Mean (SD)	xx.x (x.x)	xx.x (x.x)	xx.x (x.x)
	Median (Min, Max)	xx.x (x, xx)	xx.x (x, xx)	xx.x (x, xx)
Body Mass Index (kg/m^2)	n	xx	xx	xx
	Mean (SD)	xx.xx (x.xxx)	xx.xx (x.xxx)	xx.xx (x.xxx)
	Median (Min, Max)	xx.xx (x.xx, xx.x)	xx.x (x.xx, xx.x)	xx.x (x.xx, xx.x)
ECOG	0	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	3	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	4	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

TABLE 14.1.3.1 MEDICAL HISTORY EVENTS BY SYSTEM ORGAN CLASS AND PREFERRED TERM (EAS)

System organ class Preferred term	Treatment A N=xx n(%)	Treatment B N=xx n(%)	Total N=xx n(%)
Total	**x(xx%)**	**x(xx%)**	**x(xx%)**
Psychiatric disorders	**x(xx%)**	**x(xx%)**	**x(xx%)**
Anxiety	x(xx%)	x(xx%)	x(xx%)
Depression	x(xx%)	x(xx%)	x(xx%)
Insomnia	x(xx%)	x(xx%)	x(xx%)
Immune system disorders	**x(xx%)**	**x(xx%)**	**x(xx%)**
Hypersensitivity	x(xx%)	x(xx%)	x(xx%)
Seasonal allergy	x(xx%)	x(xx%)	x(xx%)
Metabolism and nutrition disorders	**x(xx%)**	**x(xx%)**	**x(xx%)**
Type 1 diabetes mellitus	x(xx%)	x(xx%)	x(xx%)
General disorders and administration site conditions	**x(xx%)**	**x(xx%)**	**x(xx%)**
Chronic fatigue syndrome	x(xx%)	x(xx%)	x(xx%)
Nervous system disorders	**x(xx%)**	**x(xx%)**	**x(xx%)**
Narcolepsy	x(xx%)	x(xx%)	x(xx%)
Reproductive system and breast disorders	**x(xx%)**	**x(xx%)**	**x(xx%)**
Premenstrual syndrome	x(xx%)	x(xx%)	x(xx%)
Respiratory, thoracic and mediastinal disorders	**x(xx%)**	**x(xx%)**	**x(xx%)**
Asthma	x(xx%)	x(xx%)	x(xx%)
Vascular disorders	**x(xx%)**	**x(xx%)**	**x(xx%)**
Hypertension	x(xx%)	x(xx%)	x(xx%)

n, number of subjects;

Percentages are based on the number of subjects in the evaluable analysis set

TABLE 14.1.3.2 MEDICAL HISTORY EVENTS BY SYSTEM ORGAN CLASS AND PREFERRED TERM (SAF)

System organ class Preferred term	Treatment A N=xx n(%)	Treatment B N=xx n(%)	Total N=xx n(%)
Total	**x(xx%)**	**x(xx%)**	**x(xx%)**
Psychiatric disorders	**x(xx%)**	**x(xx%)**	**x(xx%)**
Anxiety	x(xx%)	x(xx%)	x(xx%)
Depression	x(xx%)	x(xx%)	x(xx%)
Insomnia	x(xx%)	x(xx%)	x(xx%)
Immune system disorders	**x(xx%)**	**x(xx%)**	**x(xx%)**
Hypersensitivity	x(xx%)	x(xx%)	x(xx%)
Seasonal allergy	x(xx%)	x(xx%)	x(xx%)
Metabolism and nutrition disorders	**x(xx%)**	**x(xx%)**	**x(xx%)**
Type 1 diabetes mellitus	x(xx%)	x(xx%)	x(xx%)
General disorders and administration site conditions	**x(xx%)**	**x(xx%)**	**x(xx%)**
Chronic fatigue syndrome	x(xx%)	x(xx%)	x(xx%)
Nervous system disorders	**x(xx%)**	**x(xx%)**	**x(xx%)**
Narcolepsy	x(xx%)	x(xx%)	x(xx%)
Reproductive system and breast disorders	**x(xx%)**	**x(xx%)**	**x(xx%)**
Premenstrual syndrome	x(xx%)	x(xx%)	x(xx%)
Respiratory, thoracic and mediastinal disorders	**x(xx%)**	**x(xx%)**	**x(xx%)**
Asthma	x(xx%)	x(xx%)	x(xx%)
Vascular disorders	**x(xx%)**	**x(xx%)**	**x(xx%)**
Hypertension	x(xx%)	x(xx%)	x(xx%)

n, number of subjects;

Percentages are based on the number of subjects in the evaluable analysis set

Prior and Concomitant Medications

TABLE 14.1.4.1 PRIOR MEDICATION BY ATC LEVEL 4 AND 5 (SAF)

	Treatment A N=xx	Treatment B N=xx	Total N=xx
ATC Name Level 4 ATC Name Level 5	n(%)	n(%)	n(%)
Total	**x(xx%)**	**x(xx%)**	**x(xx%)**
Level 4	**x(xx%)**	**x(xx%)**	**x(xx%)**
Level 5	x(xx%)	x(xx%)	x(xx%)
Level 5	x(xx%)	x(xx%)	x(xx%)
Level 5	x(xx%)	x(xx%)	x(xx%)
Level 4	**x(xx%)**	**x(xx%)**	**x(xx%)**
Level 5	x(xx%)	x(xx%)	x(xx%)
Level 5	x(xx%)	x(xx%)	x(xx%)

n, number of subjects;

Percentages are based on the number of subjects in the safety analysis set

TABLE 14.1.4.2 CONCOMITANT MEDICATION BY ATC LEVEL 4 AND 5 (SAF)

	Treatment A N=xx	Treatment B N=xx	Total N=xx
ATC Name Level 4			
ATC Name Level 5	n(%)	n(%)	n(%)
Total	**x(xx%)**	**x(xx%)**	**x(xx%)**
Level 4	**x(xx%)**	**x(xx%)**	**x(xx%)**
Level 5	x(xx%)	x(xx%)	x(xx%)
Level 5	x(xx%)	x(xx%)	x(xx%)
Level 5	x(xx%)	x(xx%)	x(xx%)
Level 4	**x(xx%)**	**x(xx%)**	**x(xx%)**
Level 5	x(xx%)	x(xx%)	x(xx%)
Level 5	x(xx%)	x(xx%)	x(xx%)

n, number of subjects;

Percentages are based on the number of subjects in the safety analysis set

Study Drug Administration

TABLE 14.1.6 STUDY DRUG ADMINISTRATION (EAS)

Description of Planned Arm	Name of Treatment	Visit Name	N	Mean (SD)	Median (Min, Max)
Study Arm	^{18}F-rhPSMA-7.3	VISIT X	x	x.xx (x.xx)	xx (x.x, x.x)
…		…	…	…	…

Pregnancy test

TABLE 14.1.6 PREGNANCY TEST RESULTS (EAS) – FEMALE SUBJECTS ONLY

Assessment	Visit Name	Result	Treatment A	Treatment B
Post-Menopausal	Visit X	Yes	x(xx%)/x	x(xx%)/x
		No	x(xx%)/x	x(xx%)/x
Surgically Sterile	Visit X	Yes	x(xx%)/x	x(xx%)/x
		No	x(xx%)/x	x(xx%)/x
Pregnancy test	Visit X	Negative	x(xx%)/x	x(xx%)/x
		Positive	x(xx%)/x	x(xx%)/x

Vital Signs

TABLE 14.2.1.1.1 VITAL SIGNS MEASUREMENTS, PULSE (SAF)

Assessment (unit)	Result Category	Visit Name	Planned Study Day of Visit	Planned Time Point Name		TREATMENT GROUP	Total
Pulse Rate (beats/min)	Measured value	VISIT X			N	x	x
					Mean (SD)	xx.x (x.x)	xx.x (x.x)
					Median (Min, Max)	xx.x (xx, xx)	xx.x (xx, xx)
					…	…	…
	Absolute change from baseline	VISIT X			N	x	x
					Mean (SD)	x.x (x.x)	x.x (x.x)
					Median (Min, Max)	x.x (x, x)	x.x (x, x)
					…	…	…

TABLE 14.2.1.1.2 VITAL SIGNS MEASUREMENTS, BLOOD PRESSURE (SAF)

Assessment (unit)	Result Category	Visit Name	Planned Study Day of Visit	Planned Time Point Name		TREATMENT GROUP	Total
Diastolic Blood Pressure (mmHg)	Measured value	VISIT X			N	x	x
					Mean (SD)	xx.x (x.x)	xx.x (x.x)
					Median (Min, Max)	xx.x (xx, xx)	xx.x (xx, xx)
					…	…	…
	Absolute change from baseline	VISIT X			N	x	x
					Mean (SD)	x.x (x.x)	x.x (x.x)
					Median (Min, Max)	x.x (x, x)	x.x (x, x)
					…	…	…
Systolic Blood Pressure (mmHg)	Measured value	VISIT X			N	x	x
					Mean (SD)	xxx.x (x.x)	xxx.x (x.x)
					Median (Min, Max)	xxx.x (xxx, xxx)	xxx.x (xxx, xxx)
					…	…	…
	Absolute change from baseline	VISIT X			N	x	x
					Mean (SD)	x.x (x.x)	x.x (x.x)
					Median (Min, Max)	x.x (x, x)	x.x (x, x)

TABLE 14.2.1.1.3 VITAL SIGNS MEASUREMENTS, BODY TEMPERATURE (SAF)

Assessment (unit)	Result Category	Visit Name	Planned Study Day of Visit	Planned Time Point Name		TREATMENT GROUP	Total
Temperature (C)	Measured value	VISIT X			N	x	x
					Mean (SD)	xx.xx (x.xx)	xx.x (x.x)
					Median (Min, Max)	xx.xx (xx.x, xx.x)	xx.x (xx, xx)
					…	…	…
	Absolute change from baseline	VISIT X			N	x	x
					Mean (SD)	x.xx (x.xx)	x.xx (x.xx)
					Median (Min, Max)	x.xx (x.x, x.x)	x.xx (x.x, x.x)
					…	…	…

TABLE 14.2.1.1.4 VITAL SIGNS MEASUREMENTS, RESPIRATORY RATE (BREATHS/MIN) (SAF)

Assessment (unit)	Result Category	Visit Name	Planned Study Day of Visit	Planned Time Point Name		TREATMENT GROUP	Total
Respiratory rate (breath/min)	Measured value	VISIT X			N	x	x
					Mean (SD)	xx.xx (x.xx)	xx.x (x.x)
					Median (Min, Max)	xx.xx (xx.x, xx.x)	xx.x (xx, xx)
					…	…	…
	Absolute change from baseline	VISIT X			N	x	x
					Mean (SD)	x.xx (x.xx)	x.xx (x.xx)
					Median (Min, Max)	x.xx (x.x, x.x)	x.xx (x.x, x.x)
					…	…	…

TABLE 14.2.1.2 VITAL SIGNS INTERPRETATIONS, (SAF)

Assessment	Visit Name	Planned Study Day of Visit	Planned Time Point Name	Result	TREATMENT GROUP	Total
Pulse Rate (beats/min)	VISIT X			xxx	x(x%)/x	x(xx%)/x
				…	…	…
Systolic Blood Pressure (mmHg)	VISIT X			xxx	x(x%)/x	x(xx%)/x
				…	…	…
Diastolic Blood Pressure (mmHg)	VISIT X			xxx	x(x%)/x	x(xx%)/x
				…	…	…
Temperature (C)	VISIT X			xxx	x(x%)/x	x(xx%)/x
				…	…	…
Respiratory rate (breath/min)	VISIT X			xxx	x(x%)/x	x(xx%)/x
				…	…	…

ECG

TABLE 14.2.2.1.1 12-LEAD ECG MEASURMENTS, QRS DURATION (SAF)

Assessment (unit)	Result Category	Visit Name	Planned Study Day of Visit	Planned Time Point Name		TREATMENT GROUP	Total
QRS Duration, Aggregate (ms)	Measured value	VISIT X			N	x	x
					Mean (SD)	xx.x (x.x)	xx.x (x.x)
					Median (Min, Max)	xx.x (xx, xx)	xx.x (xx, xx)
					…	…	…
	Absolute change from baseline	VISIT X			N	x	x
					Mean (SD)	x.x (x.x)	x.x (x.x)
					Median (Min, Max)	x.x (x, x)	x.x (x, x)
					…	…	…

TABLE 14.2.2.1.2 12-LEAD ECG MEASURMENTS, QT INTERVAL (SAF)

Assessment (unit)	Result Category	Visit Name	Planned Study Day of Visit	Planned Time Point Name		TREATMENT GROUP	Total
QT Interval, Aggregate (ms)	Measured value	VISIT X			N	x	x
					Mean (SD)	xx.x (x.x)	xx.x (x.x)
					Median (Min, Max)	xx.x (xx, xx)	xx.x (xx, xx)
					…	…	…
	Absolute change from baseline	VISIT X			N	x	x
					Mean (SD)	x.x (x.x)	x.x (x.x)
					Median (Min, Max)	x.x (x, x)	x.x (x, x)
					…	…	…

TABLE 14.2.2.1.3 12-LEAD ECG MEASURMENTS, QTCF INTERVAL (SAF)

Assessment (unit)	Result Category	Visit Name	Planned Study Day of Visit	Planned Time Point Name		TREATMENT GROUP	Total
QTcF Interval, Aggregate (ms)	Measured value	VISIT X			N	x	x
					Mean (SD)	xx.x (x.x)	xx.x (x.x)
					Median (Min, Max)	xx.x (xx, xx)	xx.x (xx, xx)
					…	…	…
	Absolute change from baseline	VISIT X			N	x	x
					Mean (SD)	x.x (x.x)	x.x (x.x)
					Median (Min, Max)	x.x (x, x)	x.x (x, x)
					…	…	…

TABLE 14.2.2.1.4 12-LEAD ECG MEASURMENTS, PR INTERVAL (SAF)

Assessment (unit)	Result Category	Visit Name	Planned Study Day of Visit	Planned Time Point Name		TREATMENT GROUP	Total
PR Interval, Aggregate (ms)	Measured value	VISIT X			N	x	x
					Mean (SD)	xx.x (x.x)	xx.x (x.x)
					Median (Min, Max)	xx.x (xx, xx)	xx.x (xx, xx)
					…	…	…
	Absolute change from baseline	VISIT X			N	x	x
					Mean (SD)	x.x (x.x)	x.x (x.x)
					Median (Min, Max)	x.x (x, x)	x.x (x, x)
					…	…	…

TABLE 14.2.2.1.5 12-LEAD ECG MEASURMENTS, ECG MIN HEART RATE (SAF)

Assessment (unit)	Result Category	Visit Name	Planned Study Day of Visit	Planned Time Point Name		TREATMENT GROUP	Total
ECG heart rate (beats/min)	Measured value	VISIT X			N	x	x
					Mean (SD)	xx.x (x.x)	xx.x (x.x)
					Median (Min, Max)	xx.x (xx, xx)	xx.x (xx, xx)
					…	…	…
	Absolute change from baseline	VISIT X			N	x	x
					Mean (SD)	x.x (x.x)	x.x (x.x)
					Median (Min, Max)	x.x (x, x)	x.x (x, x)
					…	…	…

TABLE 14.2.2.2 ECG INTERPRETATIONS (SAF)

Assessment	Visit Name	Planned Study Day of Visit	Planned Time Point Name	Result	TREATMENT GROUP	Total
QRS Duration, Aggregate	VISIT X			xxx	x(x%)/x	x(xx%)/x
				…	…	…
QT Interval, Aggregate	VISIT X			xxx	x(x%)/x	x(xx%)/x
				…	…	…
QTcF Interval, Aggregate	VISIT X			xxx	x(x%)/x	x(xx%)/x
				…	…	…
PR Interval, Aggregate	VISIT X			xxx	x(x%)/x	x(xx%)/x
				…	…	…
ECG min heart rate (beats/min)	VISIT X			xxx	x(x%)/x	x(xx%)/x
				…	…	…

TABLE 14.2.3.1.1 SAFETY LABORATORY RESULTS, HAEMATOLOGY (SAF)

Assessment (unit)	Result Category	Visit Name		TREATMENT GROUP
Haemoglobin (g/L)	Measured value	VISIT X	N	x
			Mean (SD)	xxx.x (x.x)
			Median (Min, Max)	xxx.x (xxx, xxx)
			…	…
	Absolute change from baseline	VISIT X	N	x
			Mean (SD)	x.x (x.x)
			Median (Min, Max)	x.x (xx, x)
			…	…

TABLE 14.2.3.1.2 SAFETY LABORATORY RESULTS, HAEMATOCRIT (SAF)

Assessment (unit)	Result Category	Visit Name		TREATMENT GROUP
Haematocrit (ratio)	Measured value	VISIT X	N	x
			Mean (SD)	xxx.x (x.x)
			Median (Min, Max)	xxx.x (xxx, xxx)
			…	…
	Absolute change from baseline	VISIT X	N	x
			Mean (SD)	x.x (x.x)
			Median (Min, Max)	x.x (xx, x)
			…	…

TABLE 14.2.3.1.3 SAFETY LABORATORY RESULTS, ERYTHROCYTES (SAF)

Assessment (unit)	Result Category	Visit Name		TREATMENT GROUP
Erythrocytes (10^12/L)	Measured value	VISIT X	N	x
			Mean (SD)	xxx.x (x.x)
			Median (Min, Max)	xxx.x (xxx, xxx)
			…	…
	Absolute change from baseline	VISIT X	N	x
			Mean (SD)	x.x (x.x)
			Median (Min, Max)	x.x (xx, x)
			…	

TABLE 14.2.3.1.4 SAFETY LABORATORY RESULTS, MCV (SAF)

Assessment (unit)	Result Category	Visit Name		TREATMENT GROUP
MCV (/L)	Measured value	VISIT X	N	x
			Mean (SD)	xxx.x (x.x)
			Median (Min, Max)	xxx.x (xxx, xxx)
			…	…
	Absolute change from baseline	VISIT X	N	x
			Mean (SD)	x.x (x.x)
			Median (Min, Max)	x.x (xx, x)
			…	…

TABLE 14.2.3.1.5 SAFETY LABORATORY RESULTS, MCH (SAF)

Assessment (unit)	Result Category	Visit Name		TREATMENT GROUP
MCH (pg)	Measured value	VISIT X	N	x
			Mean (SD)	xxx.x (x.x)
			Median (Min, Max)	xxx.x (xxx, xxx)
			…	…
	Absolute change from baseline	VISIT X	N	x
			Mean (SD)	x.x (x.x)
			Median (Min, Max)	x.x (xx, x)
			…	…

TABLE 14.2.3.1.6 SAFETY LABORATORY RESULTS, PLATELETS (SAF)

Assessment (unit)	Result Category	Visit Name		TREATMENT GROUP
Platelets (10^9/L)	Measured value	VISIT X	N	x
			Mean (SD)	xxx.x (x.x)
			Median (Min, Max)	xxx.x (xxx, xxx)
			…	…
	Absolute change from baseline	VISIT X	N	x
			Mean (SD)	x.x (x.x)
			Median (Min, Max)	x.x (xx, x)
			…	…

TABLE 14.2.3.1.7 SAFETY LABORATORY RESULTS, NEUTROPHILS (SAF)

Assessment (unit)	Result Category	Visit Name		TREATMENT GROUP
Neutrophils (10^9/L)	Measured value	VISIT X	N	x
			Mean (SD)	xxx.x (x.x)
			Median (Min, Max)	xxx.x (xxx, xxx)
			…	…
	Absolute change from baseline	VISIT X	N	x
			Mean (SD)	x.x (x.x)
			Median (Min, Max)	x.x (xx, x)
			…	…

TABLE 14.2.3.1.8 SAFETY LABORATORY RESULTS, EOSINOPHILS (SAF)

Assessment (unit)	Result Category	Visit Name		TREATMENT GROUP
Eosinophils (10^9/L)	Measured value	VISIT X	N	x
			Mean (SD)	xxx.x (x.x)
			Median (Min, Max)	xxx.x (xxx, xxx)
			…	…
	Absolute change from baseline	VISIT X	N	x
			Mean (SD)	x.x (x.x)
			Median (Min, Max)	x.x (xx, x)
			…	…

TABLE 14.2.3.1.9 SAFETY LABORATORY RESULTS, BASOPHILS (SAF)

Assessment (unit)	Result Category	Visit Name		TREATMENT GROUP
Basophils (10^9/L)	Measured value	VISIT X	N	x
			Mean (SD)	xxx.x (x.x)
			Median (Min, Max)	xxx.x (xxx, xxx)
			…	…
	Absolute change from baseline	VISIT X	N	x
			Mean (SD)	x.x (x.x)
			Median (Min, Max)	x.x (xx, x)
			…	…

TABLE 14.2.3.1.10 SAFETY LABORATORY RESULTS, LYMPHOCYTES (SAF)

Assessment (unit)	Result Category	Visit Name		TREATMENT GROUP
Lymphocytes (10^9/L)	Measured value	VISIT X	N	x
			Mean (SD)	xxx.x (x.x)
			Median (Min, Max)	xxx.x (xxx, xxx)
			…	…
	Absolute change from baseline	VISIT X	N	x
			Mean (SD)	x.x (x.x)
			Median (Min, Max)	x.x (xx, x)
			…	…

TABLE 14.2.3.1.12 SAFETY LABORATORY RESULTS, MONOCYTES (SAF)

Assessment (unit)	Result Category	Visit Name		TREATMENT GROUP
Monocytes (10^9/L)	Measured value	VISIT X	N	x
			Mean (SD)	xxx.x (x.x)
			Median (Min, Max)	xxx.x (xxx, xxx)
			…	…
	Absolute change from baseline	VISIT X	N	x
			Mean (SD)	x.x (x.x)
			Median (Min, Max)	x.x (xx, x)
			…	…

TABLE 14.2.3.1.2.1 SAFETY LABORATORY INTERPRETATIONS, HAEMATOLOGY (SAF)

Assessment	Visit Name	Planned Study Day of Visit	Planned Time Point Name	Result	TREATMENT GROUP	Total
Haemoglobin	VISIT X			Normal/high/low	x(x%)/x	x(xx%)/x
				…	…	…
Haematocrit	VISIT X			xxx	x(x%)/x	x(xx%)/x
				…	…	…
Erythrocytes	VISIT X			xxx	x(x%)/x	x(xx%)/x
				…	…	…
Leucocytes	VISIT X			xxx	x(x%)/x	x(xx%)/x
				…	…	…
MCV	VISIT X			xxx	x(x%)/x	x(xx%)/x
				…	…	…
MCH	VISIT X			xxx	x(x%)/x	x(xx%)/x
				…	…	…
Platelets	VISIT X			xxx	x(x%)/x	x(xx%)/x
				…	…	…

Assessment	Visit Name	Planned Study Day of Visit	Planned Time Point Name	Result	TREATMENT GROUP	Total
Neutrophils	VISIT X			xxx	x(x%)/x	x(xx%)/x
				…	…	…
Eosinophils	VISIT X			xxx	x(x%)/x	x(xx%)/x
				…	…	…
Basophils	VISIT X			xxx	x(x%)/x	x(xx%)/x
				…	…	…
Lymphocytes	VISIT X			xxx	x(x%)/x	x(xx%)/x
				…	…	…
Monocytes	VISIT X			xxx	x(x%)/x	x(xx%)/x
				…	…	…

Safety Laboratory – Clinical Chemistry

TABLE 14.2.3.2.1 SAFETY LABORATORY RESULTS, ALKALINE (SAF)

Assessment (unit)	Result Category	Visit Name		TREATMENT GROUP
Alkaline Phosphatase (U/L)	Measured value	VISIT X	N	x
			Mean (SD)	xxx.x (x.x)
			Median (Min, Max)	xxx.x (xxx, xxx)
			…	…
	Absolute change from baseline	VISIT X	N	x
			Mean (SD)	x.x (x.x)
			Median (Min, Max)	x.x (xx, x)
			…	…

TABLE 14.2.3.2.2 SAFETY LABORATORY RESULTS, ALANINE AMINOTRANSFERASE (SAF)

Assessment (unit)	Result Category	Visit Name		TREATMENT GROUP
Alanine aminotransferase (U/L)	Measured value	VISIT X	N	x
			Mean (SD)	xxx.x (x.x)
			Median (Min, Max)	xxx.x (xxx, xxx)
			…	…
	Absolute change from baseline	VISIT X	N	x
			Mean (SD)	x.x (x.x)
			Median (Min, Max)	x.x (xx, x)
			…	…

TABLE 14.2.3.2.3 SAFETY LABORATORY RESULTS, ASPARTATE AMINOTRANSFERASE (SAF)

Assessment (unit)	Result Category	Visit Name		TREATMENT GROUP
Aspartate aminotransferase (U/L)	Measured value	VISIT X	N	x
			Mean (SD)	xxx.x (x.x)
			Median (Min, Max)	xxx.x (xxx, xxx)
			…	…
	Absolute change from baseline	VISIT X	N	x
			Mean (SD)	x.x (x.x)
			Median (Min, Max)	x.x (xx, x)
			…	…

TABLE 14.2.3.2.4 SAFETY LABORATORY RESULTS, GAMMA-GLUTAMYL TRANSFERASE (SAF)

Assessment (unit)	Result Category	Visit Name		TREATMENT GROUP
Gamma-glutamyl transferase (U/L)	Measured value	VISIT X	N	x
			Mean (SD)	xxx.x (x.x)
			Median (Min, Max)	xxx.x (xxx, xxx)
			…	…
	Absolute change from baseline	VISIT X	N	x
			Mean (SD)	x.x (x.x)
			Median (Min, Max)	x.x (xx, x)
			…	…

TABLE 14.2.3.2.5 SAFETY LABORATORY RESULTS, ALBUMIN (SAF)

Assessment (unit)	Result Category	Visit Name		TREATMENT GROUP
Albumin (g/L)	Measured value	VISIT X	N	x
			Mean (SD)	xxx.x (x.x)
			Median (Min, Max)	xxx.x (xxx, xxx)
			…	…
	Absolute change from baseline	VISIT X	N	x
			Mean (SD)	x.x (x.x)
			Median (Min, Max)	x.x (xx, x)
			…	…

TABLE 14.2.3.2.6 SAFETY LABORATORY RESULTS, TOTAL PROTEIN (SAF)

Assessment (unit)	Result Category	Visit Name		TREATMENT GROUP
Total protein (g/L)	Measured value	VISIT X	N	x
			Mean (SD)	xxx.x (x.x)
			Median (Min, Max)	xxx.x (xxx, xxx)
			…	…
	Absolute change from baseline	VISIT X	N	x
			Mean (SD)	x.x (x.x)
			Median (Min, Max)	x.x (xx, x)
			…	…

TABLE 14.2.3.2.7 SAFETY LABORATORY RESULTS, TOTAL BILIRUBIN (SAF)

Assessment (unit)	Result Category	Visit Name		TREATMENT GROUP
Total bilirubin (umol/L)	Measured value	VISIT X	N	x
			Mean (SD)	xxx.x (x.x)
			Median (Min, Max)	xxx.x (xxx, xxx)
			…	…
	Absolute change from baseline	VISIT X	N	x
			Mean (SD)	x.x (x.x)
			Median (Min, Max)	x.x (xx, x)
			…	…

TABLE 14.2.3.2.8 SAFETY LABORATORY RESULTS, CONJUGATED BILIRUBIN (SAF)

Assessment (unit)	Result Category	Visit Name		TREATMENT GROUP
Conjugated bilirubin (umol/L)	Measured value	VISIT X	N	x
			Mean (SD)	xxx.x (x.x)
			Median (Min, Max)	xxx.x (xxx, xxx)
			…	…
	Absolute change from baseline	VISIT X	N	x
			Mean (SD)	x.x (x.x)
			Median (Min, Max)	x.x (xx, x)
			…	…

TABLE 14.2.3.2.9 SAFETY LABORATORY RESULTS, CREATININE (SAF)

Assessment (unit)	Result Category	Visit Name		TREATMENT GROUP
Creatinine (umol/L)	Measured value	VISIT X	N	x
			Mean (SD)	xxx.x (x.x)
			Median (Min, Max)	xxx.x (xxx, xxx)
			…	…
	Absolute change from baseline	VISIT X	N	x
			Mean (SD)	x.x (x.x)
			Median (Min, Max)	x.x (xx, x)

TABLE 14.2.3.2.10 SAFETY LABORATORY RESULTS, UREA NITROGEN (BUN) (SAF)

Assessment (unit)	Result Category	Visit Name		TREATMENT GROUP
BUN (mmol/L)	Measured value	VISIT X	N	x
			Mean (SD)	xxx.x (x.x)
			Median (Min, Max)	xxx.x (xxx, xxx)
			…	…
	Absolute change from baseline	VISIT X	N	x
			Mean (SD)	x.x (x.x)
			Median (Min, Max)	x.x (xx, x)
			…	….

TABLE 14.2.3.2.11 SAFETY LABORATORY RESULTS, CHLORIDE (SAF)

Assessment (unit)	Result Category	Visit Name		TREATMENT GROUP
Chloride (mmol/L)	Measured value	VISIT X	N	x
			Mean (SD)	xxx.x (x.x)
			Median (Min, Max)	xxx.x (xxx, xxx)
			…	…
	Absolute change from baseline	VISIT X	N	x
			Mean (SD)	x.x (x.x)
			Median (Min, Max)	x.x (xx, x)

TABLE 14.2.3.2.12 SAFETY LABORATORY RESULTS, POTASSIUM (SAF)

Assessment (unit)	Result Category	Visit Name		TREATMENT GROUP
Potassium (mmol/L)	Measured value	VISIT X	N	x
			Mean (SD)	xxx.x (x.x)
			Median (Min, Max)	xxx.x (xxx, xxx)
			…	…
	Absolute change from baseline	VISIT X	N	x
			Mean (SD)	x.x (x.x)
			Median (Min, Max)	x.x (xx, x)
			…	…

TABLE 14.2.3.2.13 SAFETY LABORATORY RESULTS, SODIUM (SAF)

Assessment (unit)	Result Category	Visit Name		TREATMENT GROUP
Sodium (mmol/L)	Measured value	VISIT X	N	x
			Mean (SD)	xxx.x (x.x)
			Median (Min, Max)	xxx.x (xxx, xxx)
			…	…
	Absolute change from baseline	VISIT X	N	x
			Mean (SD)	x.x (x.x)
			Median (Min, Max)	x.x (xx, x)

TABLE 14.2.3.2.14 SAFETY LABORATORY RESULTS, C-REACTIVE PROTIEN (SAF)

Assessment (unit)	Result Category	Visit Name		TREATMENT GROUP
C-reactive protein (mg/L)	Measured value	VISIT X	N	x
			Mean (SD)	xxx.x (x.x)
			Median (Min, Max)	xxx.x (xxx, xxx)
			…	…
	Absolute change from baseline	VISIT X	N	x
			Mean (SD)	x.x (x.x)
			Median (Min, Max)	x.x (xx, x)
			…	…

TABLE 14.2.3.2.16 SAFETY LABORATORY RESULTS, FSH (FEMALE VOLUNTEERS ONLY) (SAF)

Assessment (unit)	Result Category	Visit Name		TREATMENT GROUP
FSH (female volunteers only) (U/L)	Measured value	VISIT X	N	x
			Mean (SD)	xxx.x (x.x)
			Median (Min, Max)	xxx.x (xxx, xxx)
			…	…
	Absolute change from baseline	VISIT X	N	x
			Mean (SD)	x.x (x.x)
			Median (Min, Max)	x.x (xx, x)
			…	…

TABLE 14.2.3.2.17 SAFETY LABORATORY RESULTS, SERUM β-hCG-PREGNANCY TEST (FEMALE VOLUNTEERS ONLY) (SAF)

Assessment (unit)	Result Category	Visit Name		TREATMENT GROUP
Serum β-hCG pregnancy test (female volunteers only) (U/L)	Measured value	VISIT X	N	x
			Mean (SD)	xxx.x (x.x)
			Median (Min, Max)	xxx.x (xxx, xxx)
			…	…
	Absolute change from baseline	VISIT X	N	x
			Mean (SD)	x.x (x.x)
			Median (Min, Max)	x.x (xx, x)
			…	…

TABLE 14.2.3.3.1 PSA (SAF)

Assessment (unit)	Result Category	Visit Name		TREATMENT GROUP
PSA (ng/mL))	Measured value	VISIT X	N	x
			Mean (SD)	xxx.x (x.x)
			Median (Min, Max)	xxx.x (xxx, xxx)
			…	…
	Absolute change from baseline	VISIT X	N	x
			Mean (SD)	x.x (x.x)
			Median (Min, Max)	x.x (xx, x)
			…	…

TABLE 14.2.3.2.2 SAFETY LABORATORY INTERPRETATIONS, CLINICAL CHEMISTRY (SAF)

Assessment	Visit Name	Planned Study Day of Visit	Planned Time Point Name	Result	TREATMENT GROUP	Total
Alkaline (ukat/L)	VISIT X			Low	x(x%)/x	x(x%)/x
				Normal	x(x%)/x	x(x%)/x
				High	x(x%)/x	x(x%)/x
				…	…	…
Alanine aminotransferase (ukat/L)	VISIT X			xxx	x(x%)/x	x(xx%)/x
				…	…	…
Aspartate aminotransferase (ukat/L)	VISIT X			xxx	x(x%)/x	x(xx%)/x
				…	…	…
Gamma-glutamyl transferase (ukat/L)	VISIT X			xxx	x(x%)/x	x(xx%)/x
				…	…	…
Total bilirubin (unit)	VISIT X			xxx	x(x%)/x	x(xx%)/x
				…	…	…
Conjugated bilirubin (unit)	VISIT X			xxx	x(x%)/x	x(xx%)/x
				…	…	…
Creatinine (umol/L)	VISIT X			xxx	x(x%)/x	x(xx%)/x

Assessment	Visit Name	Planned Study Day of Visit	Planned Time Point Name	Result	TREATMENT GROUP	Total
				…	…	…
Urea nitrogen (BUN) (mmol/L)	VISIT X			xxx	x(x%)/x	x(xx%)/x
				…	…	…
Potassium (mmol/L)	VISIT X			xxx	x(x%)/x	x(xx%)/x
				…	…	…
Sodium (mmol/L)	VISIT X			xxx	x(x%)/x	x(xx%)/x
				…	…	…
C-reactive protein (mg/L)	VISIT X			xxx	x(x%)/x	x(xx%)/x
				…	…	…
FSH (female volunteers only) (U/L)	VISIT X			xxx	x(x%)/x	x(xx%)/x
				…	…	…
Serum β-hCG pregnancy test (female volunteers only) (U/L)	VISIT X			xxx	x(x%)/x	x(xx%)/x
				…	…	…

Safety Laboratory – Coagulation

TABLE 14.2.3.3.1 SAFETY LABORATORY RESULTS, COAGULATION (SAF)

Assessment (unit)	Result Category	Visit Name		TREATMENT GROUP
Activated Partial Thromboplastin Time (s)	Measured value	VISIT X	N	x
			Mean (SD)	xxx.x (x.x)
			Median (Min, Max)	xxx.x (xxx, xxx)
			…	…
	Absolute change from baseline	VISIT X	N	x
			Mean (SD)	x.x (x.x)
			Median (Min, Max)	x.x (xx, x)
			…	…
Prothrombin Intl. Normalized Ratio (ratio)	Measured value	VISIT X	N	x
			Mean (SD)	xxx.x (x.x)
			Median (Min, Max)	xxx.x (xxx, xxx)
			…	…
	Absolute change from baseline	VISIT X	N	x
			Mean (SD)	x.x (x.x)
			Median (Min, Max)	x.x (xx, x)
			…	….

TABLE 14.2.3.3.2 SAFETY LABORATORY INTERPRETATIONS, COAGULATION (SAF)

Assessment	Visit Name	Planned Study Day of Visit	Planned Time Point Name	Result	TREATMENT GROUP	Total
Activated Partial Thromboplastin Time	VISIT X			xxx	x(x%)/x	x(xx%)/x
				…	…	…
Prothrombin Intl. Normalized Ratio	VISIT X			xxx	x(x%)/x	x(xx%)/x
				…	…	…

Safety Laboratory – Urine

TABLE 14.2.3.4.1.1 SAFETY LABORATORY RESULTS, URINE - pH (SAF)

Assessment	Result Category	Visit Name		TREATMENT GROUP
pH	Measured value	VISIT X	N	x
			Mean (SD)	xxx.x (x.x)
			Median (Min, Max)	xxx.x (xxx, xxx)
			…	…
	Absolute change from baseline	VISIT X	N	x
			Mean (SD)	x.x (x.x)
			Median (Min, Max)	x.x (xx, x)

TABLE 14.2.3.4.1.2 SAFETY LABORATORY RESULTS, URINE - RBC (SAF)

Assessment	Result Category	Visit Name		TREATMENT GROUP
RBC	Measured value	VISIT X	N	x
			Mean (SD)	xxx.x (x.x)
			Median (Min, Max)	xxx.x (xxx, xxx)
			…	…
	Absolute change from baseline	VISIT X	N	x
			Mean (SD)	x.x (x.x)
			Median (Min, Max)	x.x (xx, x)

TABLE 14.2.3.4.1.3 SAFETY LABORATORY RESULTS, URINE - WBC (SAF)

Assessment	Result Category	Visit Name		TREATMENT GROUP
WBC	Measured value	VISIT X	N	x
			Mean (SD)	xxx.x (x.x)
			Median (Min, Max)	xxx.x (xxx, xxx)
			…	…
	Absolute change from baseline	VISIT X	N	x
			Mean (SD)	x.x (x.x)
			Median (Min, Max)	x.x (xx, x)

TABLE 14.2.3.4.1.4 SAFETY LABORATORY RESULTS, URINE - NITRITE (SAF)

Assessment	Result Category	Visit Name		TREATMENT GROUP
Nitrite	Measured value	VISIT X	N	x
			Mean (SD)	xxx.x (x.x)
			Median (Min, Max)	xxx.x (xxx, xxx)
			…	…
	Absolute change from baseline	VISIT X	N	x
			Mean (SD)	x.x (x.x)
			Median (Min, Max)	x.x (xx, x)

TABLE 14.2.3.4.1.5 SAFETY LABORATORY RESULTS, URINE - PROTEIN (SAF)

Assessment	Result Category	Visit Name		TREATMENT GROUP
Protein	Measured value	VISIT X	N	x
			Mean (SD)	xxx.x (x.x)
			Median (Min, Max)	xxx.x (xxx, xxx)
			…	…
	Absolute change from baseline	VISIT X	N	x
			Mean (SD)	x.x (x.x)
			Median (Min, Max)	x.x (xx, x)

TABLE 14.2.3.4.1.6 SAFETY LABORATORY RESULTS, URINE - GLUCOSE (SAF)

Assessment	Result Category	Visit Name		TREATMENT GROUP
Glucose	Measured value	VISIT X	N	x
			Mean (SD)	xxx.x (x.x)
			Median (Min, Max)	xxx.x (xxx, xxx)
			…	…
	Absolute change from baseline	VISIT X	N	x
			Mean (SD)	x.x (x.x)
			Median (Min, Max)	x.x (xx, x)

TABLE 14.2.3.4.1.7 SAFETY LABORATORY RESULTS, URINE KETONES (SAF)

Assessment	Result Category	Visit Name		TREATMENT GROUP
Ketones	Measured value	VISIT X	N	x
			Mean (SD)	xxx.x (x.x)
			Median (Min, Max)	xxx.x (xxx, xxx)
			…	…
	Absolute change from baseline	VISIT X	N	x
			Mean (SD)	x.x (x.x)
			Median (Min, Max)	x.x (xx, x)

TABLE 14.2.3.4.2 SAFETY LABORATORY INTERPRETATIONS, URINE (SAF)

					TREATMENT GROUP	Total
Assessment	Visit Name	Planned Study Day of Visit	Planned Time Point Name	Result		
pH	VISIT X			xxx	x(x%)/x	x(xx%)/x
				…	…	…
RBC	VISIT X			xxx	x(x%)/x	x(xx%)/x
				…	…	…
WBC	VISIT X			xxx	x(x%)/x	x(xx%)/x
				…	…	…
Nitrite	VISIT X			xxx	x(x%)/x	x(xx%)/x
				…	…	…
Protein	VISIT X			xxx	x(x%)/x	x(xx%)/x
				…	…	…
Glucose	VISIT X			xxx	x(x%)/x	x(xx%)/x
				…	…	…
Ketones	VISIT X			xxx	x(x%)/x	x(xx%)/x
				…	…	…

Physical Examination

TABLE 14.2.4 PHYSICAL EXAMINATION (SAF)

			TREATMENT GROUP	Total
Assessment				
Head	Visit X	Normal	x(x%)/x	x(xx%)/x
	…	…	…	…
Eyes, Ears, Nose, Throat	Visit X	Normal	x(x%)/x	x(xx%)/x
	…	…	…	…
Cardiovascular	Visit X	Normal	x(x%)/x	x(xx%)/x
	…	…	…	…
Respiratory	Visit X	Normal	x(x%)/x	x(xx%)/x
	…	…	…	…
Musculoskeletal	Visit X	Normal	x(x%)/x	x(xx%)/x
	….	…	…	…
Gastrointestinal	Visit X	Normal	x(x%)/x	x(xx%)/x
	…	…	…	…
Hepatic	Visit X	Normal	x(x%)/x	x(xx%)/x
	…	…	…	…

Assessment			TREATMENT GROUP	Total
Psyche	Visit X	Normal	x(x%)/x	x(xx%)/x
	…	…	…	…
Endocrine	Visit X	Normal	x(x%)/x	x(xx%)/x
	…	…	…	…
Dermatologic	Visit X	Normal	x(x%)/x	x(xx%)/x
	…	…	…	…
Lymph nodes	Visit X	Normal	x(x%)/x	x(xx%)/x
	…	…	…	…

Gleason Grade and Score

TABLE 14.2.9 GLEASON GRADE AND SCORE, (PATIENT ONLY)

Assessment	Visit	Grade	Patient only
Primary Grade	Visit X	1	x(x%)/x
		2	x(x%)/x
		3	x(x%)/x
		4	x(x%)/x
		5	x(x%)/x
	…	…	…
Secondary Grade	Visit X	1	x(x%)/x
		2	x(x%)/x
		3	x(x%)/x
		4	x(x%)/x
		5	x(x%)/x
	…	…	…
Tertiary Grade	Visit X	1	x(x%)/x
		2	x(x%)/x
		3	x(x%)/x
		4	x(x%)/x
		5	x(x%)/x
	…	…	…
Gleason Grade	Visit X	1	x(x%)/x
		2	x(x%)/x

Assessment	Visit	Grade	Patient only
		3	x(x%)/x
		4	x(x%)/x
		5	x(x%)/x
	…	…	x(x%)/x

Histopathology Results

TABLE 14.2.10 HISTOPATHOLOGY RESULTS, (PATIENT ONLY)

Overview of Treatment Emergent Adverse Events

TABLE 14.3.1.1.1 OVERVIEW OF TREATMENT EMERGENT ADVERSE EVENTS, EAS

	Treatment A N=XX	Treatment B N=XX	Total N=XX
	n(%)	n(%)	n(%)
Any TEAE	x(xx%)	x(xx%)	x(xx%)
Any IMP-related TEAE	x(xx%)	x(xx%)	x(xx%)
Any SAE	x(xx%)	x(xx%)	x(xx%)
Any IMP-related SAE	x(xx%)	x(xx%)	x(xx%)
Any AE leading to withdrawal	x(xx%)	x(xx%)	x(xx%)
Any AE leading to death	x(xx%)	x(xx%)	x(xx%)
Severity			
Mild	x(xx%)	x(xx%)	x(xx%)
Moderate	x(xx%)	x(xx%)	x(xx%)
Sever	x(xx%)	x(xx%)	x(xx%)

n, number of subjects; m, number of events

Percentages are based on the number of subjects in the treatment period included in the evaluable analysis set.

Adverse events that occurred during follow-up are omitted from summary.

Overview of Pre-Treatment Adverse Events

TABLE 14.3.1.1.2 OVERVIEW OF PRE-TREATMENT ADVERSE EVENTS, SAF

	Treatment A N=XX n(%)	Treatment B N=XX n(%)	Total N=XX n(%)
Any TEAE	x(xx%)	x(xx%)	x(xx%)
Any IMP-related TEAE	x(xx%)	x(xx%)	x(xx%)
Any SAE	x(xx%)	x(xx%)	x(xx%)
Any IMP-related SAE	x(xx%)	x(xx%)	x(xx%)
Any AE leading to withdrawal	x(xx%)	x(xx%)	x(xx%)
Any AE leading to death	x(xx%)	x(xx%)	x(xx%)
Severity			
Mild	x(xx%)	x(xx%)	x(xx%)
Moderate	x(xx%)	x(xx%)	x(xx%)
Sever	x(xx%)	x(xx%)	x(xx%)
Relationship			
Not related	x(xx%)	x(xx%)	x(xx%)
Related	x(xx%)	x(xx%)	x(xx%)
Not applicable	x(xx%)	x(xx%)	x(xx%)

n, number of subjects;

Percentages are based on the number of subjects in the treatment period included in the evaluable analysis set.

Adverse events that occurred during follow-up are omitted from summary.

Treatment Emergent Adverse Events by System Organ Class and Preferred Term

TABLE 14.3.1.2.1 TREATMENT EMERGENT ADVERSE EVENTS BY SYSTEM ORGAN CLASS AND PREFERRED TERM, EAS

	Treatment A N=XX	Treatment B N=XX	Total N=XX
System organ class Preferred term	n(%)	n(%)	n(%)
Gastrointestinal disorders	**x(xx%)**	**x(xx%)**	**x(xx%)**
Dry mouth	**x(xx%)**	**x(xx%)**	**x(xx%)**
Gingival blister	**x(xx%)**	**x(xx%)**	**x(xx%)**
Lip pain	**x(xx%)**	**x(xx%)**	**x(xx%)**
Nausea	**x(xx%)**	**x(xx%)**	**x(xx%)**
Infections and infestations	**x(xx%)**	**x(xx%)**	**x(xx%)**
Diarrhoea infectious	**x(xx%)**	**x(xx%)**	**x(xx%)**
Gastroenteritis viral	**x(xx%)**	**x(xx%)**	**x(xx%)**
Influenza	**x(xx%)**	**x(xx%)**	**x(xx%)**
Nasopharyngitis	**x(xx%)**	**x(xx%)**	**x(xx%)**
Nervous system disorders	**x(xx%)**	**x(xx%)**	**x(xx%)**
Dizziness	**x(xx%)**	**x(xx%)**	**x(xx%)**

n, number of subjects;

Percentages are based on the number of subjects in the treatment period included in the evaluable analysis set.

Adverse events that occurred during follow-up are omitted from summary.

Pre-Treatment Adverse Events by System Organ Class and Preferred Term

TABLE 14.3.1.2.2 PRE-TREATMENT ADVERSE EVENTS BY SYSTEM ORGAN CLASS AND PREFERRED TERM, EAS

	Treatment A N=XX	Treatment B N=XX	Total N=XX
System organ class Preferred term	n(%)	n(%)	n(%)
Gastrointestinal disorders	**x(xx%)**	**x(xx%)**	**x(xx%)**
Dry mouth	**x(xx%)**	**x(xx%)**	**x(xx%)**
Gingival blister	**x(xx%)**	**x(xx%)**	**x(xx%)**
Lip pain	**x(xx%)**	**x(xx%)**	**x(xx%)**
Nausea	**x(xx%)**	**x(xx%)**	**x(xx%)**
Infections and infestations	**x(xx%)**	**x(xx%)**	**x(xx%)**
Diarrhoea infectious	**x(xx%)**	**x(xx%)**	**x(xx%)**
Gastroenteritis viral	**x(xx%)**	**x(xx%)**	**x(xx%)**
Influenza	**x(xx%)**	**x(xx%)**	**x(xx%)**
Nasopharyngitis	**x(xx%)**	**x(xx%)**	**x(xx%)**
Nervous system disorders	**x(xx%)**	**x(xx%)**	**x(xx%)**
Dizziness	**x(xx%)**	**x(xx%)**	**x(xx%)**

n, number of subjects;

Percentages are based on the number of subjects in the treatment period included in the evaluable analysis set.

Adverse events that occurred during follow-up are omitted from summary.

13.2Listings

Discontinued Subjects

LISTING 16.2.1.1 DISCONTINUED SUBJECTS (ALL SUBJECTS)

Description of Planned Arm	Unique Subject Identifier	Date of discontinuation (Study Day)	Reason for discontinuation	Standardised term for reason for discontinuation
Study Arm	Subject ID	YYYY-MM-DD (XX)	Disposition Event	Disposition Event
…	…	…	…	…

Protocol Deviations

LISTING 16.2.2. PROTOCOL DEVIATIONS (ALL SUBJECTS)

Description of Planned Arm	Subject Identifier for the Study	Sequence Number	Protocol Deviation Term	Other Action Taken
Study Arm	Subject ID	x	Deviation Term	Action Term
	…	…	…	…

Analysis Sets

LISTING 16.2.3.1 ANALYSIS SETS (ALL SUBJECTS)

Description of Planned Arm	Subject Identifier for the Study	Evaluable Analysis Set	Safety Analysis Set
Study Arm	Subject ID	Y/N	Y/N
…	…	…	…

Reason for Exclusion from Analysis Sets

LISTING 16.2.3.2 REASON FOR EXCLUSION FROM ANALYSIS SETS (ALL SUBJECTS)

Description of Planned Arm	Subject Identifier for the Study	Population	Reason for Exclusion
Study Arm	Subject ID	EAS/SAF	Reason
…	…		…

Inclusion/Exclusion Exceptions

LISTING 16.2.3.3 INCLUSION/EXCLUSION EXPECTIONS (ALL SUBJECTS)

Description of Planned Arm	Subject Identifier for the Study	Date/Time of Collection (Study Day)	Inclusion/Exclusion Category	Inclusion/Exclusion Criterion	I/E Criterion Result in Std Format
Study Arm	Subject ID	YYYY-MM-DD (xx)	Exclusion	Exclusion Criterion	Y/N
…	…	…	…	…	…

Demography

LISTING 16.2.4.1. DEMOGRAPHIC DATA (SAF)

Description of Planned Arm	Subject Identifier for the Study	Age	Sex	Ethnicity	Race	Use of Nicotine
Study Arm	Subject ID	xx	M/F	xxx	xxx	Y/N
…	…	…	…	…	…	…

Alcohol and Drug Abuse During Study Period

LISTING 16.2.4.3 ALCOHOL AND DRUG ABUSE DURING STUDY (SAF)

Description of Planned Arm	Subject Identifier for the Study	Visit Name	Date/Time of Alcohol Test (Study Day)	Alcohol Test Result	Date/Time of Drug Test (Study Day)	Drug Test Result
Study Arm	Subject ID	Visit x	YYYY-MM-DD (XX)	Negative/Positive	YYYY-MM-DD (XX)	Negative/Positive
Study Arm	Subject ID	Visit x	YYYY-MM-DD (XX)	Negative/Positive	YYYY-MM-DD (XX)	Negative/Positive
…	…	…	…	…	…	…

Virology Screen

LISTING 16.2.4.4 VIROLOGY SCREEN, ECOG (SAF)

Description of Planned Arm	Subject Identifier for the Study	Visit Name	Date/Time of Virology Screen (Study Day)	Test Result
Study Arm	Subject ID	Visit 1	YYYY-MM-DD (xx)	Negative/Positive
…	…		…	…

Pregnancy Test

LISTING 16.2.4.5 PREGNANCY TEST RESULTS (SAF) – FEMALE SUBJECTS ONLY

Description of Planned Arm	Subject Identifier for the Study	Visit Name	Post-menopausal	Surgically Sterile	Lab Test or Examination Name	Date/Time of Pregnancy Test (Study Day)	Type of Pregnancy Test	Test Result
Study Arm	Subject ID	Visit 1	Yes/No	Yes/No	Pregnancy test	YYYY-MM-DD (xx)	Urine / Serum	Negative/Positive
…	…				…	…		…

Medical History

LISTING 16.2.5.1 MEDICAL HISTORY (SAF)

Description of Planned Arm	Subject Identifier for the Study	Reported Term for the Medical History	Dictionary-Derived Term	Body System or Organ Class	Start Date of Medical History Event (Study Day)	End Date of Medical History Event (Study Day)
Study Arm	Subject ID	Medical Term	Term	System	YYYY-MM-DD (XX)	YYYY-MM-DD (XX)
…	…	…	…	…	…	…

Disease History and Therapies for PSA

LISTING 16.2.5.2. PROSTATE CANCER HISTORY

Description of Planned Arm	Subject Identifier for the Study	Date of initial prostate cancer diagnosis (Study Day)	Therapy	Therapy Name	Dose	Unit	Route	Start Date (Study Day)	End Date (Study Day)	Ongoing
Study Arm	Subject ID	YYYY-MM-DD (XX)	xx	xx	xx	xx	xx	xx	xx	xx
…	…	…	…	…	…	…	…	…	…	…

LISTING 16.2.5.3. DISEASE THERAPIES FOR PSA (ONLY PATIENT POPULAITON)

Description of Planned Arm	Subject Identifier for the Study	Sequence Number	Start Date/Time of Medical History Event	End Date/Time of Medical History Event	Study Day of Start of Observation	Study Day of End of Observation	PSA value	PSA baseline
Study Arm	Subject ID	x	YYYY-MM-DD	YYYY-MM-DD	xxx	xxx	x	Y/N
…	…	…	…	…	…	…		

PSA Laboratory Results (Historic Measurements)

LISTING 16.2.5.3. PSA LABORATORY RESULTS (HISTORIC MEASUREMENTS) (ONLY PATIENT POPULAITON)

Description of Planned Arm	Subject Identifier for the Study	Date of PSA (Study Day)	Result (ng/mL)
Study Arm	Subject ID	YYYY-MM-DD (XX)	xx.x
…	…	…	…

Concomitant medications

LISTING 16.2.6.1 CONCOMITANT MEDICATIONS, INDICATIONS (SAF)

TREATMENT GROUP = XXX

Subject Identifier for the Study	Reported Name of Drug, Med, or Therapy	Standardized Medication Name ATC Level 5 (ATC Level 4)	Medication Class Code	Category for Medication	Details	Dose Description	Dose Units	Route of Administration	Dosing Frequency per Interval	Dose Form	Start Date (Study Day)	End Date (Study Day)
Subject ID	Xxx	xxx (xxx)	xx	Medical/ surgical history	MH/AE term	xx	mg	Oral	Daily	Tablet	YYYY-MM-DD (XX)	YYYY-MM-DD (XX)
…	…	…	…	…		…	…	…	…	…	…	…

Study Drug Administration

LISTING 16.2.7. ADMINISTRATION OF (SAF) ^{18}F-rhPSMA-7.3 (SAF)

Descripted of Planned Arm	Subject Identifier for the Study	Visit Name	Start Date/time (Study Day)	Planned Time Point Name	Injection site reaction	Site of administration	Total Volume of undiluted IMP (mL)	Total administration activity (MBq)	Administration per protocol	Injection site reaction
Study Arm	Subject ID	VISIT X	YYYY-MM-DDTHH:MM (XX)	Time Point	xxx	xxx	xxx	xxx	xxx	xxx
…	…	…	…	…	…	…				

LISTING 16.2.4.2. VITAL SIGNS – BMI, HEIGHT AND WEIGHT (SAF)

Description of Planned Arm	Subject Identifier for the Study	Visit Name	Planned Time Point Name	Date/Time of Measurements (Study Day)	Height (cm)	Weight (kg)	Body Mass Index (kg/m^2)
Study Arm	Subject ID	VISIT X	Time point	YYYY-MM-DD THH:MM (XX)	xxx	xx	xx.x
…	…	…	…	…	…	…	…

LISTING 16.2.4.3. VITAL SIGNS (SAF)

Description of Planned Arm	Subject Identifier for the Study	Visit Name	Planned Time Point Name	Date/Time of Measurements (Study Day)	Temperature (C°)	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Pulse Rate (beats/min)	Respiratory Rate (breaths/min)
Study Arm	Subject ID	VISIT X	Time point	YYYY-MM-DD THH:MM (XX)	xx.x	xxx	xxx	xx	xx
…	…	…	…	…	…	…	…	…	…

12-lead ECG Measurements

LISTING 16.2.9. 12-LEAD ECG MEASUREMENTS (SAF)

Description of Planned Arm	Subject Identifier for the Study	Visit Name	Planned Time Point Name	Date/Time of ECG (Study Day)	QRS Duration Aggregate (ms)	QT Interval Aggregate (ms)	QTcF Interval Aggregate (ms)	PR Interval (ms)	ECG Mean Heart Rate (beats/min)	Interpretation of ECG results
Study Arm	Subject ID	VISIT X	Time point	YYYY-MM-DDTHH:MM (xx)	xx	xx	xx	xx	xx	Normal/Abnormal. NCS/Abnormal, CS
…	…	…	…	…	…	…	…	…	…	…

Safety Laboratory Results – Haematology

LISTING 16.2.10.1. LABORATORY VALUES. HAEMATOLOGY (SAF)

Description of Planned Arm	Subject Identifier for the Study	Lab Test or Examination Name	Visit Name	Planned Time Point Name	Date/Time of Specimen Collection (Study Day)	Character Result/Finding in Std Format	Standard Units	Normal Range Indicator	Lower Reference Limit	Upper Reference Limit	Interpretation
Study Arm	Subject ID	Haemoglobin	VISIT X	Time point	YYYY-MM-DDTHH:MM (XX)	xx	g/L	x	x	x	x
…	…	…	…	…	…	…	…	…	…	…	…
Study Arm	Subject ID	Haematocrit	VISIT X	Time point	YYYY-MM-DDTHH:MM (XX)	xx	L/L	x	x	x	x
…	…	…	…	…	…	…	…	…	…	…	…
Study Arm	Subject ID	Erythrocytes	VISIT X	Time point	YYYY-MM-DDTHH:MM (XX)	xx	10^12/L	x	x	x	x
…	…	…	…	…	…	…	…	…	…	…	…
Study Arm	Subject ID	MCV	VISIT X	Time point	YYYY-MM-DDTHH:MM (XX)	xx		x	x	x	x
…	…	…	…	…	…	…	…	…	…	…	…
Study Arm	Subject ID	MCH	VISIT X	Time point	YYYY-MM-DDTHH:MM (XX)	xx	pg/cell	x	x	x	x
…	…	…	…	…	…	…	…	…	…	…	…
Study Arm	Subject ID	Platelets	VISIT X	Time point	YYYY-MM-DDTHH:MM (XX)	xx	10^9/L	x	x	x	x
…	…	…	…	…	…	…	…	…	…	…	…
Study Arm	Subject ID	Neutrophils	VISIT X	Time point	YYYY-MM-DDTHH:MM (XX)	xx	10^9/L	x	x	x	x
…	…	…	…	…	…	…	…	…	…	…	…

Description of Planned Arm	Subject Identifier for the Study	Lab Test or Examination Name	Visit Name	Planned Time Point Name	Date/Time of Specimen Collection (Study Day)	Character Result/Finding in Std Format	Standard Units	Normal Range Indicator	Lower Reference Limit	Upper Reference Limit	Interpretation
Study Arm	Subject ID	Eosinophils	VISIT X	Time point	YYYY-MM-DDTHH:MM (XX)	xx	10^9/L	x	x	x	x
…	…	…	…	…	…	…	…	…	…	…	…
Study Arm	Subject ID	Basophils	VISIT X	Time point	YYYY-MM-DDTHH:MM (XX)	xx	10^9/L	x	x	x	x
…	…	…	…	…	…	…	…	…	…	…	…
Study Arm	Subject ID	Lymphocytes	VISIT X	Time point	YYYY-MM-DDTHH:MM (XX)	xx	10^9/L	x	x	x	x
…	…	…	…	…	…	…	…	…	…	…	…
Study Arm	Subject ID	Monocytes	VISIT X	Time point	YYYY-MM-DDTHH:MM (XX)	xx	10^9/L	x	x	x	x
…	…	…	…	…	…	…	…	…	…	…	…

Safety Laboratory Results – Clinical Chemistry

LISTING 16.2.10.2. LABORATORY VALUES – CLINICAL CHEMISTRY (SAF)

Description of Planned Arm	Subject Identifier for the Study	Lab Test or Examination Name	Visit Name	Planned Time Point Name	Date/Time of Specimen Collection (Study Day)	Character Result/Finding in Std Format	Standard Units	Normal Range Indicator	Lower Reference Limit	Upper Reference Limit	Interpretation
Study Arm	Subject ID	Alkaline phosphatase	VISIT X	Time point	YYYY-MM-DDTHH:MM (XX)	xx	U/L	x	x	x	x
…	…	…	…	…	…	…	…	…	…	…	…
Study Arm	Subject ID	Alanine Aminotransferase	VISIT X	Time point	YYYY-MM-DDTHH:MM (XX)	xx	U/L	x	x	x	x
…	…	…	…	…	…	…	…	…	…	…	…
Study Arm	Subject ID	Aspartate aminotransferase	VISIT X	Time point	YYYY-MM-DDTHH:MM (XX)	xx	U/L	x	x	x	x
…	…	…	…	…	…	…	…	…	…	…	…
Study Arm	Subject ID	Gamma-glutamyl transferase	VISIT X	Time point	YYYY-MM-DDTHH:MM (XX)	xx	U/L	x	x	x	x
…	…	…	…	…	…	…	…	…	…	…	…
Study Arm	Subject ID	Albumin	VISIT X	Time point	YYYY-MM-DDTHH:MM (XX)	xx	g/L	x	x	x	x
…	…	…	…	…	…	…	…	…	…	…	…
Study Arm	Subject ID	Total protein	VISIT X	Time point	YYYY-MM-DDTHH:MM (XX)	xx	unit	x	x	x	x
…	…	…	…	…	…	…	…	…	…	…	…
Study Arm	Subject ID	Total bilirubin	VISIT X	Time point	YYYY-MM-DDTHH:MM (XX)	xx	umol/L	x	x	x	x
…	…	…	…	…	…	…	…	…	…	…	…
Study Arm	Subject ID	Conjugated bilirubin	VISIT X	Time point	YYYY-MM-DDTHH:MM (XX)	xx	umol/L	x	x	x	x
…	…	…	…	…	…	…	…	…	…	…	…
Study Arm	Subject ID	Creatine	VISIT x	Time point	YYYY-MM-DDTHH:MM (XX)	xx	umol/L	x	x	x	x
…	…	…	…	…	…	…	…	…	…	…	…
Study Arm	Subject ID	Blood Urea Nitrogen (BUN)	VISIT x	Time point	YYYY-MM-DDTHH:MM (XX)	xx	mmol/L	x	x	x	x

Description of Planned Arm	Subject Identifier for the Study	Lab Test or Examination Name	Visit Name	Planned Time Point Name	Date/Time of Specimen Collection (Study Day)	Character Result/Finding in Std Format	Standard Units	Normal Range Indicator	Lower Reference Limit	Upper Reference Limit	Interpretation
…	…	…	…	…	…	…	…	…	…	…	…
Study Arm	Subject ID	Chloride	VISIT x	Time point	YYYY-MM-DDTHH:MM (XX)	xx	mmol/L	x	x	x	x
…	…	…	…	…	…	…	…	…	…	…	…
Study Arm	Subject ID	Potassium	VISIT x	Time point	YYYY-MM-DDTHH:MM (XX)	xx	mmol/L		X	X	x
…	…	…	…	…	…	…	…		…	…	…
Study Arm	Subject ID	Sodium	VISIT x	Time point	YYYY-MM-DDTHH:MM (XX)	xx	mmol/L		X	X	X
…	…	…	…	…	…	…	…		…	…	…
Study Arm	Subject ID	C-reactive Protein	VISIT x	Time point	YYYY-MM-DDTHH:MM (XX)	xx	umol/L		X	X	X
…	…	…	…	…	…	…	…		…	…	…
Study Arm	Subject ID	FSH (female volunteers only)	VISIT x	Time point	YYYY-MM-DDTHH:MM (XX)	xx	unit		X	X	X
…	…	…	…	…	…	…	…		…	…	…
Study Arm	Subject ID	Serum β-hCG pregnancy test (female volunteers only)	VISIT x	Time point	YYYY-MM-DDTHH:MM (XX)	xx	unit		X	x	X
…	…	…	…	…	…	…	…		…	…	…

Safety Laboratory Results – Coagulation

LISTING 16.2.10.3. LABORATORY VALUES - COAGULATION (SAF)

Description of Planned Arm	Subject Identifier for the Study	Lab Test or Examination Name	Visit Name	Planned Time Point Name	Date/Time of Specimen Collection (Study Day)	Character Result/Finding in Std Format	Standard Units	Interpretation
Study Arm	Subject ID	Activated Partial Thromboplastin Time	VISIT X	Time point	YYYY-MM-DDTHH:MM (XX)	xx	x	x
…	…	…	…	…	…	…	…	…
Study Arm	Subject ID	Prothrombin Intl. Normalized Ratio	VISIT X	Time point	YYYY-MM-DDTHH:MM (xx)	xx	x	x
…	…	…	…	…	…	…	…	…

Safety Laboratory Results – Urine

LISTING 16.2.10.4. LABORATORY VALUES - URINE (SAF)

Description of Planned Arm	Subject Identifier for the Study	Lab Test or Examination Name	Visit Name	Planned Time Point	Date/Time of Specimen Collection (study day)	Character Result/Finding in Std Format	Standard Units	Interpretation
Study Arm	Subject ID	pH	VISIT X	Time point	YYYY-MM-DDTHH:MM (XX)	xx	xx	xx
…	…	…	…	…	…	…	…	…
Study Arm	Subject ID	RBC	VISIT X	Time point	YYYY-MM-DDTHH:MM (XX)	xx	xx	xx
…	…	…	…	…	…	…	…	…
Study Arm	Subject ID	WBC	VISIT X	Time point	YYYY-MM-DDTHH:MM (XX)	xx	xx	xx
…	…	…	…	…	…	…	…	…
Study Arm	Subject ID	Nitrite	VISIT X	Time point	YYYY-MM-DDTHH:MM (XX)	xx	xx	xx
…	…	…	…	…	…	…	…	…
Study Arm	Subject ID	Protein	VISIT X	Time point	YYYY-MM-DDTHH:MM (XX)	xx	xx	xx
…	…	…	…	…	…	…	…	…
Study Arm	Subject ID	Glucose	VISIT X	Time point	YYYY-MM-DDTHH:MM (XX)	xx	xx	xx
…	…	…	…	…	…	…	…	…
Study Arm	Subject ID	Ketones	VISIT X	Time point	YYYY-MM-DDTHH:MM (XX)	xx	xx	xx
…	…	…	…	…	…	…	…	…

Physical Examinations

LISTING 16.2.11. PHYSICAL EXAMINATIONS (SAF)

Subject Identifier for the Study	Visit name	Date/Time of Examination (Study Day)	Abdominal	Cardiac	Dermatologic	Eyes, Ears, Nose, Throat	Head	Lymphatic	Musculoskeletal	Neurologic	Peripheral Vascular	Pulmonary
Subject ID	VISIT X	YYYY-MM-DDTHH:MM (xx)	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
…	…	…	…	…	…	…	…	…	…	…	…	…

Gleason Grade and Score

LISTING 16.2.12. GLEASON GRADE AND SCORE (SAF)

Subject Identifier for the Study	Date/Time of Test	Study Day	Primary Grade	Secondary Grade	Tertiary Grade	Gleason Grade
Subject ID	YYYY-MM-DD	xx	xxx	xxx	xxx	xxx
Subject ID	YYYY-MM-DD	xx	xxx	xxx	xxx	xxx
Subject ID	YYYY-MM-DD	xx	xxx	xxx	xxx	xxx
Subject ID	YYYY-MM-DD	xx	xxx	xxx	xxx	xxx
…	…	…	…	…	…	…

LISTING 16.2.13. HISTOPATHOLOGY RESULTS (SAF)

Adverse Events

LISTING 16.2.14.1. ADVERSE EVENTS PART 1 (ALL SUBJECTS)

Description of Planned Arm	Subject Identifier for the Study	Reported Term for the Adverse Event	Serious Event	Start Date/Time of Adverse Event (Study Day)	End Date/Time of Adverse Event (Study Day)	Action Taken with Study Treatment	Outcome of Adverse Event	Description of Element
Study Arm	Subject ID	Reported Term	Y/N	YYYY-MM-DD THH:MM (xx)	YYYY-MM-DD THH:MM (xx)	Action	Outcome	Treatment Element
…	…	…	…	…	…	…	…	…

LISTING 16.2.14.2. ADVERSE EVENTS PART 2 (ALL SUBJECTS)

Description of Planned Arm	Subject Identifier for the Study	Reported Term/Preferred term/System organ class	Start date/time/Study day	End date/time (Study day)	Treatment emergent	Severity/intensity	Causality	Action	Outcome
Study Arm	Subject ID	Reported term/AEDECOD/AEBODSYS	YYYY-MM-DDTHH:MM/xxx	YYYY-MM-DDTHH:MM (xx)	Y/N	MILD/MODERATE/ SEVERE	RELATED/UNRELATED	xxx	xxx
…	…	…	…	…	…	…	…	…	…

Serious Adverse Events

LISTING 16.2.15.1. SERIOUS ADVERSE EVENTS PART 1 (ALL SUBJECTS)

Description of Planned Arm	Subject Identifier for the Study	Sequence Number	Reported Term for the Adverse Event	Serious Event	Start Date/Time of Adverse Event (Study Day)	End Date/Time of Adverse Event (Study Day)	Action Taken with Study Treatment	Outcome of Adverse Event	Description of Element
Study Arm	Subjects ID	x	Reported Term	Y/N	YYYY-MM-DD THH:MM (xx)	YYYY-MM-DD THH:MM (xx)	Action	Outcome	Treatment Group
…	…	…	…	…	…	…	…	…	…

LISTING 16.2.15.2. SERIOUS ADVERSE EVENTS PART 2 (ALL SUBJECTS)

Description of Planned Arm	Subject Identifier for the Study	Sequence Number	Reported Term for the Adverse Event	Serious Event	Dictionary-Derived Term	Body System or Organ Class	Severity/intensity	Causality	Description of Element
Study Arm	Subject ID	x	Reported Term	Y/N	Term	xxx	MILD/MODERATE/SEVERE	RELATED/UNRELATED	xxx
…	…	…	…	…	…	…	…	…	…

LISTING 16.2.15.3. SERIOUS ADVERSE EVENTS – SERIOUSNESS CRITERIA (ALL SUBJECTS)

Description of Planned Arm	Subject Identifier for the Study	Sequence Number	Reported Term for the Adverse Event	Serious Event	Start Date/Time of Adverse Event (Study Day)	End Date/Time of Adverse Event (Study Day)	Action Taken with Study Treatment	Outcome of Adverse Event	Description of Element
Study Arm	Subject ID	x	Action	Y/N	YYYY-MM-DD THH:MM (xx)	YYYY-MM-DD THH:MM (xx)	Action	Outcome	Treatment Group
…	…	…	…	…	…	…	…	…	…