THERAGNOSTICS

STATISTICAL ANALYSIS PLAN

A Phase II, Open-label Study to Assess Safety and Clinical Utility of ^{68}Ga-THP-PSMA PET/CT in Patients with High Risk Primary Prostate Cancer or Biochemical Recurrence after Radical treatment

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SAP Approvals:

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Date

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LIST OF ABBREVIATIONS

AE	Adverse Event
AST	Aspartate aminotransferase
BCR	Biochemical Recurrence
CMPR	Change in Management Plan Rate
CRF	Case Report Form
CT	Computed Tomography
CTC	Common Toxicity Criteria
DCO	Data cut-off
ECG	Electrocardiogram
ECOG	Eastern Cooperative Oncology Group
eGFR	estimated Glomerular Filtration Rate
FAS	Full Analysis Set
^{68}Ga	^{68}Gallium
HP	Histopathology
IMP	Investigational Medicinal Product
MedDRA	Medical Dictionary for Regulatory Activities
MRI	Magnetic Resonance Imaging
NCI	National Cancer Institute
PCa	Prostate Cancer
PET	Positron Emission Tomography
PP	Per Protocol
PSA	Prostate Specific Antigen
PSMA	Prostate Specific Membrane Antigen
PT	Preferred Term
RP	Revised Plan
SAP	Statistical Analysis Plan
SOC	System Organ Class

1. STUDY OBJECTIVES

1.1 Primary Objectives

The primary study objective is to evaluate the impact of ^{68}Ga-THP-PSMA PET on the management of patients with prostate cancer (PCa) in the setting of:

- Biochemical recurrence (BCR) in patients treated with radical prostatectomy
- BCR in patients treated with radiotherapy
- Newly diagnosed high risk prostate cancer

The primary objective will be measured by the proportion of patients with a change in management plan following 68GA-THP-PSMA PET scan, compared to the pre-scan intended management plan

1.2 Secondary Objectives

- Evaluation of the safety of 68Ga-PSMA in patients with PCa as assessed via adverse events (AEs), vital signs (including heart rate and blood presurre), ECGs, clinical laboratory assessments (haematology, ,biochemistry and urinalysis)

1.3 Tertiary Objectives

- Evaluation of the technical feasibility of ^{68}Ga-THP-PSMA in patients with PCa, as measured by:
  - The technical success/failure of the scan
  - The need for a re-scan
  - The presence/absence of artefacts on the scan
  - The rate of scans reported to have interpretation limitations
- Correlation of PSMA on imaging with PSMA within tumour

Note: The final tertiary objective relating to tumour PSMA data will be reported outside of the main CSR, and is not covered by this SAP.

2. Study Design

2.1 Overall Study Design

The study is open-labelled, non-randomised trial conducted in the UK. The whole study group consists of three groups of patients being studied. The three studied groups are:

- Group A: newly diagnosed with primary high-risk prostate cancer and are scheduled for radical prostatectomy surgery

- Group B: participants with PCa and a diagnosis of BCR, previously treated with radical prostatectomy, being considered for radical salvage therapy (with curative intent).

- Group C: participants with PCa and a diagnosis of BCR, previously treated with radical radiotherapy, being considered for radical salvage therapy (with curative intent).

The study will consist of measurements to be taken at four timepoints. These are:

- Visit 1 - Pre-scan. At any point within 4 weeks of scan date
- Visit 2 - Day of scan. Data collected both pre-scan and post scan
- Visit 3 - Post scan. Via telephone, 24-72 hours post scan
- Visit 4 - Post scan. Approximately 2 weeks post scan

On the day of the scan (visit 2), the participant will be cannulated, and receive one ≤5 mL dose of 68Ga-THP-PSMA. This will be injected via the cannula with arms down, and a slow push over 1 minute followed by ~ 10mL flush. The participant will be scanned in the supine position in the direction of mid-thigh to skull base, with the arms positioned overhead following the dose and flush. Patients who have an imaging technical failure will be injected and scanned again.

2.2 Methods of Assigning Patients to Groups

This is an open label, non-randomised study. For the purpose of reporting the study data, patients will be allocated to one of the three groups described in Section 2.1 based on their disease status (newly diagnosed = Group A or BCR= Group B or C) and prior treatment received (radical prostatectomy = Group B, radical radiotherapy = Group C) .

2.2.1 Procedures for Randomization

Not applicable. This is a non-randomized study.

3. ENDPOINTS

3.1 Primary Clinical Utility Endpoint

3.1.1 Change in Management Plan Rate (CMPR)

The primary endpoint is the percentage of patients in the full analysis set with a change in the revised management plan as a result of 68GA-THP-PSMA PET scan, documented after scan, compared with the pre-scan management plan.

As per the study case report form (CRF), the management plan is recorded to indicate the specific types of interventions planned for the patient both pre-scan and post-scan.

A list of the specific interventions captured is provided in Table 1.

Table 1 Treatment Categories

CRF Intervention Name
TRUS Biopsy
Targeted Biopsy
Template Biopsy
Prostatectomy
Prostatectomy with limited node dissection
Prostatectomy with extended lymph node dissection (incl internal, external illiac and obturator nodes)
Radiotherapy to Prostate/Prostate bed
Radiotherapy to Prostate/Prostate bed with boost to areas guided by conventional imaging
Radiotherapy to Prostate/Prostate bed and whole pelvis
Radiotherapy to Prostate/Prostate bed and whole pelvis with boost to areas guided by conventional imaging
Stereotactic body radiotherapy (SBRT)/cyberknife
Brachytherapy
Cryotherapy
HIFU
Hormone therapy with a combination of any of the above
Hormone therapy alone
Chemotherapy
Radionucleide therapy
Other, Specify

For each patient, each management plan may include multiple interventions.

In order to derive the primary endpoint, a binary endpoint will be created. A change status of 'Yes' will be assigned if there is any difference in treatment options between the intended and revised management plans. A change status of 'No' will be assigned if the intended and revised management plans are identical.

For the analysis set of interest, the CMPR will be calculated as the proportion of patients with a change status of "yes", taking as a denominator the number of patients in the analysis set.

The primary analysis of CMPR will be based on the Full Analysis Set (FAS, Section 4.2), thus the CMPR will be defined as:

$$CMPR = \frac{Number\ of\ patients\ in\ the\ FAS\ with\ a\ Change\ Status\ of\ Yes}{Number\ of\ Patients\ in\ the\ FAS}$$

As a sensitivity analysis, the CMPR based on the Per Protocol Analysis Set (PP, section 4.3) will also be presented. The derivation of CMPR for the PP set will be analogous to the derivation shown above for the FAS, except the PP set will be used instead of the FAS for both the numerator and denominator.

3.2 Safety and Tolerability

3.2.1 Safety Endpoints

The assessment of safety of ^{68}Ga-THP-PSMA PET in patients will be assessed using the following endpoints:

- Adverse Events (AEs)
- Vital Signs (blood pressure [systolic and diastolic] and heart rate)
- Laboratory assessments (biochemistry chemistry, hematology and urinalysis)
- Electrocardiogram (ECG) parameters: PR, QT, QTcB and QRS

Adverse events will be coded by System Organ Class (SOC) and Preferred Term (PT) using the Medical Dictionary for Regulatory Activities (MedDRA 21) for concomitant diseases and AEs and WHO Drug for medications (WHO Drug Dictionary 2017). All AEs will be evaluated for severity according to NCI-CTCAE version 5.0

Baseline will be defined as the last assessment prior to the administration of ^{68}GA-THP-PSMA. Therefore, if safety parameters were assessed at baseline Visit 1 (screening) and pre-^{68}GA-THP-PSMA administration at Visit 2, the Visit 2 values will be assumed to be the baseline value for the patient. For all endpoints that were not assessed at Visit 2, the Visit 1 value will be used as the baseline.

Furthermore, if multiple assessments are performed at the same pre-treatment timepoint, for example triplicate ECG assessments, the mean of the values will be used as the baseline reading.

Safety will be assessed in the Safety Set, Section 4.1.

3.2.1.1 General Considerations for Safety Assessments

Missing safety data will not be imputed. However, safety assessment values of the form of "< x" (i.e., below the lower limit of quantification) or > x (i.e., above the upper limit of quantification) will be imputed as "x" in the calculation of summary statistics but displayed as "< x" or "> x" in the listings.

Furthermore, the following principles will apply to the presentation of safety data:

- Listings should display all values for a patient, regardless of whether they were based on scheduled or unscheduled assessments.
- Baseline will be defined as the last non-missing measurement prior to ^{68}Ga-THP -PSMA dosing. For the cardiovascular profile, and physical examination, any assessments made on day 1 will be considered pre-dose unless explicitly indicated otherwise. Where safety data are summarized over time, study day will be calculated in relation to date of the ^{68}Ga-THP -PSMA dosing (which will be termed day 1).

4. Analysis Populations

4.1 Safety Population

The safety population will consist of all those patients who received a ^{68}Ga-THP -PSMA dose, regardless of whether they received the full intended dose, or proceeded to under-go the intended ^{68}Ga-THP-PSMA PET/CT scan.

All safety endpoints will be evaluated in the safety population.

4.2 Full Analysis Set

The full analysis set (FAS) is based on the *intention-to-treat* principle and includes the subset of the safety set who underwent the Visit 2 ^{68}Ga-THP-PSMA PET/CT scan, regardless of whether the scan was a technical success or failure.

The FAS will be the primary analysis set used to address the primary outcome variable (Section 3.1.1) and all secondary clinical utility endpoints (Section **Error! Reference s ource not found.**).

4.3 Per Protocol Set

The per-protocol set is defined as the subset of the FAS with at least one technically successful post-baseline ^{68}Ga-THP-PSMA PET/CT scan, and without any major protocol deviations as defined in Section 5.1.

The PP set will be used to assess the sensitivity of the primary outcome variable to scan failures.

4.4 Histopathology Set

The histopathology (HP) set is defined as the subset of the FAS with tumour histopathology data.

The HP set will be used to assess the tertiary objectives only for information and relating to correlation between of PSMA on imaging with PSMA within tumour. The reporting of this data is beyond the scope of this SAP.

4.5 Summary of Analysis Populations

A summary of the study outcome variables, and associated analysis sets is provided in Table 2.

Table 2 Summary of Outcome Variables and Analysis Populations

Outcome Variable	Analysis Population (Sensitivity Analysis Population)
Primary Endpoint	
CMPR	FAS (PP)
Secondary Endpoints	
Baseline Patient Characteristics	
Demography	Safety Set
Medical History	Safety Set
Concomitant Medications	Safety Set
Safety	
Adverse Events	Safety Set
Laboratory measurements	Safety Set
Vital Signs	Safety Set
ECG	Safety Set
Tertiary Objectives	
Histopathology data	HP Set

5. Protocol Deviations

5.1 Major Deviations

Major protocol deviations, are defined as those deviations that have a profound impact on the assessment of the primary objective of the study.

Patients who did not under-go the Visit 2 PET scan will be considered to have a major protocol deviation.

Additionally, violations of any key inclusion/exclusion criteria pertinent to the intended disease or indication are also considered Major Protocol deviations. Thus, the following Major Protocol Deviations are defined by Patient Group.

Group A

- Patient did not have a histologically proven adenocarcinoma of the prostate gland.
- Patient did not have at least one of the following at screening:
  - Gleason score 4+3 and above
- Patient was not considered to be suitable for surgical treatment as part of their standard of care management at screening.

Group B

- Patient did not have a previous diagnosis of PCa

- Patient has not undergone previous radical curative therapy completing at least 3 month prior to enrolment
- Patient did not have a diagnosis of BCR defined as:
  - Post RP: 2 consecutive rises in PSA and final PSA >0.l ng/mL **or**
- The patient has had previous recurrences of PCa, i.e. this is not the first diagnosis of BCR.

Group C

- The patient did not have an original diagnosis of PCa
- Patient has not undergone previous radical curative therapy at least 3 months before enrolment
- The patient has had previous recurrences of PCa, i.e. this is not the first diagnosis of BCR.

Note: If patients are found to have violated any of the above key inclusion criteria for their assigned patient group, but they do fulfil the inclusion criteria for another group, the patient will be retrospectively re-assigned to the appropriate group, rather than being classified as having a major deviation, and excluded from the PP analysis set. For example, if a patient in Group B had not had a prior prostatectomy, but did have prior radiotherapy and fulfilled the entry criteria for Group C, then they would be re-assigned for Group C for the purpose of analysis and reporting.

In addition, any other deviations which may significantly interfere with the study outcomes may also be declared a major deviation.

Major protocol deviations will be listed.

In addition to the programmatic determination of the major deviations, monitoring notes or summaries will be reviewed to determine any important post entry deviations that are not identifiable via programming, and to check that those identified via programming are correctly classified. The final classification will be made prior to database lock.

Note, failure of an inclusion/exclusion criteria will not automatically be classified as a major deviation.

5.2 Important Deviations

In addition to the programmatic determination of the major deviations as described in Section 5.1, the following *important deviations* will be programmatically derived and listed and summarized:

- Failure of any inclusion/exclusion criteria (with exception patients of those listed in Section 5.1 as major deviations)
- Administration of a non-approved modified dose of ^{68}Ga-THP -PSMA[1]

[1] Note: The term “approved” dose is used to describe either the protocol-defined dose-range, or lower doses that have been confirmed by site not to affect image quality. Instances of lower

Finally, monitoring notes or summaries will be reviewed to determine any important post entry deviations that are not identifiable via programming, and to check that those identified via programming are correctly classified. The final classification will be made prior to database lock.

All patients who failed any inclusion/exclusion criteria will be listed along with details of the failed criteria. This information will also be summarized in terms of the number (%) of patient failing any of the inclusion/exclusion criteria and will be based on the Safety Set. Note, failure of an inclusion/exclusion criteria will not automatically be classified as a major deviation.

Other deviations may occur during the trial, which are considered minor and not believed to have any significant impact on the interpretation of the study results. All of these deviations will be recorded by the study monitors but will not be listed or summarized as part of the CSR.

Examples of minor deviations include:

- Visits outside of protocol visit windows
- Incomplete assessments

This list is not exhaustive and other minor deviations may occur.

6. General Statistical Considerations

All statistical analyses will be performed by, or under the direct auspices of Theragnostics.

For the purposes of this SAP, the end of the study is formally defined as the date of database lock (DBL), which is anticipated to occur within 6 weeks after the last patient has completed their final visit. The primary data analysis will be performed after the database has been locked.

Continuous data will be summarized in terms of the mean, standard deviation, median, minimum, maximum and number of observations, unless otherwise stated. The minimum and maximum will be reported to the same number of decimal places as the raw data recorded in the database. The mean and median will be reported to one more decimal place than the raw data recorded in the database. The standard deviation will be reported to two more decimal places than the raw data recorded in the database. In general, the maximum number of decimal places reported shall be four for any summary statistic.

Categorical data will be summarized in terms of the number of patients providing data at the relevant time point (n), frequency counts and percentages.

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doses being administered and approved are captured in the trial master file and will not be classified as important deviations.

Percentages will be presented to one decimal place. Percentages will not be presented for zero counts. Percentages will be calculated using "n" as the denominator. If sample sizes are small, the data displays will show the percentages, but any textual report will describe frequencies only.

For the purpose of reporting, for each patient, Study Day 1 is defined as the date of ^{68}Ga-THP -PSMA IV dose.

The study is recruiting three distinct patient groups (Groups A, B and C), and unless stated otherwise, the following reporting conventions will apply:

- Data will be presented for Group A (Newly Diagnosed patients), Groups B + C (BCR Patients) and Overall (Groups A + B + C).

6.1 Sample Size Estimation

The sample size was based on the degree of uncertainty in the estimation of the primary outcome, the percentage of patients with a change in management, as measured by the confidence interval. Due to the phase of the study, at this stage relatively wide confidence intervals are allowed.

For Group A, previous literature suggests that approximately 25% of patients would change management. Assuming a 95% confidence level, it is calculated that 20 patients would be sufficient to obtain an estimate of the primary outcome that is within ±20% of the population figure.

For Groups B+C, previous literature suggests that approximately 45% would change management. With a 95% confidence level, a sample size of 40 patients in the two groups combined would be enable the primary outcome to be estimated to approximately ±15% of the population value.

6.1.1 Sample Size Re-estimation

There are no planned sample size re-estimations.

6.2 Adjustments for Covariates

Not applicable.

6.3 Handling of Dropouts or Missing Data

In general, missing data will remain missing and will not be included in analyses. Exceptions are described below.

- Missing Baseline Data

If a baseline (Day 1) value is not available and a screening value is available for the same parameter, then the last screening value will be used as baseline.

6.4 Monitoring and Interim Analyses

6.4.1 Monitoring

The study will be monitored to ensure that the study is conducted and documented properly according to the protocol, good clinical practice (GCP), and all applicable regulatory requirements.

6.4.2 Interim Analysis

6.4.2.1 Purpose of Interim Analyses

An interim analysis was planned in the protocol to provide some early indication of the study results, specifically for the primary outcome, CMPR.

The interim analysis was not performed.

6.4.2.2 Planned Schedule of Interim Analyses

Details of the planned interim analysis can be found in the study protocol. This analysis did not take place.

6.5 Multiple Testing Strategy

Not applicable, since there is no formal hypothesis testing.

6.6 Examination of Subgroups

Unless stated otherwise, the following reporting conventions will apply:

- Data will be presented for Group A (Newly Diagnosed patients)
- Groups B + C (BCR Patients)
- Overall (Groups A + B + C).

No further study subgroups will be considered.

6.7 Stratification Factors

Not applicable.

7. Methods of Analysis

7.1 Change in Management Plan Rate (CMPR)

The primary endpoint, CMPR, will be summarized based on the FAS to show the number and percentage of patients categorized with a change status of “yes” (Section 3.1.1). The two-sided 95% *Clopper Pearson* exact confidence interval, and the two-sided 80% *Clopper Pearson* exact confidence interval will also be presented for the CMPR.

A listing presenting each patient's change status will also be presented.

The primary analysis of CMPR will be based on the FAS. A sensitivity analysis based on the PP set will also be presented, as described above for the FAS, if the FAS and PP sets differ.

7.2 Assessment of Safety and Tolerability

7.2.1 Assessment of Adverse Events

All safety data will be assessed for the Safety population.

All AE data will be listed along with information regarding the onset date and study day, end date (or ongoing), CTC grade, SAE criteria fulfilled, causality assessment (yes/no), and action taken and outcome.

Treatment emergent AEs (TEAEs) are defined as AEs with an onset date on or after the administration of the ^{68}Ga-THP -PSMA IV dose. The following summaries will be produced for all TEAEs:

- An overview table of the incidence of TEAEs, grade 3+ TEAEs, SAEs, TEAEs leading to discontinuation from the study and TEAEs leading to death. For each summary category, the results will be shown overall (regardless of causality), and for the incidence of causally related TEAEs. For example, the overall incidence of TEAEs will be presented, as well as the incidence of TEAEs related to ^{68}Ga-THP -PSMA will be presented.
    - Note: If an AE is reported more than once during the study for an individual patient, the greatest severity and the worst-case attribution will be presented in the above summary table.
- Summary of TEAEs by system organ class (SOC) and preferred term: Both the number and percentage of patients in each category (patient-level summary) and the number of episodes (episode-level summary).
    - Note: For the patient-level summary, patients will only be counted once if they have multiple incidence of the same TEAE. For the episode-level summary, each individual episode will be counted.

Additionally, the following will be listed if any TEAEs in these categories occur during the trial:

- AEs with outcome of death along with the date of onset, study day, and investigator's assessment of severity and causality, and primary cause of death
- All SAEs along with the date of onset, study day, date of resolution (if AE is resolved), investigator's assessment of severity and causality and SAE criteria fulfilled.

Any AEs commencing >30 days after the administration of ^{68}Ga-THP -PSMA will not be included in the tabulations of AE data.

7.2.2 Assessment of Safety

All clinical laboratory data (clinical chemistry, hematology and urinalysis data), vital signs and ECG data will be listed.

In addition, hematology, blood biochemistry and vital signs data will be summarized descriptively (n, mean, std, median, min and max) by time point.

Additionally, for the ECG assessments, the following data summaries will also be produced:

- For time point, the number and percentage of patients with clinically significant abnormal ECG reading will be summarised.

Furthermore, to provide a preliminary evaluation of the cardiac effects, the following categorical data summary table will be produced:

- The proportion of patients obtaining treatment-emergent absolute QTcB values > 450 ms and ≤ 480 ms; > 480 ms and ≤ 500 ms; and > 500 msec
- The proportion of patients obtaining a QTcB increase from baseline values ≥30-60 ms and ≥60 ms
- The proportion of patients obtaining a QRS change from baseline > 25% resulting in QRS > 120 ms
- The proportion of patients obtaining a PR interval change from baseline >25% reaching a value >220 ms
- The proportion of patients obtaining a > 25% decrease from baseline in heart rate, resulting in a heart rate < 50 beats per minute (bpm) or a >25% increase from baseline in heart rate resulting in a heart rate > 100 bpm

7.3 Disposition of Patients

A summary of the number of patients that reached the various stages of the study will be summarized, along with a supporting listings outlining each patient's progression through the study. Reasons for non-participation and withdrawal will be summarized and listed.

A flow diagram will also be provided, outlining both the flow of patients, and the exclusions from the analysis sets.

7.4 Demographics and Baseline Characteristics

Demographic and baseline characteristic data will be presented based on the safety set.

Baseline demographic data, including, but not limited to:

- age
- race (Asian, White, Black or Other)

- weight
- height
- BSA
- ECOG Status

will be listed and summarised using appropriate descriptive statistics.

7.5 Primary Diagnosis Information

The following information relating to the patients' primary diagnosis will be listed and summarised:

- PSA at diagnosis
- PSA after radical treatment (nadir)
- PSA prior to scan
- Initial Diagnosis Stage
- Initial Gleason Score
- Initial Diagnosis Stage: T, N and M staging will be summarized separately

7.6 PSA At Diagnosis and After Radical Treatment (Groups B and C only)

For patients with BCR (Groups B and C), the date of radical treatment, the PSA at diagnosis and after radical treatment, and the date of BCR will be listed.

Additionally PSA at diagnosis and after radical treatment will be summarized descriptively.

7.7 Prior Cancer Therapy

Prior cancer therapies will be listed.

7.8 Medical History and Prior and Concomitant Medications

Relevant medical history will be listed.

All medications received from Study Day 1 onwards (including those that were ongoing prior to administration of ^{68}Ga-THP -PSMA) will be listed.

7.9 Treatment Management Plan Details

A listing indicating each patient's intended, revised and agreed treatment management plan will be provided.

7.10 Prior Imaging Assessments

Imaging history data will be listed.

8. Changes from the Protocol

For the purpose of patient enrolment, 3 patient groups were defined in the protocol:

- Group A: newly diagnosed with primary high-risk prostate cancer and are scheduled for radical prostatectomy surgery
- Group B: BCR patients previously treated with radical prostatectomy
- Group C: BCR patients previously treated with radical radiotherapyGroup A:

The distinction between groups B and C in the protocol was to clearly define the two types of BCR patients eligible for inclusion in this study.

For the purpose of reporting, groups B and C will be combined, to present the effects in BCR patients (regardless of prior treatment pathway).

The protocol included an interim analysis to be performed when both of the following two criteria had been met:

i. 30 of the 60 patients from all groups combined to have completed the study

ii. 10 of the 20 patients from group B to have completed the study

The interim analysis was not performed, and the study will be reported following the DCO for the primary data analysis (Section 6).

9. Programming Considerations

The data analysis will be performed using SAS version 9.4. Programs recording details of all data manipulation and data analyses will be produced and kept, so that the analyses can be externally inspected and, if necessary, re-run.

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