Supplemental Data

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Supplementary Methods

Imaging with [^{18}F]CTT1057 Positron Emission Tomography/Computed Tomography (PET/CT)

One delayed pelvic PET image (one bed position) was allowed 120–180 minutes post-injection when considered appropriate (e.g. if intense activity in the urinary bladder precluded appropriate assessment of the initial PET image). Use of diuretics was allowed before PET/CT scan image acquisition if clinically indicated.

Secondary Endpoints

Secondary endpoints included patient-level and region-level positive predictive value and accuracy, region-level sensitivity, inter- and intra-reader variability, detection rate of distant metastasis, pharmacokinetics, and safety and tolerability assessments. Owing to limitations in the spatial resolution of PET, in addition to a per-protocol analysis of region-level sensitivity excluding all pelvic lymph node (PLN) metastases (N1) <2 mm in diameter, region-level sensitivity excluding PLN micrometastases (defined in the literature as ≤2 mm in diameter) was analysed *post hoc* (*1,2*).

Exploratory Endpoints

Exploratory endpoints included the quantitative assessment of [^{18}F]CTT1057 uptake, [^{18}F]CTT1057 metabolism and the change in patient management plans attributed to [^{18}F]CTT1057 PET/CT (based on local review).

Reader Variability

[^{18}F]CTT1057 scan inter-reader variability is defined as the agreement rate among reader determinations and was calculated using the Fleiss' Kappa statistic for the Safety Analysis Set, for all regions together (e.g. prostate region, PLN region, extra-PLN region, skeletal region and visceral region).

[^{18}F]CTT1057 scan intra-reader variability is defined as the within-reader agreement rate and was assessed by the Cohen's Kappa statistic for the Safety Analysis Set, for all regions together. In total, 20 [^{18}F]CTT1057 PET/CT scans were randomly selected to be read a second time by each of the three independent readers to calculate the intra-reader variability.

Quantitative Assessment of [^{18}F]CTT1057 Uptake

Maximum standardized uptake value (SUV_{max}) and mean SUV (SUV_{mean}) values were obtained from manually drawn regions of interest by each of the three independent central readers on each prostate-specific membrane antigen (PSMA)-positive lesion reported on [^{18}F]CTT1057 PET, and from spheric regions of interest placed on each of the background regions, i.e. mediastinal blood pool (descending thoracic aorta), liver (normal parenchyma), and bone marrow (left femur). Tumour-to-background ratios were calculated as SUV_{max} lesion/SUV_{mean} background region.

Descriptive statistics (mean, median, first quartile, third quartile, minimum and maximum) for lesion SUV_{max} and SUV_{mean}, as well as tumour-to-background ratios were calculated for each participant in the Full Analysis Set.

Patient Management Questionnaire

Two patient management questionnaires were completed by the treating physician or clinical study investigator to capture the intended treatment plan; one before (questionnaire 1) and

one after obtaining the results from [^{18}F]CTT1057 PET/CT (questionnaire 2). Options were given in the questionnaire to capture possible management plan change, such as a) surgery, b) radiation alone, C) radiation plus androgen-deprivation therapy, D) androgen-deprivation therapy alone, e) observation/surveillance or f) other (free-text box). [^{18}F]CTT1057 PET/CT was assessed by one independent local nuclear medical physician or radiologist (who were experienced in reading oncology PET/CT scans) and provided to the treating physician/clinical study investigator for completion of questionnaire 2 before the scheduled surgery date. This local reader did not participate in the central read of the images and was not blinded to any clinical information.

Pharmacokinetics and Metabolism

[^{18}F]CTT1057 pharmacokinetics and the urine excretion and potential presence of radioactive metabolites/fragments in humans (radio-high-performance liquid chromatography) were assessed in a subset of approximately 10 patients from a single study site. The [^{18}F]CTT1057 pharmacokinetic analysis was performed based on decay-corrected blood radioactivity concentration data, obtained by measuring the blood samples drawn at pre-defined time points using a calibrated gamma-counting device: before [^{18}F]CTT1057 injection, 0–5 minutes, 15 (±5) minutes, 30 (±5) minutes, 1 hour (±15 minutes), 2 hours (±30 minutes) and 3–4 hours after [^{18}F]CTT1057 injection. An optional blood sample could be drawn 5 hours (±30 minutes) after [^{18}F]CTT1057 injection. Pharmacokinetic parameters were determined using the actual recorded sampling times and non-compartmental methods with Phoenix WinNonlin (version 8 or higher).

Urine samples were collected for pharmacokinetic and radio-high-performance liquid chromatography analysis at the following sampling intervals: pre-[^{18}F]CTT1057 injection

until [^{18}F]CTT1057 injection, immediately after [^{18}F]CTT1057 injection and until just before the first PET/CT acquisition, from the time of first PET/CT acquisition up to 3 hours post-injection, and from 3–5 hours post-injection. A 1 mL urine sample was withdrawn from each urine fraction and radioactivity was measured using the gamma counter. For radioactive metabolite/fragment analysis, a 10 mL aliquot of urine was withdrawn within each time frame after collection taking into account the physical radioactive decay, and was analysed by radio-high-performance-liquid chromatography.

Information related to the administration of [^{18}F]CTT1057 were recorded, including activity of the dose at administration, date and time of dosing, date and time of dose preparation and specific activity at time of dose preparation. The counts per minute value was calculated locally for all samples.

Terminal and effective half-life of [^{18}F]CTT1057 could not be estimated accurately by non-compartmental analysis because the last time point for these analyses (5 hours post-injection) was optional and data were collected only in one patient. Therefore, the terminal and effective half-life were estimated in a *post-hoc* analysis using a population pharmacokinetics model.

Safety Assessments

Safety assessments included the incidence of adverse events, graded according to the Common Toxicity Criteria for Adverse Events version 5.0, from informed consent up to 14 days after [^{18}F]CTT1057 administration.

Analysis Sets

The Efficacy Analysis Set included all enrolled patients who had both an evaluable [^{18}F]CTT1057 PET/CT scan and histopathology assessment, and had not received any prohibited systemic antineoplastic therapy before the completion of [^{18}F]CTT1057 PET/CT and surgery. Prohibited systemic antineoplastic therapy was any androgen-deprivation therapy (including luteinizing hormone-releasing hormone agonists or antagonists) as well as anti-androgens (both first- and second-generation compounds) and 5-alpha reductase inhibitors.

The Pharmacokinetic Analysis Set included all patients who provided at least one evaluable pharmacokinetic parameter.

Statistical Analysis

Regions defined in GuideView are the primary tumour (PT; prostate region comprising prostate bed/prostate gland and any local invasion of the urinary bladder, rectum or seminal vesicles), PLN region, extra-PLN region, skeletal region and visceral region. A sextant template was used by pathologists to report the location of lesions in the PT; for analysis, anatomical location and laterality for the lesion location were used. All central readers were nuclear medicine physicians or radiologists experienced in reading oncology PET scans.

For each central reader, the two co-primary endpoints (patient-level sensitivity and region-level specificity) are presented as percentages and two-tailed exact binomial 95% confidence intervals. The results of the [^{18}F]CTT1057 PET/CT scans were compared with the histopathology results in the dissected PT and/or PLN to determine the true positive, false positive, true negative and false negative regions.

PSMA true positive patients were those who showed at least one pathological [^{18}F]CTT1057 uptake either in the PT and/or metastatic PLNs with anatomically localized correspondence with the standard of truth (SoT). PSMA true negative patients were those who did not show any pathological [^{18}F]CTT1057 uptake either in the PT and/or metastatic PLNs and were confirmed as not having PT or metastatic PLNs with the SoT. PSMA false positive patients were those who showed at least one pathological [^{18}F]CTT1057 uptake either in the PT and/or metastatic PLNs but who were not verified as having PT or metastatic PLNs with the SoT or none of the lesions were correctly localized in anatomical location by the SoT. PSMA false negative patients were those who did not show any pathological [^{18}F]CTT1057 uptake either in the PT and/or metastatic PLNs but were confirmed as having PT or metastatic PLNs with the SoT.

For PLNs, anatomical correspondence was assessed based on a hemipelvis regional classification (left/right) method. PSMA true positive PLN regions were regions that tested positive for PLN on [^{18}F]CTT1057 and confirmed positive on the SoT. PSMA true negative PLN regions were regions that tested negative for PLN on [^{18}F]CTT1057 and confirmed negative on the SoT. PSMA false positive PLN regions were regions that tested positive for PLN on [^{18}F]CTT1057 but were verified negative on SoT. PSMA false negative PLN regions were regions that tested negative for PLN on [^{18}F]CTT1057 but verified positive on the SoT.

Accuracy = (true positive + true negative) / (true positive + true negative + false positive + false negative); negative predictive value = true negative / (true negative + false negative); positive predictive value = true positive / (true positive + false positive); sensitivity = true positive / (true positive + false negative); specificity = true negative / (true negative + false

positive).

The sample size calculation was based on the co-primary endpoints, patient-level sensitivity and region-level specificity. 195 patients were required to account for a potential dropout rate of 20%, to ensure that at least 156 patients were evaluable for the co-primary endpoints. For patient-level sensitivity, with a null hypothesis of H0: patient-level sensitivity p0 = 0.50 and an alternative hypothesis of H1: p1 > 0.50, assuming a sensitivity of 63% for p1, approximately 156 patients with PT and/or PLN would provide 90% power to detect a change in sensitivity of 13% using a one-sided binomial test at a targeted one-sided level of significance level of 2.5%. For region-level specificity, with a null hypothesis of H0: region-level specificity p0 = 0.70 and an alternative hypothesis of H1: p1 > 0.70, assuming a specificity of 85% for p1, approximately 123 patients (including 37 patients with PLN based on 30% prevalence) would achieve 90% statistical power to detect a change in specificity of 15% using a one-sided binomial test at a targeted one-sided level of significance level of 2.5%. These calculations were made using the software PASS 11 and R 3.6.1. No *p* values were calculated because no hypothesis testing was planned for this single arm study.

SAS version 9.4 or later was used to perform all data analyses and to generate tables, figures and listings.

References

1. van Leeuwen PJ, Emmett L, Ho B, et al. Prospective evaluation of 68Gallium-prostate-specific membrane antigen positron emission tomography/computed tomography for preoperative lymph node staging in prostate cancer. *BJU Int.* 2017;119:209–215.

2. Kolthammer JA, Su KH, Grover A, Narayanan M, Jordan DW, Muzic RF. Performance evaluation of the Ingenuity TF PET/CT scanner with a focus on high count-rate conditions. *Phys Med Biol.* 2014;59:3843–3859.

SUPPLEMENTAL TABLE 1. Inclusion and Exclusion Criteria for the GuideView Study.

Inclusion criteria
• Signed informed consent was obtained prior to participation in the study. • Participants aged at least 18 years with untreated high-risk biopsy-proven PCa according to D'Amico classification (stage ≥T2c or PSA level >20 ng/mL or Gleason score ≥8). • Scheduled or planned radical prostatectomy and extended pelvic lymph node resection up to 6 weeks after the investigational PET/CT scan followed by histopathology assessment. • Eastern Cooperative Oncology Group performance status 0–2.
Exclusion criteria
• Inability to complete the needed investigational and standard-of-care imaging examinations due to any reason (severe claustrophobia, inability to lie still for the entire imaging time, etc.). • Any additional medical condition, serious intercurrent illness, concomitant cancer or other extenuating circumstance that, in the opinion of the Investigator, would indicate a significant risk to safety or impair study participation, including, but not limited to, current severe urinary incontinence, hydronephrosis, severe voiding dysfunction, need of indwelling/condom catheters, New York Heart Association class III or IV congestive heart failure, history of congenital prolonged QT syndrome, uncontrolled infection, active hepatitis B or C, and COVID-19. • Known allergy, hypersensitivity or intolerance to [^{18}F]CTT1057 scan. • Prior and current use of PSMA-targeted therapies. • Prior and current treatment with any androgen deprivation therapy (first- or second-generation), including luteinising hormone-releasing hormone analogues (agonists or antagonists). • Any 5-alpha reductase inhibitors within 30 days before screening. • Participants with small cell or neuroendocrine PCa in more than 50% of biopsy tissue. • Participants with incidental PCa after transurethral resection. • Use of other investigational drugs within 30 days before screening.

Abbreviations: CT = computed tomography; PET = positron emission tomography; PCa = prostate cancer;

PSA = prostate-specific antigen; PSMA = prostate-specific membrane antigen.

SUPPLEMENTAL TABLE 2. Subgroup Analysis of Patient-level Sensitivity for the Identification of PSMA-positive PT and PLN Lesions in the Efficacy Analysis Set.

		n	Central Reader 1 sensitivity, % (95% CI)	Central Reader 2 sensitivity, % (95% CI)	Central Reader 3 sensitivity, % (95% CI)
PSA	≤20 ng/mL	123	81.7 (73.6, 88.1)	86.1 (78.6, 91.7)	81.8 (73.8, 88.2)
	>20 ng/mL	43	100 (91.4, 100)	100 (91.6, 100)	100 (91.4, 100)
Gleason Score	≤6	5	80.0 (28.4, 99.5)	80.0 (28.4, 99.5)	100 (47.8, 100)
	7 (3+4)	24	79.2 (57.9, 92.9)	83.3 (62.6, 95.3)	79.2 (57.9, 92.9)
	7 (4+3)	25	95.7 (78.1, 99.9)	91.7 (73.0, 99.0)	87.5 (67.6, 97.3)
	8	78	86.8 (77.1, 93.5)	92.2 (83.8, 97.1)	89.5 (80.3, 95.3)
	9–10	40	87.2 (72.6, 95.7)	90.0 (76.3, 97.2)	84.6 (69.5, 94.1)
Number of PLNs dissected	≥12	139	86.7 (79.8, 91.9)	90.5 (84.3, 94.9)	86.9 (80.0, 92.0)
	<12	33	87.5 (71.0, 96.5)	87.9 (71.8, 96.6)	87.1 (70.2, 96.4)

Both the PT and the PLN regions were used to calculate the patient-level sensitivity.

Abbreviations: CI = confidence interval; PLN = pelvic lymph node; PSA = prostate-specific antigen; PSMA = prostate-specific membrane antigen; PT = primary tumour.

SUPPLEMENTAL TABLE 3. Subgroup Analysis of Region-level Specificity for the Identification of PSMA-positive PLN Lesions in the Efficacy Analysis Set.

		n	Central Reader 1 specificity, % (95% CI)	Central Reader 2 specificity, % (95% CI)	Central Reader 3 specificity, % (95% CI)
PSA	≤20 ng/mL	123	96.2 (90.4, 98.9)	96.2 (90.4, 98.9)	96.2 (90.4, 98.9)
	>20 ng/mL	43	100 (88.4, 100)	100 (88.4, 100)	100 (88.4, 100)
Gleason Score	≤6	5	100 (47.8, 100)	100 (47.8, 100)	100 (47.8, 100)
	7 (3+4)	24	100 (82.4, 100)	94.7 (74.0, 99.9)	100 (82.4, 100)
	7 (4+3)	25	100 (82.4, 100)	100 (82.4, 100)	100 (82.4, 100)
	8	78	95.3 (86.9, 99.0)	96.9 (89.2, 99.6)	95.3 (86.9, 99.0)
	9–10	40	96.8 (83.3, 99.9)	96.8 (83.3, 99.9)	96.8 (83.3, 99.9)
Number of PLNs dissected	≥12	139	97.2 (92.0, 99.4)	97.2 (92.0, 99.4)	98.1 (93.4, 99.8)
	<12	33	96.8 (83.3, 99.9)	96.8 (83.3, 99.9)	93.5 (78.6, 99.2)

Only the PLN region was used to calculate the region-level specificity.

Abbreviations: CI = confidence interval; PLN = pelvic lymph node; PSA = prostate-specific antigen; PSMA = prostate-specific membrane antigen.

SUPPLEMENTAL TABLE 4. Region-level Sensitivity for the Identification of PSMA-positive PLN Metastases Excluding Lesions ≤2 mm (micrometastases) in the Efficacy Analysis Set.

	Central Reader 1 ***N*** **= 172**	**Central Reader 2** ***N*** **= 172**	**Central Reader 3** ***N*** **= 172**
Region-level sensitivity excluding lesions ≤2 mm[*]			
True positive	7	7	8
False positive	4	4	4
False negative	19	19	18
True negative	142	142	142
Region-level sensitivity (%) (95% CI)	26.9 (11.6, 47.8)	26.9 (11.6, 47.8)	30.8 (14.3, 51.8)

Only the PLN region was used to calculate region-level sensitivity.

[*]Results for region-level sensitivity were identical in the per-protocol analysis which excluded lesions <2 mm in diameter, as the three patients with PLN lesions equal to exactly 2 mm in diameter also had other PLN lesions >2 mm in diameter.

Abbreviations: CI = confidence interval; PLN = pelvic lymph node; PSMA = prostate-specific membrane antigen.

SUPPLEMENTAL TABLE 5. Patient-level Positive Predictive Value and Accuracy for the Identification of PSMA-positive PT and PLN Lesions in the Efficacy Analysis Set.

	Central Reader 1 *N* = 172	Central Reader 2 *N* = 172	Central Reader 3 *N* = 172
Positive predictive value (%) (95% CI)	97.3 (93.3, 99.3)	98.7 (95.4, 99.8)	98.0 (94.2, 99.6)
Accuracy (%) (95% CI)	84.9 (78.6, 89.9)	89.0 (83.3, 93.2)	85.5 (79.3, 90.4)

Both the PT regions and the PLN regions were used to calculate these patient-level endpoints.

Abbreviations: CI = confidence interval; PLN = pelvic lymph node; PSMA = prostate-specific membrane antigen; PT = primary tumour.

SUPPLEMENTAL TABLE 6. Reader Variability of the [^{18}F]CTT1057 PET/CT Scan (Safety Analysis Set).

	Central Reader 1 *N* = 184 *n*	Central Reader 2 *N* = 184 *n*	Central Reader 3 *N* = 184 *n*
Total number of patients who had their scan read by the corresponding central reader	184	184	184
Positive	160	166	160
Negative	24	18	24
Inter-reader variability* (%) (95% CI)		63.9 (55.5, 72.2)	
Standard error		0.04	
Total number of patients who had their scan read a second time	20	20	20
Positive – Positive	12	12	12
Positive – Negative	0	0	0
Negative – Positive	0	0	1
Negative – Negative	8	8	7
Intra-reader reproducibility (%) (95% CI)	100 (100, 100)	100 (100, 100)	89.4 (69.0, 100)

*Higher inter-reader variability values indicate higher agreement between readers.

Positive: Patients with at least one lesion that was visually positive on scan in any region.

Negative: Patients without any lesion that was visually positive on scan in any region.

All regions (prostate region, pelvic lymph node region, extra-pelvic lymph node region, skeletal region and visceral region) were considered to calculate the inter-reader variability and intra-reader reproducibility endpoints.

Abbreviations: CI = confidence interval; CT = computed tomography; PET = positron emission tomography.

SUPPLEMENTAL TABLE 7. Detection of Distant Metastasis using the [^{18}F]CTT1057 PET/CT Scan (Safety Analysis Set).

	Central Reader 1 *N* = 184	Central Reader 2 *N* = 184	Central Reader 3 *N* = 184
	n	***n***	***n***
Number of distant metastatic lesions per patient	6	9	10
Median	1.0	1.0	1.0
IQR	1.0–3.0	1.0–1.0	1.0–1.0
Minimum–Maximum	1–3	1– 3	1–3
Patients with at least one distant metastatic lesion (%)	6 (3.3)	9 (4.9)	10 (5.4)
95% CI	1.2, 7.0	2.3, 9.1	2.6, 9.8

Only lesions that were outside the PT region and PLN region were considered as distant metastases.

Abbreviations: CI = confidence interval; CT = computed tomography; IQR = interquartile range; PET = positron emission tomography; PLN = pelvic lymph node; PT = primary tumour.

SUPPLEMENTAL TABLE 8. Summary of the Number of PSMA-positive Lesions Identified in Each Distant Metastatic Region on [^{18}F]CTT1057 PET/CT (Safety Analysis Set).

	Central Reader 1 *N* = 184 *n* (%)	Central Reader 2 *N* = 184 *n* (%)	Central Reader 3 *N* = 184 *n* (%)
Total number of distant metastatic lesions read by central reader, *n*	10 (100)	13 (100)	12 (100)
Extra-PLN	9 (90.0)	7 (53.8)	7 (58.3)
Common iliac lymph node	8 (80.0)	5 (38.5)	6 (50.0)
Inguinal lymph node	1 (10.0)	1 (7.7)	1 (8.3)
Para-aortic lymph node	0	1 (7.7)	0
Skeletal	1 (10.0)	6 (46.2)	4 (33.3)
Cervical spine	0	1 (7.7)	0
Lumbar spine	0	0	1 (8.3)
Pelvic bone	1 (10.0)	0	0
Rib	0	4 (30.8)	2 (16.7)
Thoracic spine	0	1 (7.7)	1 (8.3)
Visceral	0	0	1 (8.3)
Liver	0	0	1 (8.3)

Percentage is based on the total number of metastatic lesions detected in the extra-PLN, visceral and skeletal regions read by the corresponding central reader.

Abbreviations: CT = computed tomography; PET = positron emission tomography; PLN = pelvic lymph node; PSMA = prostate-specific membrane antigen.

SUPPLEMENTAL TABLE 9. Overview of the Answers to Questionnaires on Change in Intended Treatment Plan following the [^{18}F]CTT1057 PET/CT Scan (Safety Analysis Set).

Planned treatment	**Questionnaire 1** ***N*** **= 184** ***n*** **(%)**	**Questionnaire 2** ***N*** **= 184** ***n*** **(%)**
Surgery	183 (99.5)	177 (96.2)
Radiation alone	0	0
Radiation plus androgen deprivation therapy	1 (0.5)	6 (3.3)*
Androgen deprivation therapy alone	0	1 (0.5)†
Observation/surveillance	0	0
Other	0	0
Missing	0	0
Patients with change in treatment plan		6 (3.3)

*Including one patient with initially planned radiotherapy + androgen deprivation therapy (deviation to inclusion criteria) who had no change and kept the same plan.

†Patient with a negative [^{18}F]CTT1057 PET/CT scan for whom intended treatment changed from surgery to androgen deprivation therapy.

Abbreviations: CT = computed tomography; PET = positron emission tomography.

SUPPLEMENTAL TABLE 10. Mean Cumulative Percentage of Injected Radioactivity Excreted in the Urine (Pharmacokinetic Analysis Set).

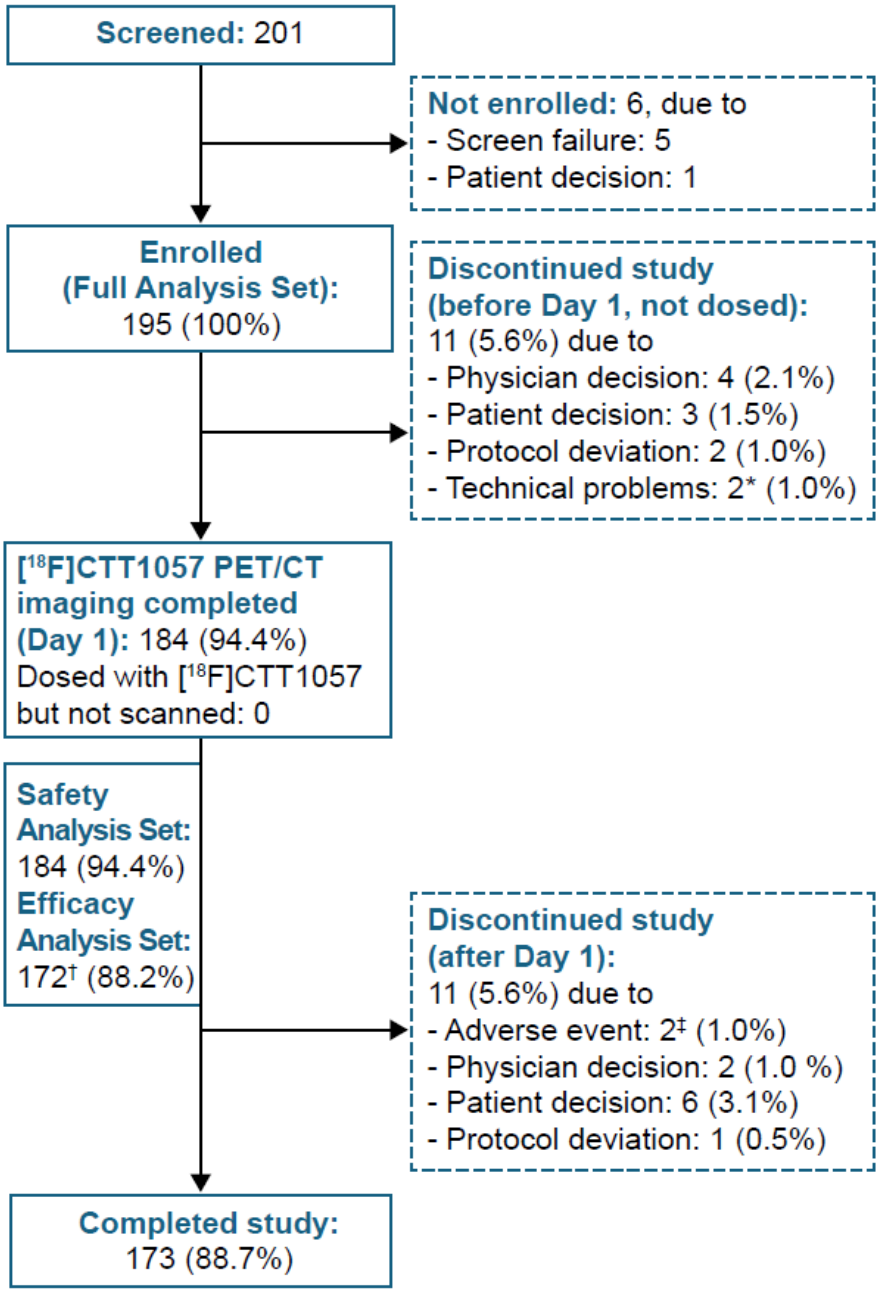
Collection interval	*N*	Mean (standard deviation), percentage
Pre-injection – 0 hours (injection)	10	<0.1 (0.0)
0 hours (injection) – image acquisition starting time	10	15.8 (11.9)
Image acquisition starting time – 3 hours post-injection	9	27.1 (17.7)
3–5 hours post-injection	10	37.0 (21.4)

SUPPLEMENTAL TABLE 11. Summary (Mean and Standard Deviation) of Relative Concentrations (%) of [^{18}F]CTT1057 and Metabolites in Urine (Pharmacokinetic Analysis Set).

	M1		M2		M3		Parent	
Collection interval	**Mean (%)**	**Standard deviation (%)**	**Mean (%)**	**Standard deviation (%)**	**Mean (%)**	**Standard deviation (%)**	**Mean (%)**	**Standard deviation (%)**
Pre-injection – 0 hours (injection)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
0 hours (injection) – image acquisition starting time	0.6	0.5	1.8	1.4	1.0	0.9	96.8	2.3
Image acquisition starting time – 3 hours post-injection	1.4	1.3	4.6	2.9	1.7	1.5	92.2	4.9
3–5 hours post-injection	3.1	2.0	6.5	4.3	2.6	1.9	87.9	6.9

Data were collected from 10 patients to calculate the relative concentrations of [^{18}F]CTT1057 (parent) and metabolites (M1 to M4) in urine.

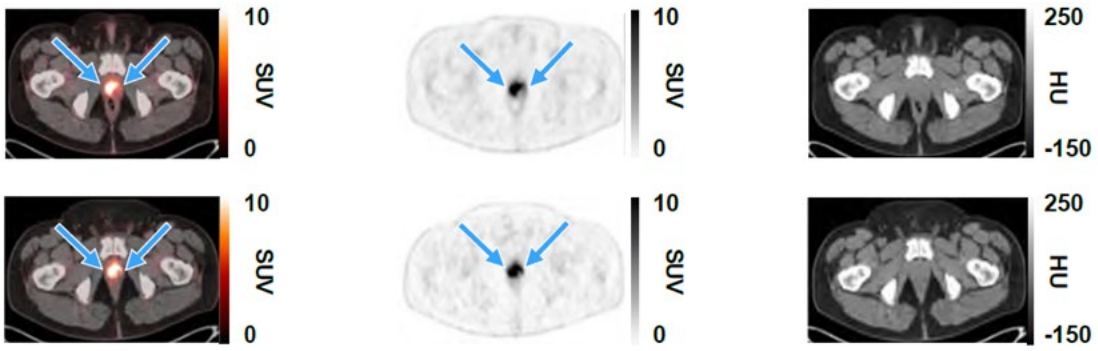
Abbreviations: M = metabolite.



SUPPLEMENTAL FIGURE 1. STARD Flow Diagram of the Study Participants.

*[18F]CTT1057 manufacturing issue or batch failure. †173 patients completed the study; one patient who completed the study was excluded from the efficacy analysis set owing to use of prohibited concomitant medications. ‡Two serious adverse events (myocardial ischaemia, sepsis syndrome) in two patients, unrelated to [18F]CTT1057.

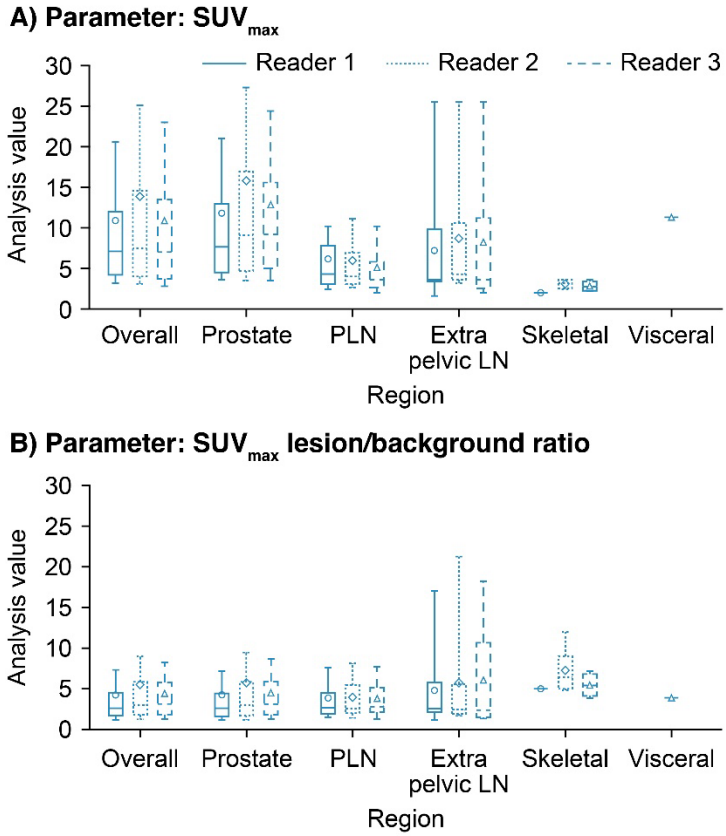
Abbreviations: CT = computed tomography; PET = positron emission tomography; STARD = Standards for Reporting of Diagnostic Accuracy.



SUPPLEMENTAL FIGURE 2. A Representative [^{18}F]CTT1057 PET/CT Scan Case Showing True Positive Lesions in the PT Following Standard and Delayed Imaging.

True positive lesions in the PT (blue arrows) visualized with [^{18}F]CTT1057 from a 52–year old patient (cT2, Gleason score 8 (4+4), PSA 23.1 ng/mL), scanned at A) 89 minutes post-injection (whole-body PET scan) showing SUV_{max}: 23; and B) 184 minutes post-injection (delayed pelvic PET image), showing SUV_{max}: 35.

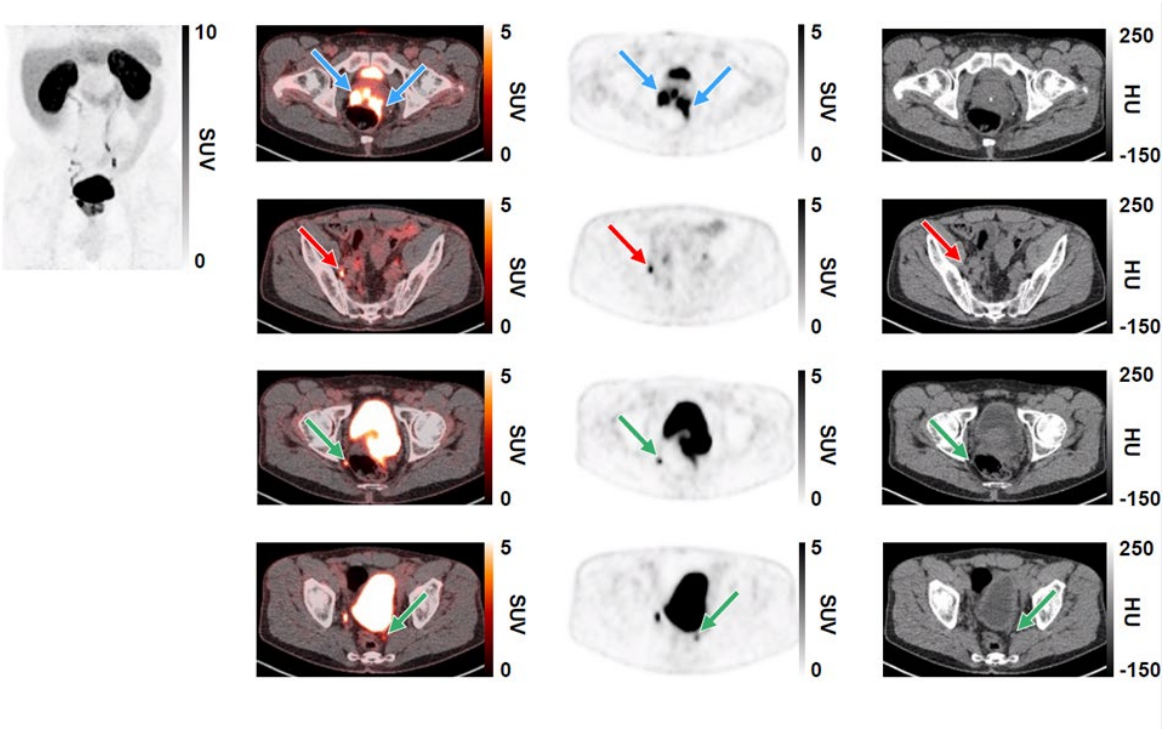
Abbreviations: cT = clinical staging for primary tumour; CT = computed tomography; HU = Hounsfield units; PET = positron emission tomography; PSA = prostate-specific antigen; PT = primary tumour; SUV_{max} = maximum standardized uptake value.



SUPPLEMENTAL FIGURE 3. Quantitative Assessment (SUV_{max}) of [^{18}F]CTT1057 Uptake in Reported Lesions (Safety Analysis Set).

Plots show boxes (25th–75th percentiles) with the median as a horizontal line. The dots in the boxes represent the mean values. Whiskers (vertical lines) extend to the 10th–90th percentiles. Values outside this range are not displayed.

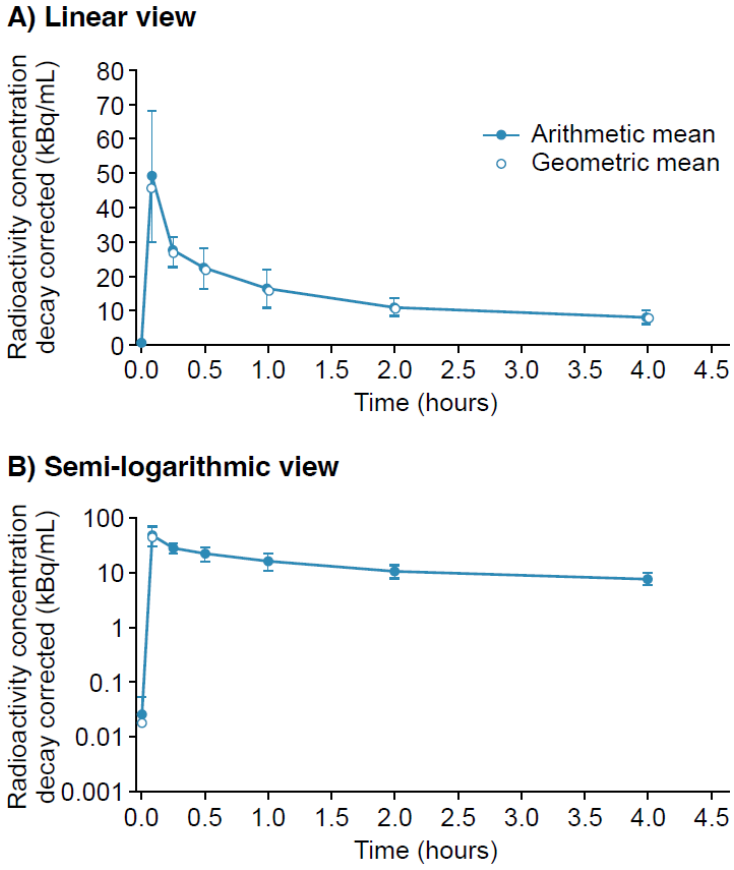
Abbreviations: LN = lymph node; PLN = pelvic lymph node; SUV_{max} = maximum standardized uptake value.



SUPPLEMENTAL FIGURE 4. A Representative Scan Case of a Patient who had a Change in Treatment Plan from Initially Planned Surgery Following Detection of PLN and Extra-PLN Lesions by [^{18}F]CTT1057 PET/CT.

Delayed pelvic [^{18}F]CTT1057 PET scan (143 min. post injection) from a 65-year old man (cT3b, Gleason score 9 (4+5), PSA 11.8 ng/mL). Initial planned treatment was surgery. However, besides bilateral locally advanced PT (blue arrows) the patient showed positive [^{18}F]CTT1057 PLNs in right internal iliac (red arrow) and right and left perirectal (green arrows). Subsequently, the patient did not undergo surgery and treatment plan was changed to radiotherapy plus androgen deprivation therapy.

Abbreviations: cT = clinical staging for primary tumour; CT = computed tomography; HU = hounsfield units; PET = positron emission tomography; PLN = pelvic lymph node; PSA = prostate-specific antigen; SUV = standardized uptake value.



SUPPLEMENTAL FIGURE 5. The Arithmetic Mean (Standard Deviation) and Geometric Mean Blood Radioactivity Concentration of [^{18}F]CTT1057 Over 4 hours Post-injection (Pharmacokinetic Analysis Set).

Abbreviations: kBq = kilobecquerels.